

Sourcing Strategic Review Meeting

Objectives, agenda and participants

July 2015

Objectives: 2015 Sourcing strategic review meeting

Share an update on Sourcing team progress since October 2014 strategic review

Share current thinking on strategies under development and gather partner perspectives

- > TB
- > RDTs
- > LLINs

Conduct focused stakeholder consultation on the market shaping strategy

- > Strategic objectives, Global Fund role and guiding principles
- > Key strategic questions

Share other relevant initiatives and progress at the Global Fund

Provide an opportunity for a diverse set of partners to come together and share perspectives

Agenda: July Strategic Review meeting – Day 1 (9 July)

Time	Topic	Proposed presenter(s)
08:30 – 08:55	Registration (coffee and tea available)	
09:00 – 09:20	Welcome, introductions and overview of agenda	Christopher Game
09:20 – 09:40	Opening remarks	
09:40 – 10:00	Strategic overview: P4i key achievements and priorities	
10:00 – 11:00	Update on Sourcing Strategies <ul style="list-style-type: none"> • Summary overview • ARV and viral load tenders 	Mariatou Tala Jallow Martin Auton
11:00 – 11:20	Break	
11:20 – 12:20	Update on Sourcing Strategies <ul style="list-style-type: none"> • RDTs • TB 	Aziz Jafarov Silas Holland
12:20 – 13:20	Lunch	
13:20 – 13:50	Keynote address	Mark Dybul
13:50 – 14:20	Overview of market shaping strategy: context and process	Rebecca Solow
14:20 – 14:40	Feedback and Q&A	
14:40 – 15:00	Break	
15:00 – 16:30	Pooled procurement: Current status, benefits, mitigating risks,	Mariatou Tala Jallow
16:30 – 17:00	Closing remarks	Daniel Camus

Agenda: July Strategic Review meeting – Day 2 (10 July)

Time	Topic	Proposed presenter(s)
08:30 – 08:55	Coffee and tea available	
09:00 – 09:20	Opening remarks and agenda for today	Christopher Game
09:20 – 10:00	Additional feedback and Q&A on Day 1	
10:00 – 10:45	Update on e-marketplace	Maxime Parmentier
10:45 – 11:00	Break	
11:00 – 12:30	Break-out sessions: Strategies to address opportunities and collaboration <ul style="list-style-type: none"> • TB drugs & diagnostics • RDTs • LLINs • Sustainability & transition • Coordination on market intelligence • Role in markets not directly financed by GF (e.g., COIM products, private sector markets) 	Silas Holland Martin Auton Aziz Jafarov Rebecca Solow Nana Boohene & Richard Kettle Melisse Murray
12:30 – 13:15	Report back from break-out sessions	Break-out facilitators
13:15 – 14:00	Lunch	
14:00 – 14:30	Next steps	Mariatou Tala Jallow
14:30 – 15:00	Closing remarks	Christopher Game

Confirmed attendees from partner organizations (I / II)

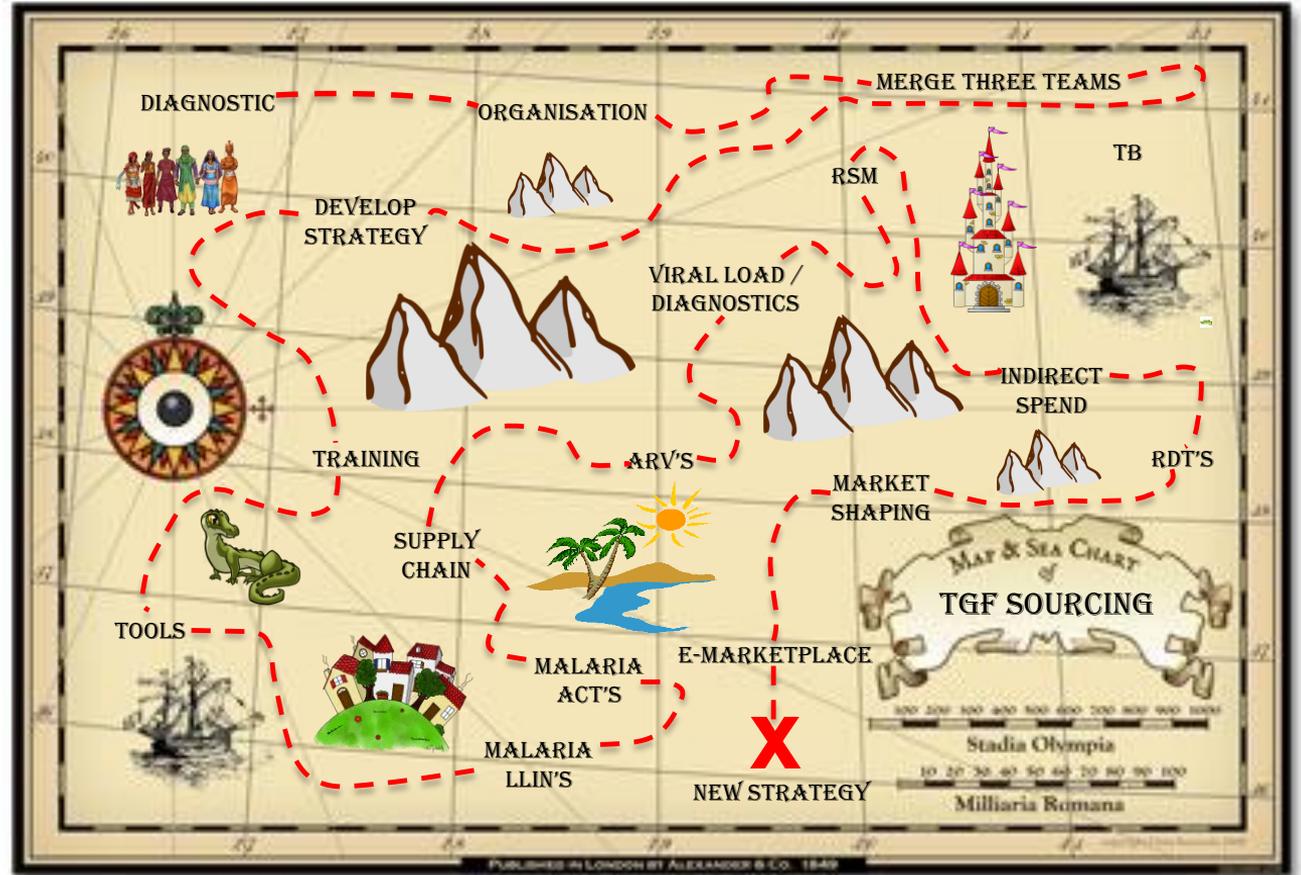
Name	Organization
Xu Ming	CCCMHPIE
John Nkengasong	CDC
Bill Coggin	CDC
Bhawani Singh	CHAI
Jessica Fast	CHAI
Regina Osih	CHAI
Patrick Hynes	DFID
Kate McSheffrey	DFID
Sarah Boulton	DFID
Janice S.F. Lee	DNDi
Alastair White	DNDi
Thomas Nicholson	Duke University
Michael Wilson	Duke University
Dan Collins	Eli Lilly Foundation
Amy Israel	Eli Lilly Foundation
Catharina Boehme	FIND
Sandra Incardona	FIND
Susan Nazzaro	BMGF
Deepali Patel	GAVI
Aurelia Nguyen	GAVI
Edwin de Voogd	IDA
Tom McLean	IVCC
Alnaaze Nathoo	Medicines Patent Pool
Esteban Burrone	Medicines Patent Pool
George Jagoe	MMV
Jennifer Cohn	MSF
Christophe Perrin	MSF
Andre Zagorski	MSH
Michelle Childs	Open Society Foundations
Jordi Balleste	PAHO
David Jamieson	PFSCM
Gitanjali Sakhuja	PFSCM
Fatoumata Nafo-Traore	RBM

Name	Organization
Martins Pavelsons	RBM
Lucica Ditiu	Stop TB Partnership
Brenda Waning	Stop TB Partnership
Magali Babaley	Stop TB Partnership
Thomas Verges	Stop TB Partnership
Elana Robertson	TB Alliance
Shelly Malhotra	TB Alliance
Ian Boulton	TropMed Pharma Consulting
Badara Samb	UNAIDS
Abdoul Dieng	UNAIDS
Benoit Marquet	UNDP
Ignacio Gimenez	UNICEF
Gian Gandhi	UNICEF
John Crowley	USAID
Thomas Chiang	USAID
Alexis Leonard	USAID
Jude Nwokike	USP
Kelly Willis	USP
Fatiha Terki	WFP
Benjamin Syme	WFP
Rajpal Singh Yadav	WHO
Vincent Habiyambere	WHO
Joseph Perriens	WHO
Boniface Dongmo Nguimfack	WHO
Lembit Rago	WHO
Nani Nair	WHO
Moredreck Chibi	WHO
Christophe Rerat	WHO
Prashant Yadav	William Davidson Institute

Sourcing & Procurement – The Last Two and a Half Years

9 July
Geneva, Switzerland

What we set out to do 2 ½ years ago

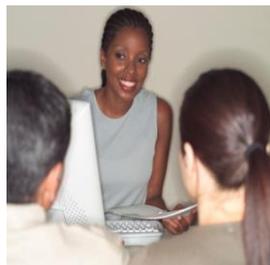


Over the last two and a half years, the Global Fund has transformed its sourcing operations and strategy through the *Procurement 4 Impact (P4i)* transformation

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

Where we started -

Jan 2013

- **Reactive procurement based on grant disbursement**
- **Spot tendering through PSA's**
- **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**

Progress to-date



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

July 2013



Approximate Time

Dec 2015



Successes

Supplier performance

- Increased the on-time and in-full delivery of core health products purchased through pooled procurement from 36% to over 80%
- Approaching same performance as private sector in emerging markets (86% in 2013)

Availability and supply security

- Implemented rapid supply mechanism through vendor managed inventory allowing fast response to product shortages
- Supplier panels selected to ensure diversity, resulting in increased number of suppliers for LLINs and ACTs; 8 suppliers retained for ARVs

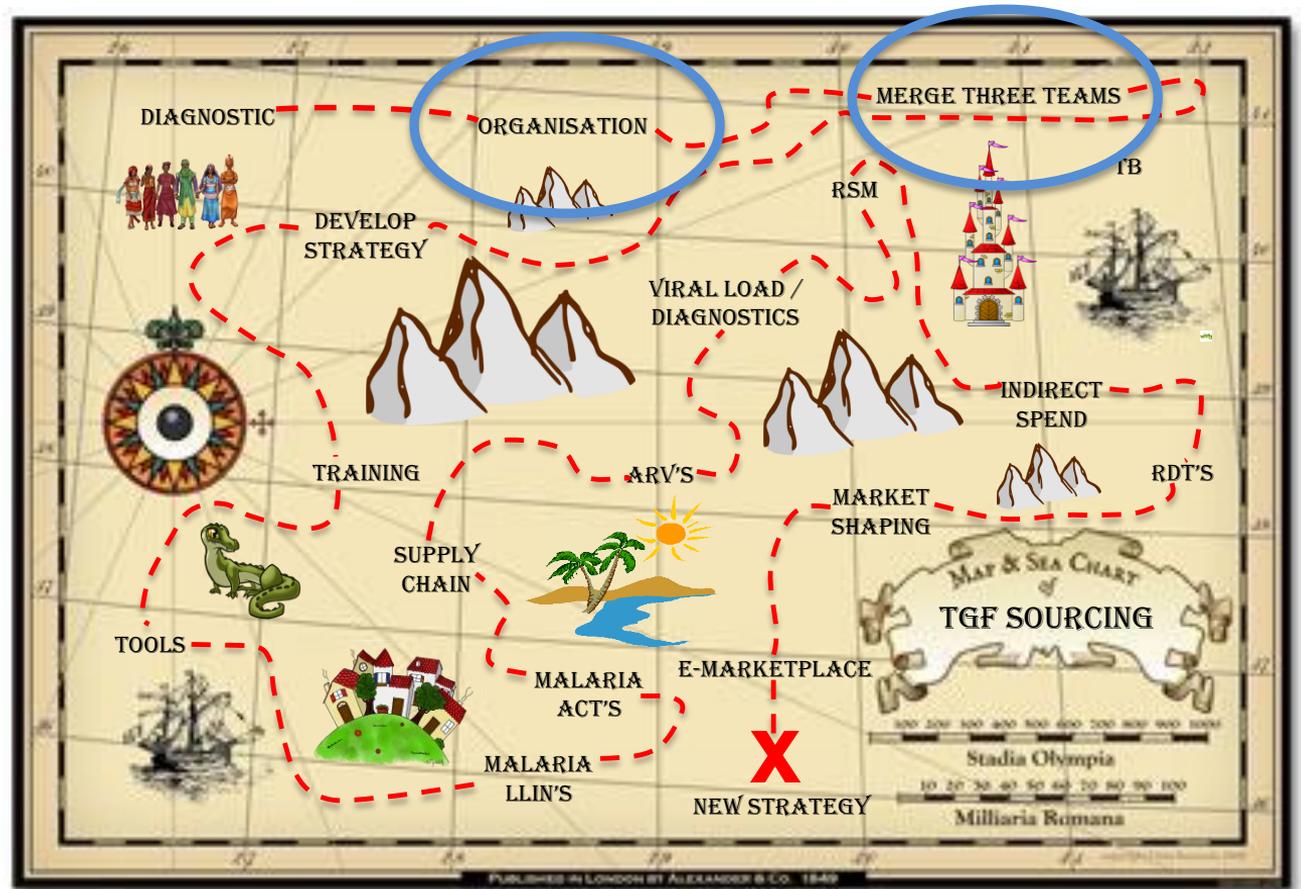
Innovation

- Level of innovation included as tender evaluation criteria
- Volume explicitly set aside for new entrants and new products in recent ARV tender
- Collaborative supplier projects focused on new products or formulations

Affordability and savings

- Nearly \$500 million in estimated savings achieved through tenders so far. Spend penetration up to \$1.5 Billion
- In LLIN and ACT tenders, largely through volume discounts
- ARV tender also used lifecycle segmentation and COGS-based benchmarking to inform negotiations

The Organisation



Sourcing team has evolved

Team re-organized and reinforced...

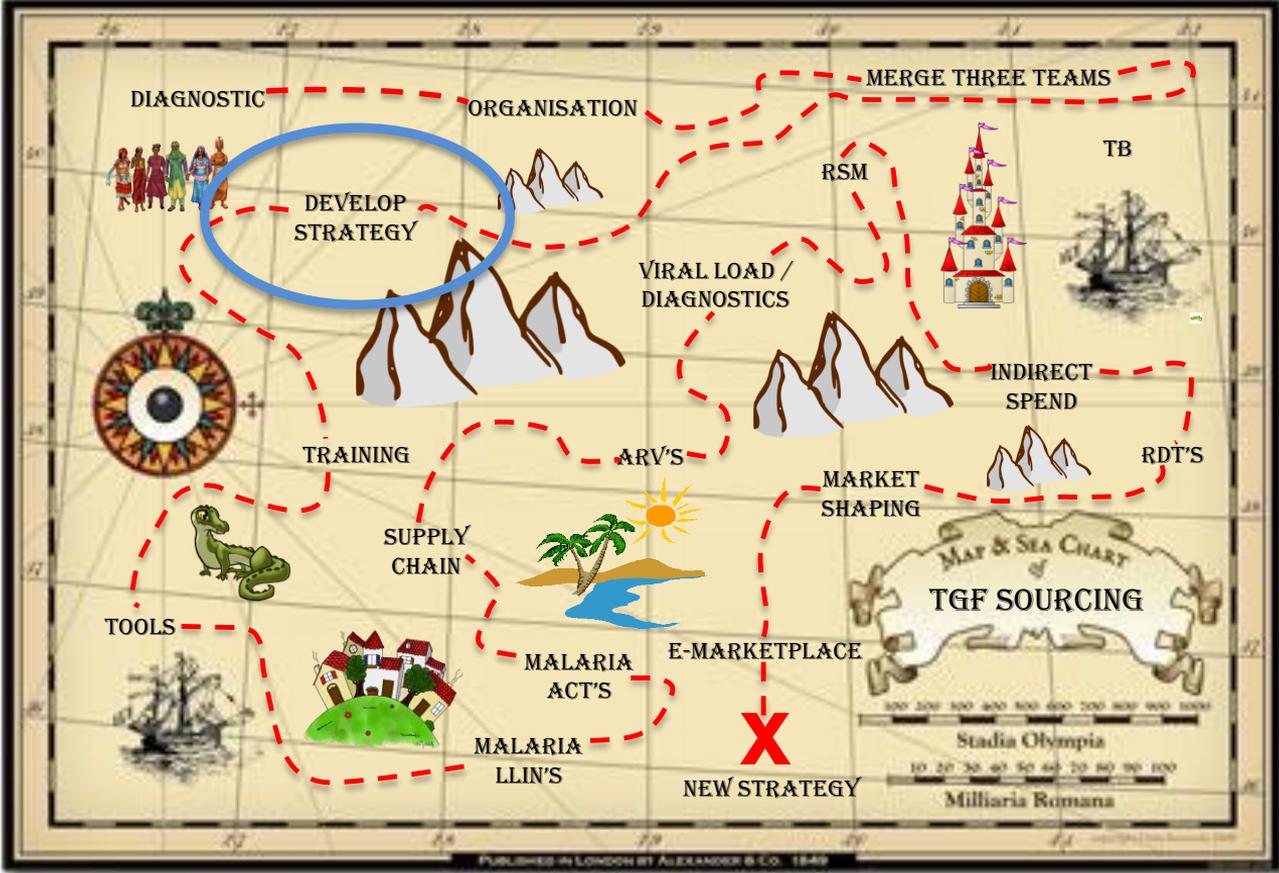
- (In)Voluntary Pooled Procurement, Corporate procurement and Amfm merged into one single Sourcing team
- New Indirect – Category Management / Direct Sourcing, and Supply Chain teams created, with greater capability
- Product, market and supply experts created (e.g., Business Planning and analysis, Active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



With greater responsibilities...

- Spend under control is increasing, PPM up to \$1.2Bn
- Relationships upstream and downstream are managed and accountable
- Sharing of the locus of control between manufacturer and buyer

Strategy Development



Procurement 4 Impact (P4i) followed 6 objectives fully aligned with the Global Fund' strategy ----- with the focus on industrialising thought leadership

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

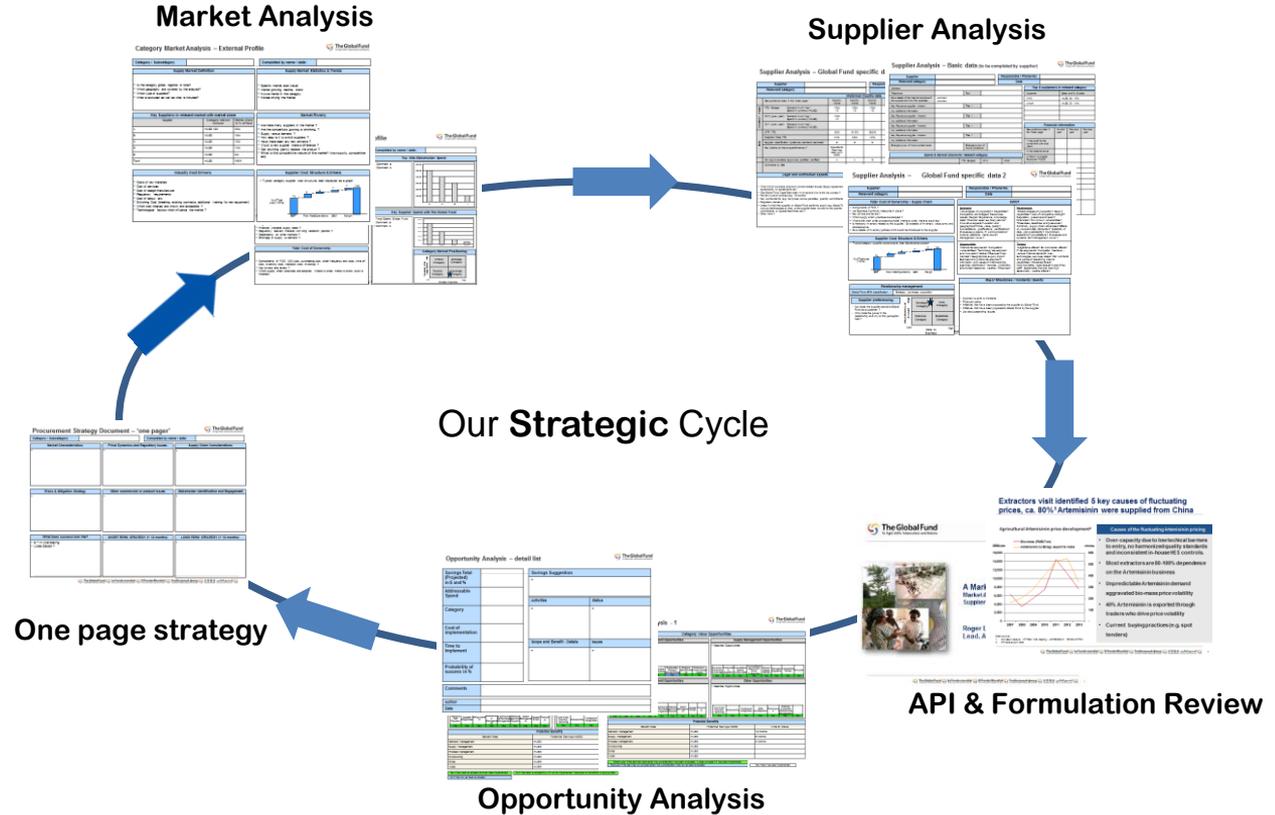
Ensuring **effective governance** and **watertight compliance**

4

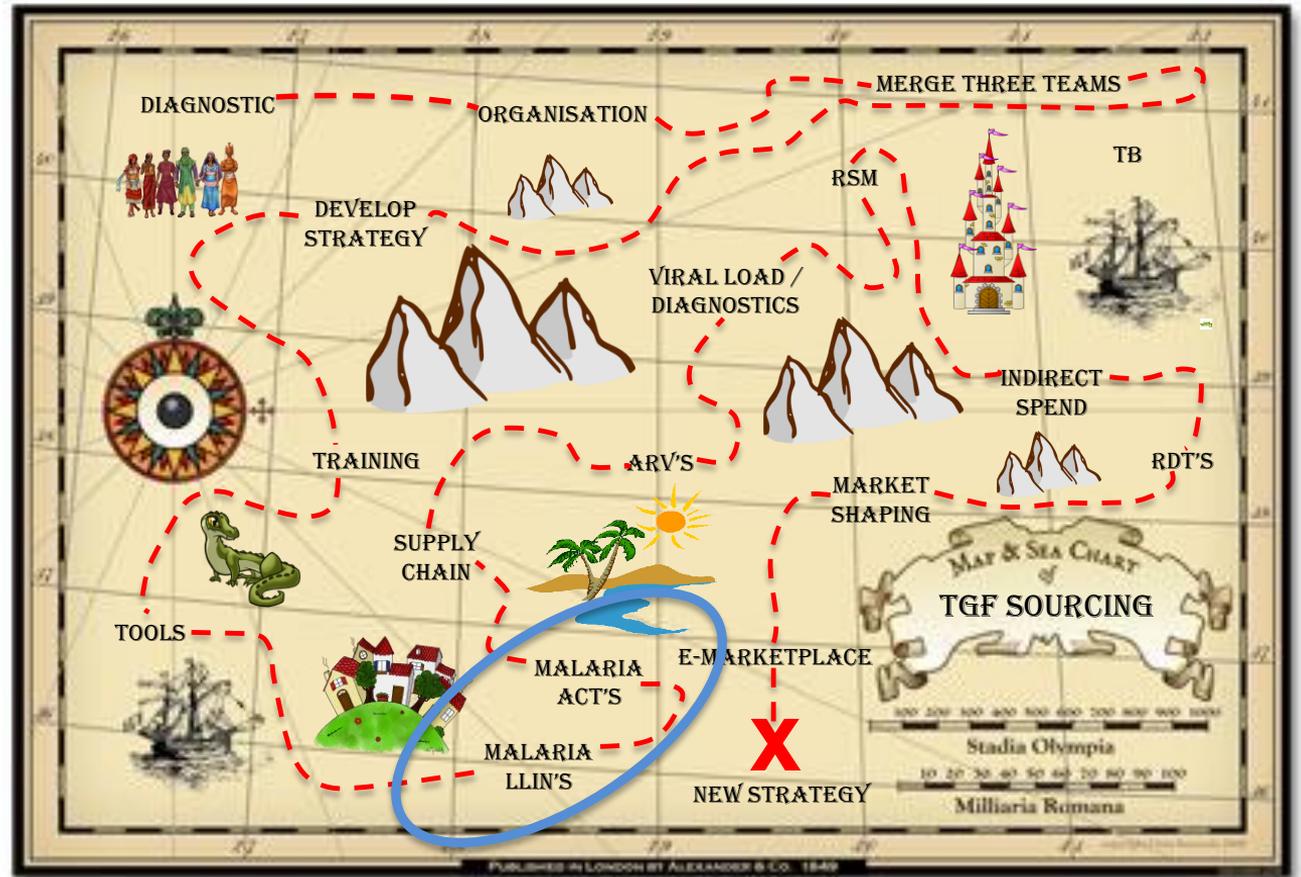
Building **collaborative relationships** with partner agencies, suppliers and donors

Training & Tools

- External Expert Support
- Track & Trace
- Red Flag Tool
- Advanced Metrics
- Strategic Process



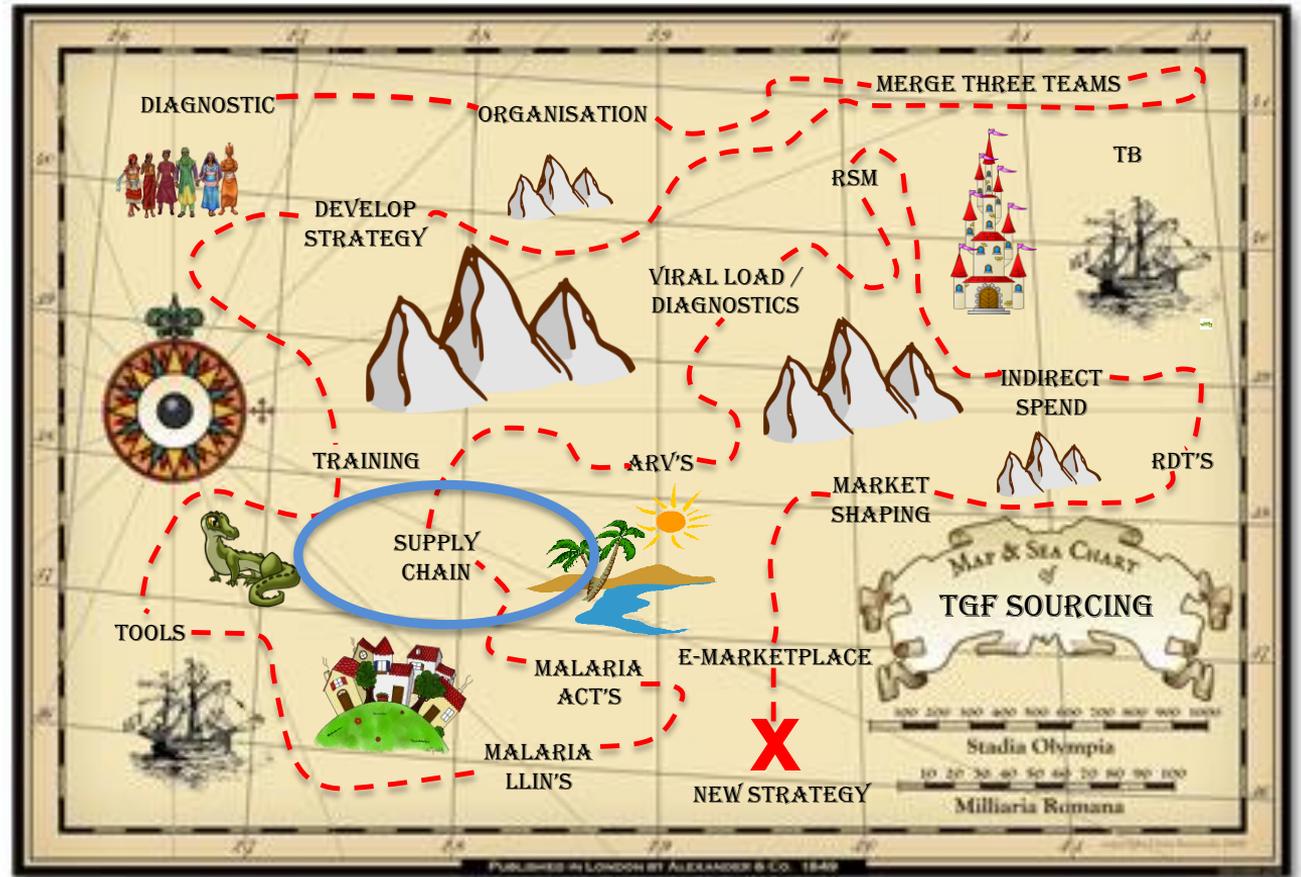
Malaria



Malaria

- LLIN Global tender concluded & entering 2nd cycle
 - UNICEF / PMI / DFID engaged
 - Specification Harmonised
 - Demand flattened
 - \$140M Value contribution
 - Market re-structured from duopoly
 - Open to non-funded country procurement
- AMFm.....Private Sector Co-Payment
 - Integrated into our conventional operations
- ACT Global Tender concluded
 - Value contribution of \$102M
 - Different landscape, strong competition between Originators and Generics
 - Includes private sector co-payment
 - COGS transparency and API proved revealing
 - Originators moving close to generic pricing

Supply Chain



We started with the big little number that many of you will remember

~~36.8%~~ → 80%

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

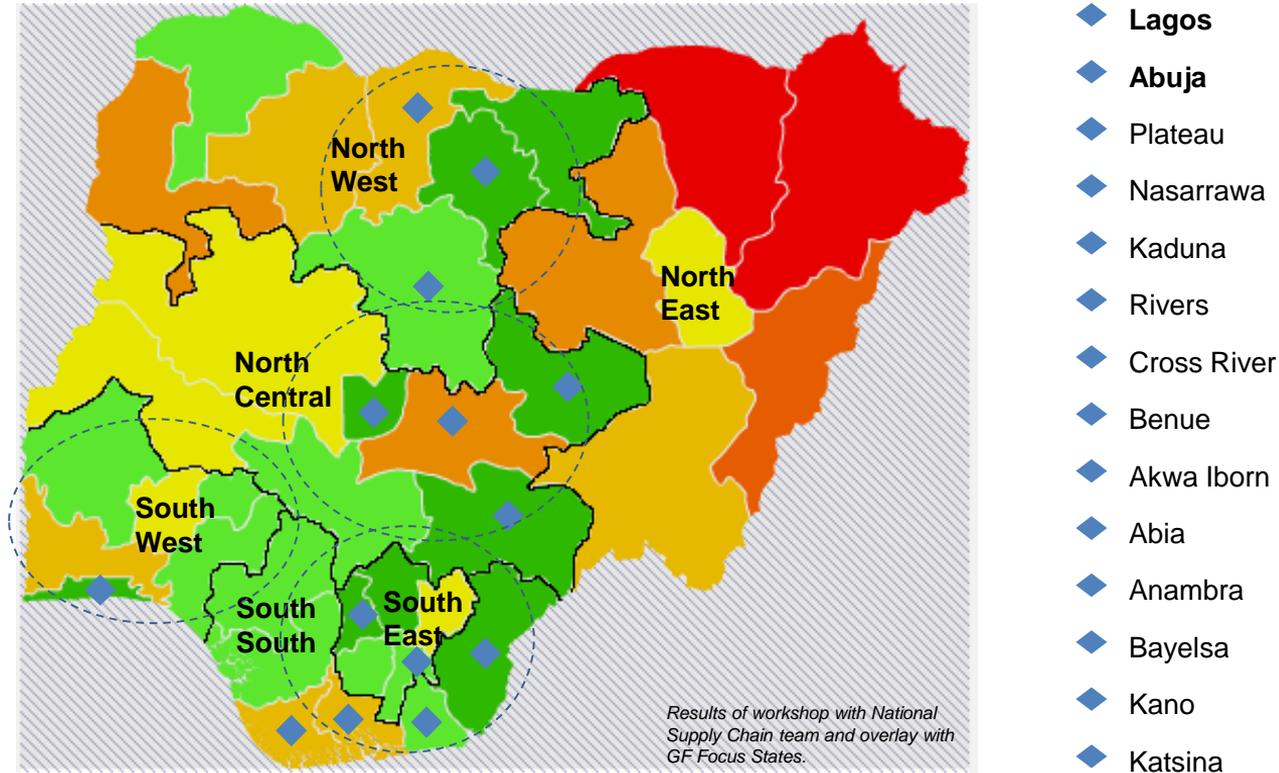
Supply chain aims at several objectives to improve delivery performance and mitigate risks

Objectives

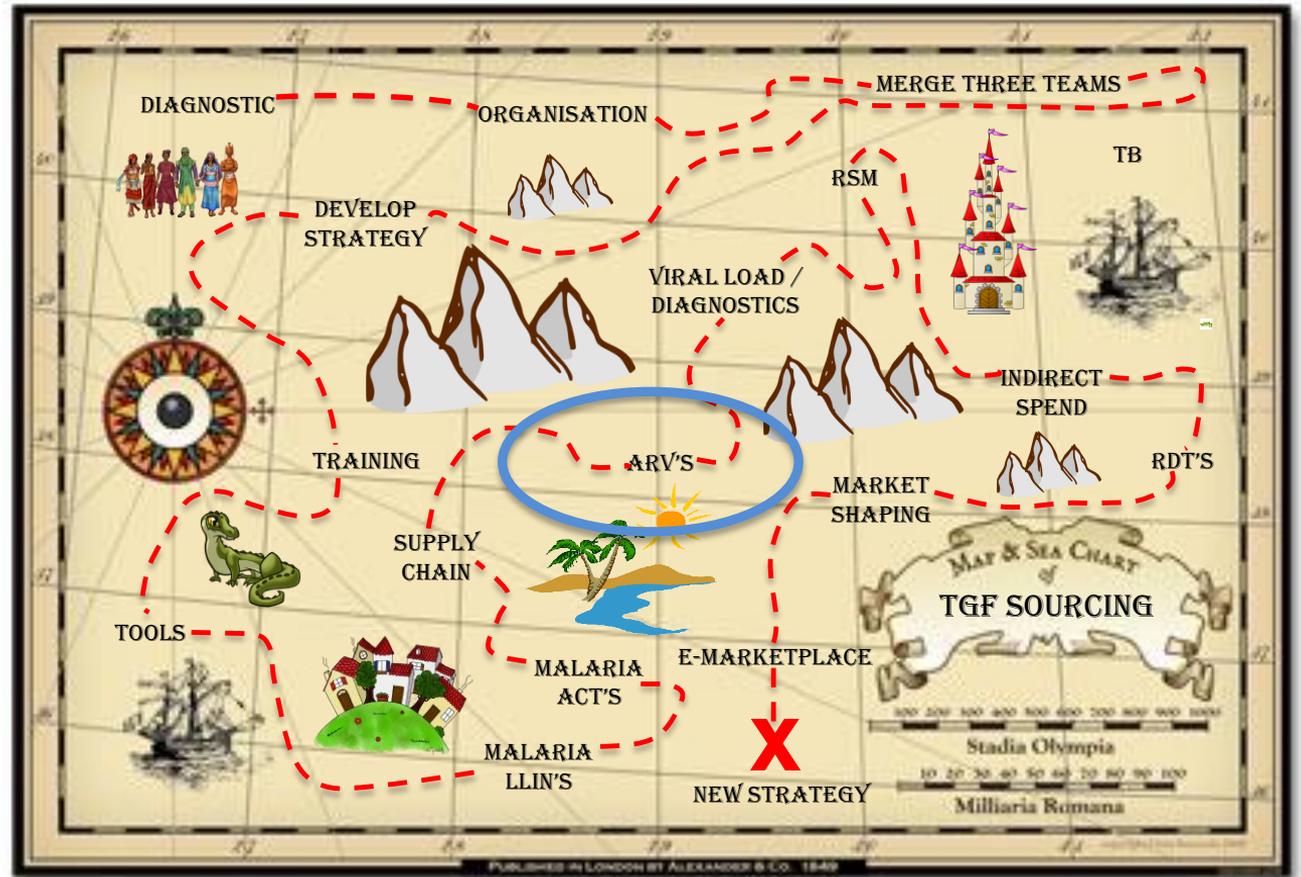
- Improve availability of products/reduce stock-outs, improve OTIF and reduce lead-time
- Increase visibility on supply chain
- Improve in-country supply chain capability
- Improve counterfeiting/theft/diversion avoidance
- Improve manufacturers quality
- Take an integrated approach with partners
- Build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

Downstream :- In country supply chain: example of Nigeria

Program scope – 2014 to 2017 for 14 Focus States



ARV's



HIV

- Coordinated procurement of paediatric ARVs transitioned from UNITAID to the Global Fund
- Viral Load / CD4
 - Worked with PEPFAR / SA Gov. / CHAI / UNAIDS & others on viral load pricing
 - Viral load scale-up strategy launched with PEPFAR
 - Inclusive tender issued by SA Gov.
- ARV strategy launched with ARV manufacturers and Global Fund partners
- Collaborative approach with partners to leverage our scale
- Tender run and concluded, currently in implementation

The ARV tender objectives are aligned to the Board approved Global Fund Market Shaping Strategy

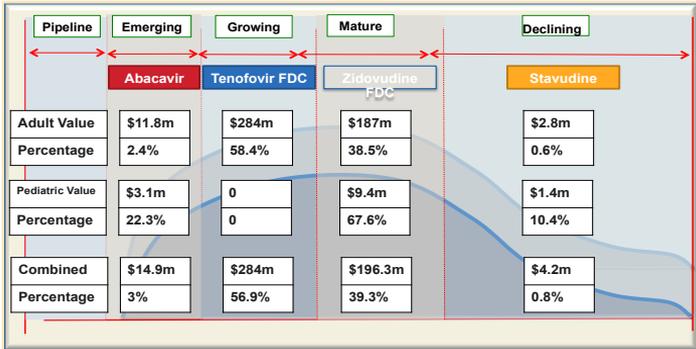


New Approaches Support Market Shaping

The tender incorporated new concepts to support the market shaping strategy

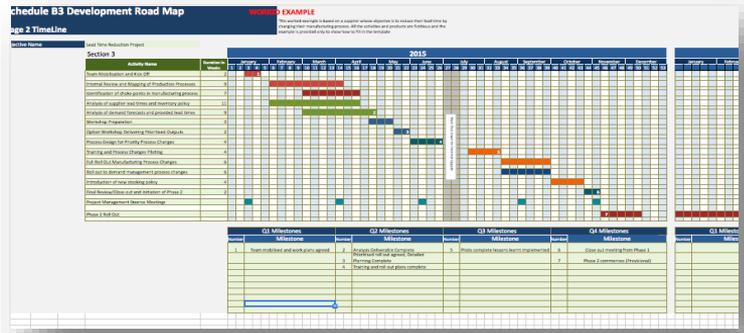
1. Lifecycle Management

A lifecycle model was built for ARVs and products allocated to a segment within it. Each segment had different strategic objectives



2. Strategic Partnerships

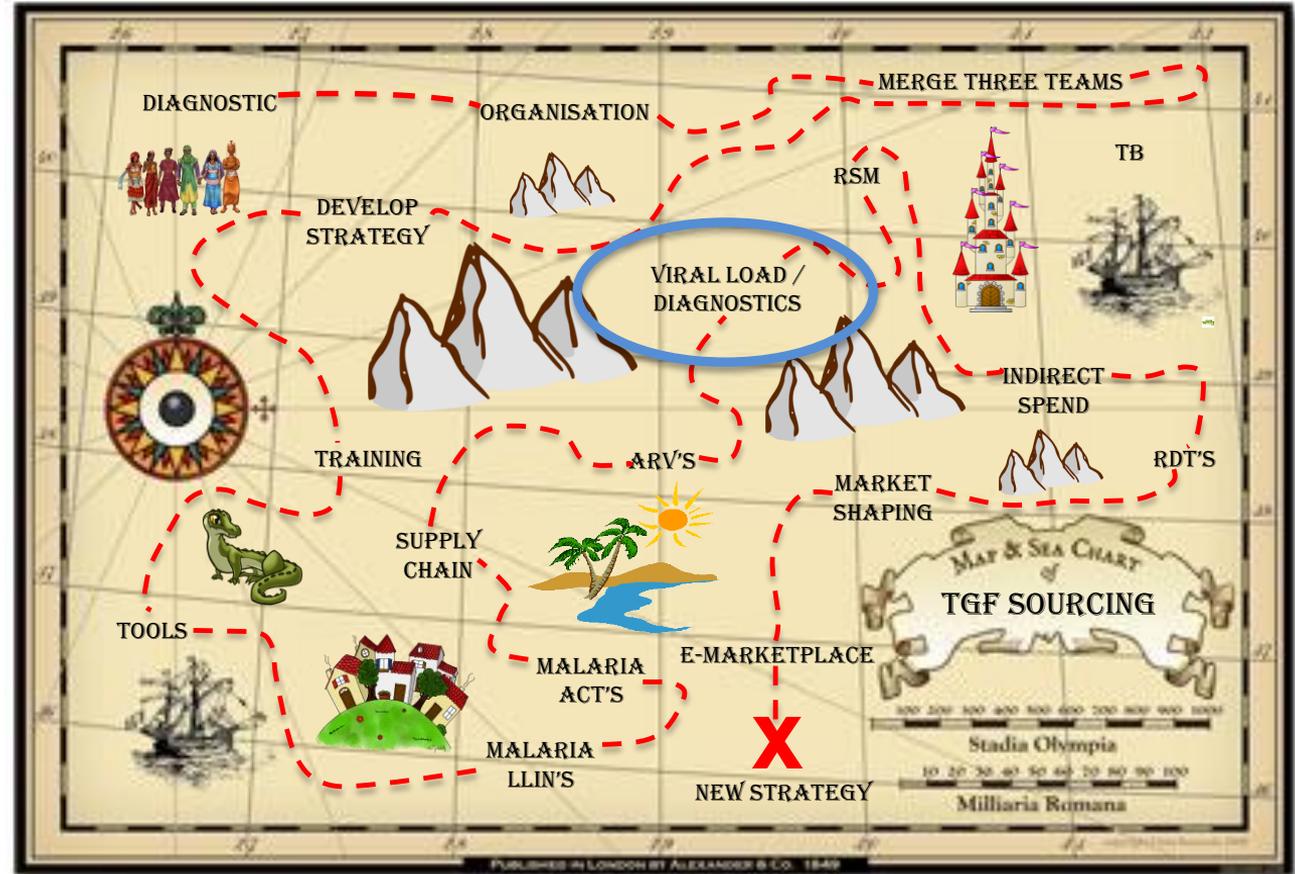
Selected suppliers would be offered 3 year strategic partnerships based on collaborative projects with defined objectives. This will promote investment and market sustainability



Adopting the new approach based on long term, strategic relationships has, from the evidence of the tender, proven successful.

- ✓ Through the tender the Secretariat has **supported the Board approved the Global Fund market shaping strategy** through underpinning long term sustainability both at a product and market level.
- ✓ **Direct savings of \$96m for PPM grants** have been achieved with a future price roadmap that will increase affordability equating to at least 800,000 people on treatment for 1 year.
- ✓ Further **budgetary headroom of up to \$125m for non PPM grants** has been identified which equates to up to at least 1,000,000 people on treatment for 1 year.
- ✓ Supplier relationships have now moved to a state where **future value can be created** for mutual benefit.

Viral Load / Diagnostics



Diagnostics – Viral Load

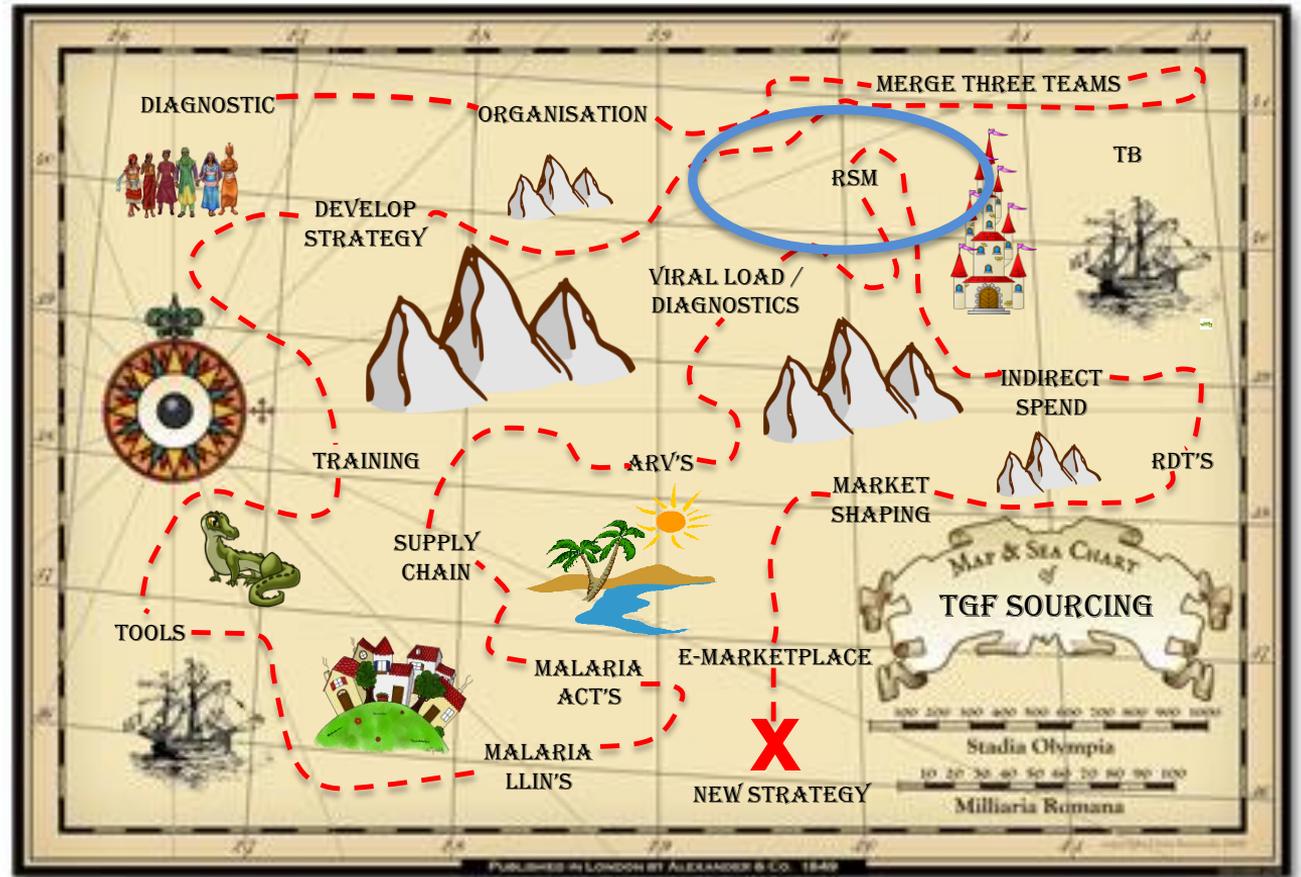


- Silo'd data and approach on response to WHO HIV guidelines has created division on the strategy for CD4 / Viral Load / Point of Care. To deal with this :
 - We brought together the USG / SA Gov. / UNICEF / UNITAID / WHO / CHAI / GATES
 - We have aligned our studies, data and strategy and leveraged our collective leadership into a strategic roadmap.
 - This also gives us the opportunity to leverage demand and cost.
 - We have launched and concluded a global tender based on total cost of ownership.

Diagnostics – Tender Outcome

- Framework agreements between the Global Fund and seven diagnostic manufacturers which aim to make the market for HIV viral load testing more transparent and competitive, driving cost reductions of up to one third.
- The agreements should deliver net savings of at least US\$30 million over three years to the Global Fund, and potentially more.
- The new agreements between the Global Fund and the seven manufacturers provide clarity on prices, aiming for an all-inclusive price as low as US\$15, including equipment and other costs such as consumables, maintenance and shipping. It establishes benchmarks at which the Global Fund's implementing partners can expect to purchase.
- While pricing for new diagnostic equipment will be more transparent and reliable, the agreements also aim to expand the use of existing equipment, by providing better benchmark prices for maintenance and servicing.
- The seven manufacturers are Abbott, Alere, bioMérieux, Cepheid, Hologic, QIAGEN and Roche. Each has been through a technical and commercial evaluation before being added to the panel of suppliers. The agreements initially last three years. Other public health funders and agencies will also be able to enter into agreements based on the benchmark prices negotiated.
- Builds on the HIV Diagnostic Access Program agreed last September, which was co-ordinated by UNAIDS and included Roche and the Government of South Africa, World Health Organization, U.S. Centers for Disease Control and Prevention, African Society for Laboratory Medicine, UNITAID, the Global Fund, PEPFAR, Clinton Health Access Initiative and UNICEF.

Rapid Supply Mechanism



Rapid Supply Mechanism – Prevent Stock Outs



What to expect

- 4-6 weeks lead time on key ARVs and ACTs, stocked at manufacturer level, expedited for catalogue items
- 5% RSM premium fee charged on the grants to manage RSM operations

Availability

- Available for all GF PRs (PPM/non PPM)

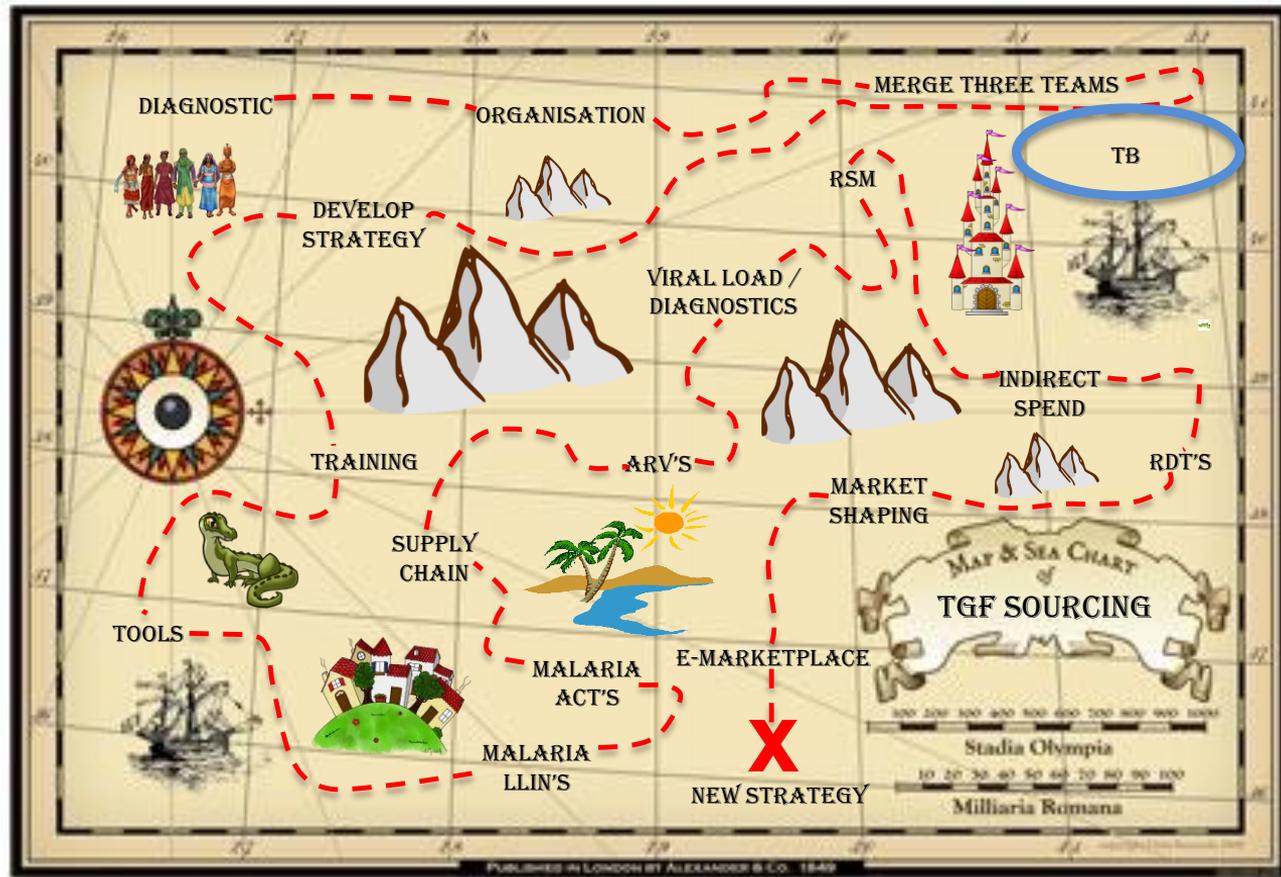
Approach: Stock at manufacturer

- Agreements with selected suppliers to hold stock of optimal ARV, ACT products, either as finished goods or raw material as per framework agreements.
- PPM procurement agent, PFSCM, will execute the orders
- PPM procurement and disbursement processes will be used (details in PPM OPN)

Products

- Optimal first line and second ARVs, ACTs, available at supplier level or as direct procurement
- Standard packaging

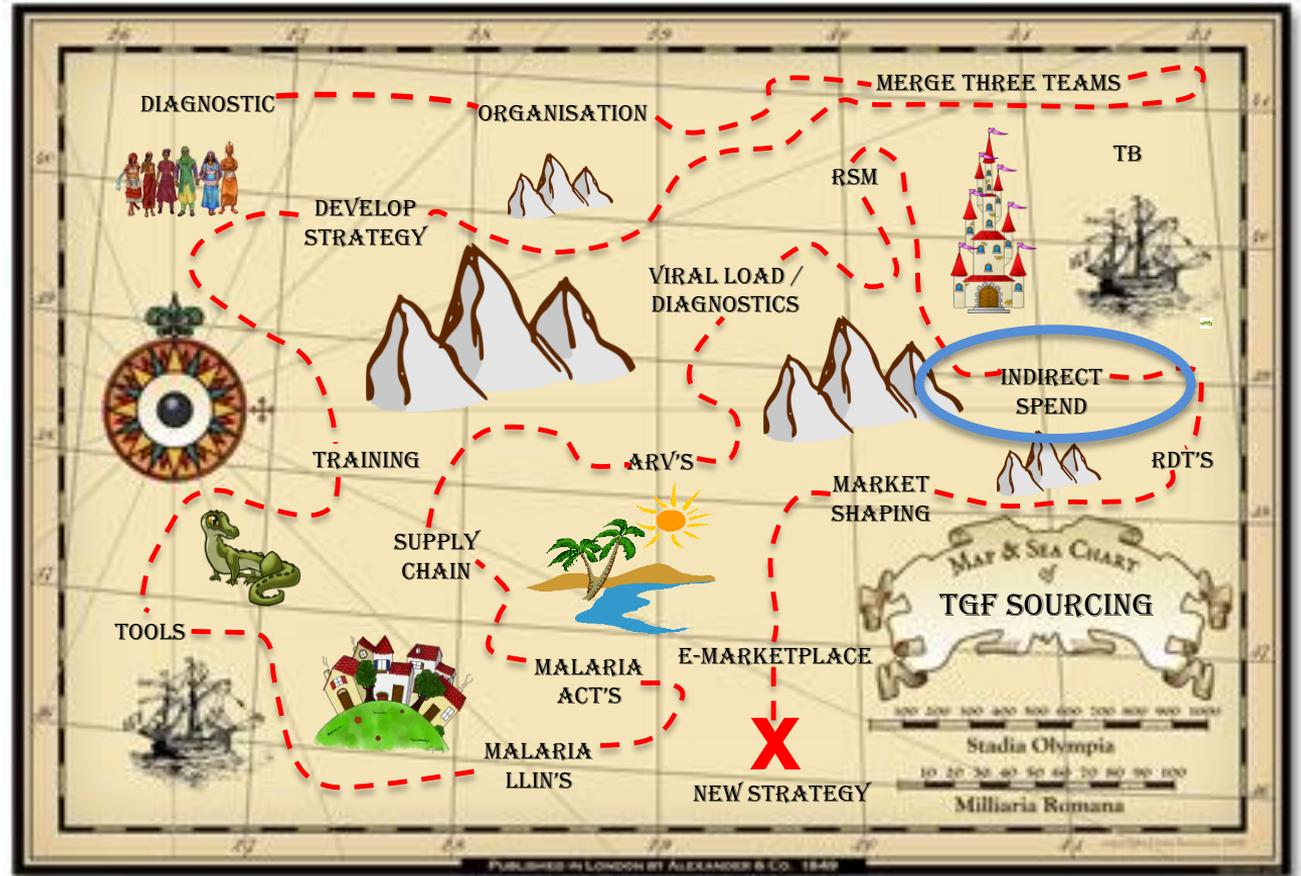
TB



TB

- Working on MoU with Stop TB Partnership /GDF on procurement of TB products with Global Fund resources
- Consultations with TB manufacturers as part of the market analysis / TB strategy process
- Partner mapping
- Working with GDF to understand current performance along the supply chain
- Develop Global Fund TB Sourcing Strategy

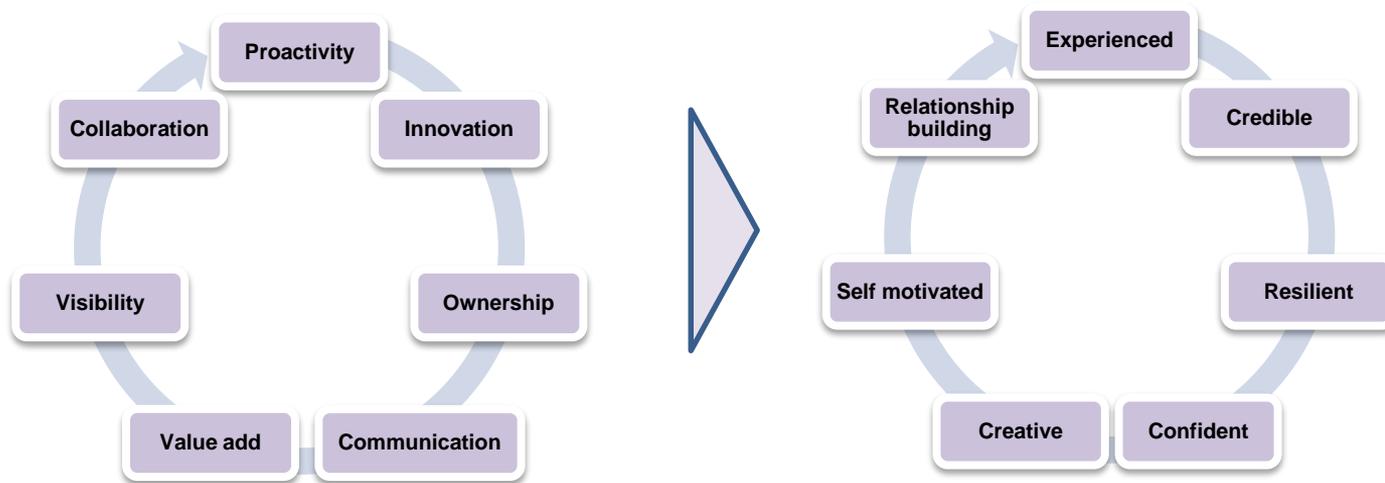
Indirect Spend / Category Management



The Category Management Strategy – Indirect Spend

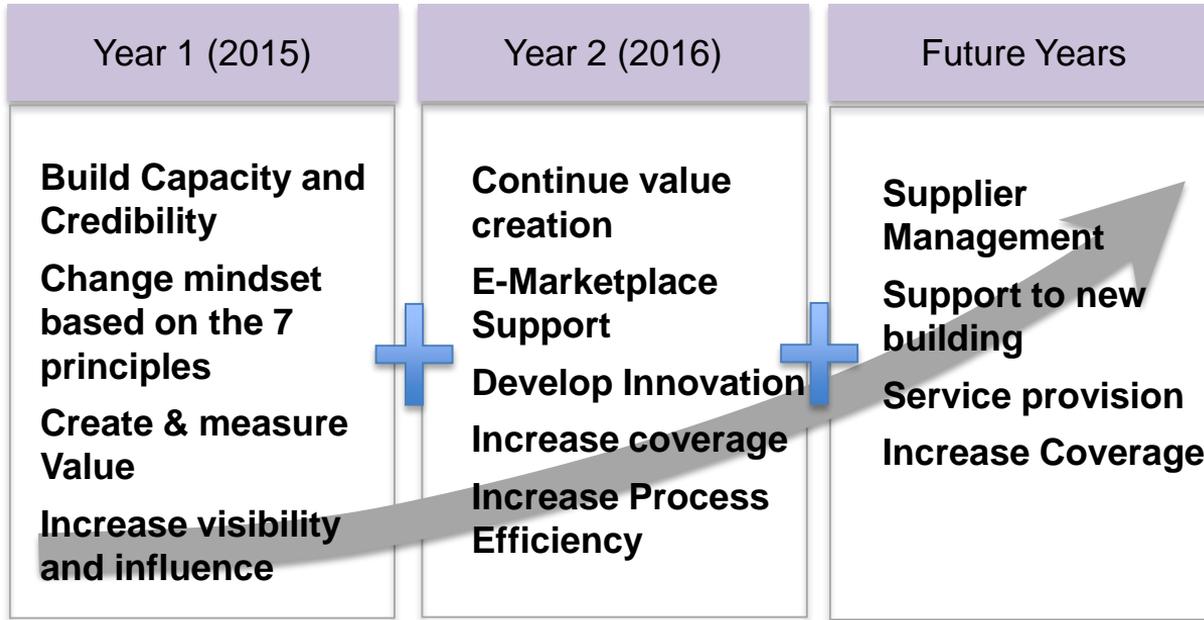
The objective is to transform the current Indirect team from what has historically been a reactive, transaction focused team into something more akin to a private sector, proactive category management team, becoming increasingly more visible, influential and adding significant benefit to the wider organization.

The intent is to focus our efforts around 7 core principles, with the emphasis on **continuous improvement**. The intent is to develop a team of procurement professionals, with industry recognized qualifications and strong personal credentials.

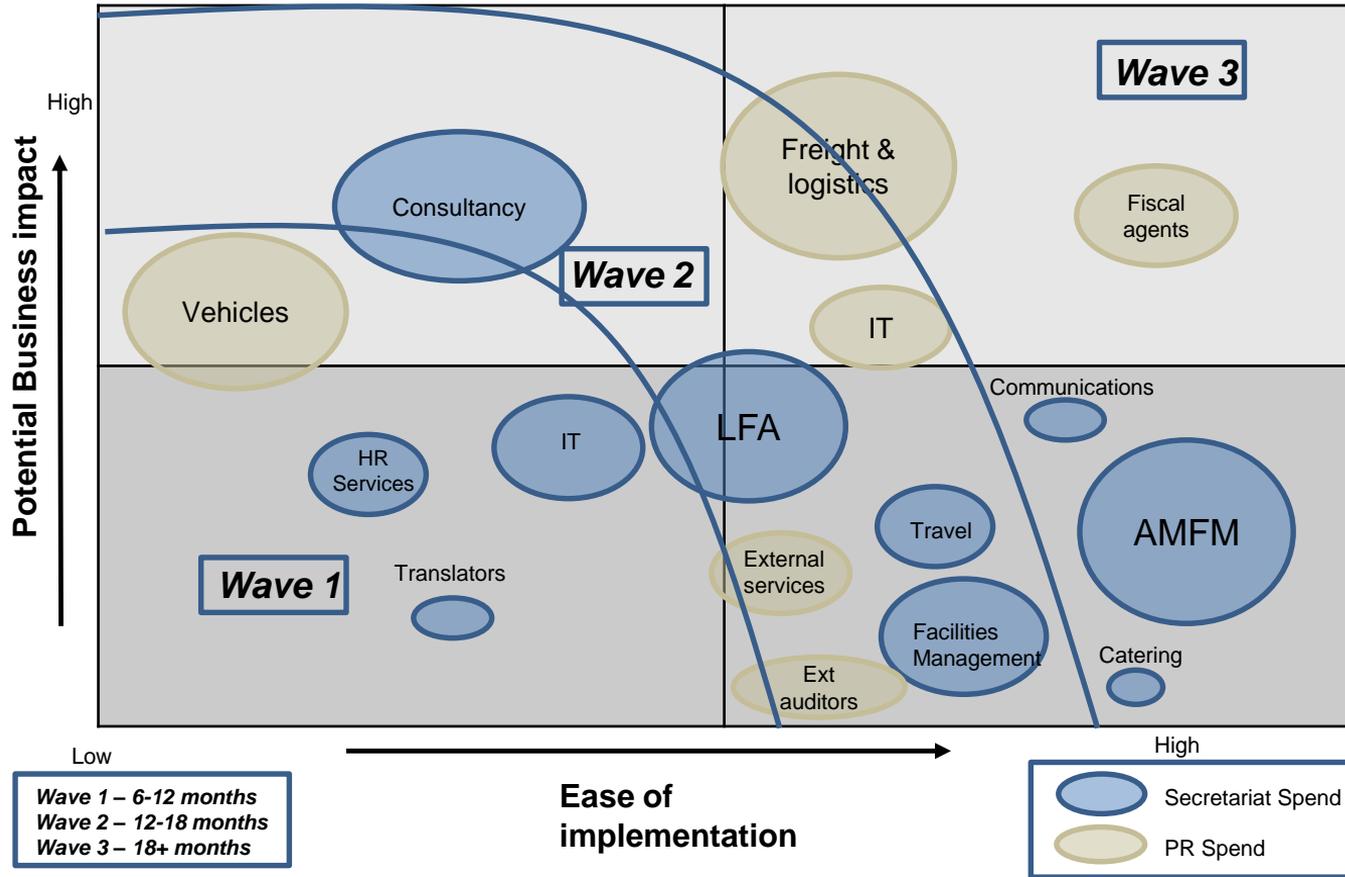


The transition process

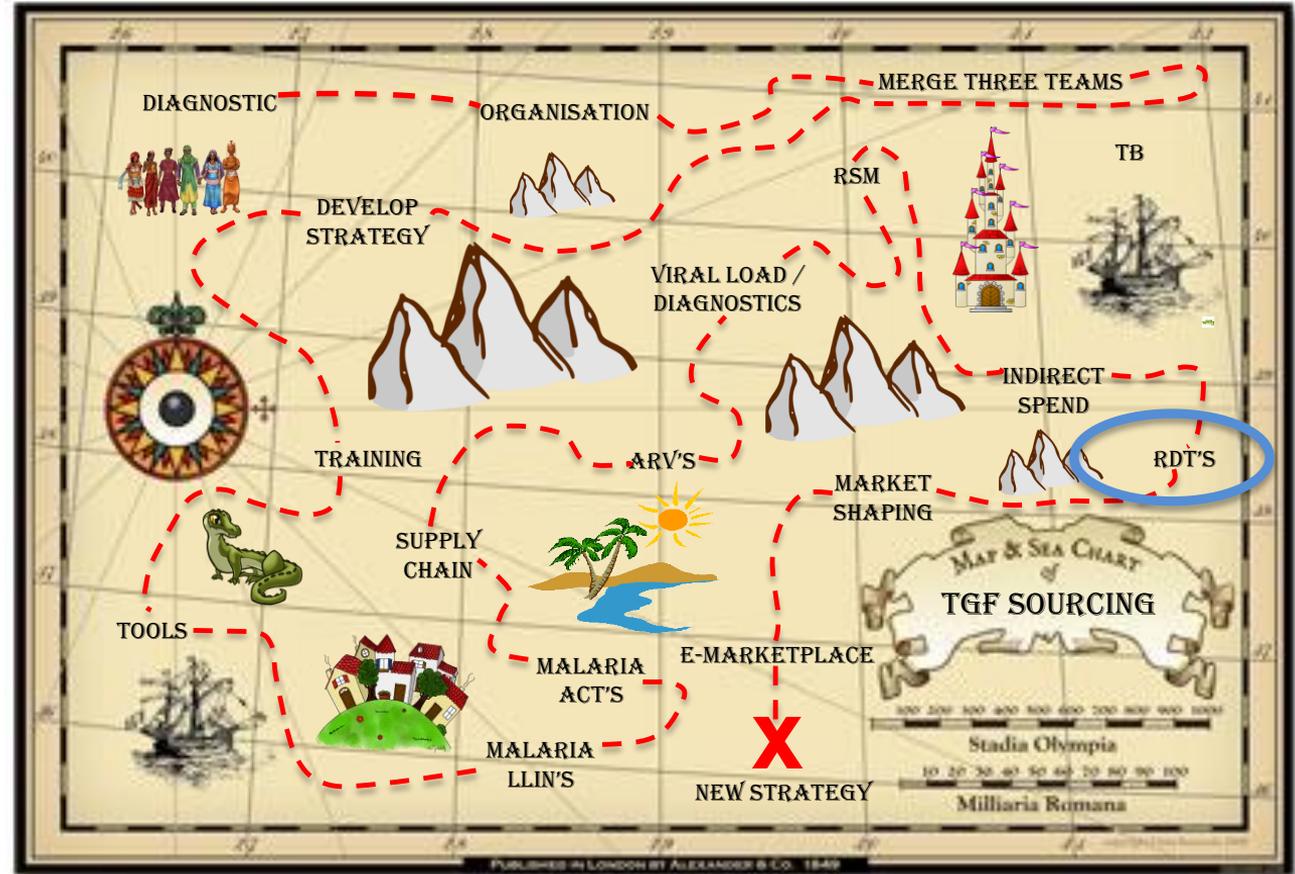
The category management plans form one element of a longer term strategy to re-position the function to provide greater support for the Secretariat and PRs



Implementation plan



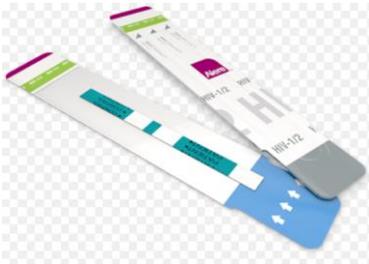
Rapid Diagnosis Tests



Sourcing of Rapid Diagnostic Tests



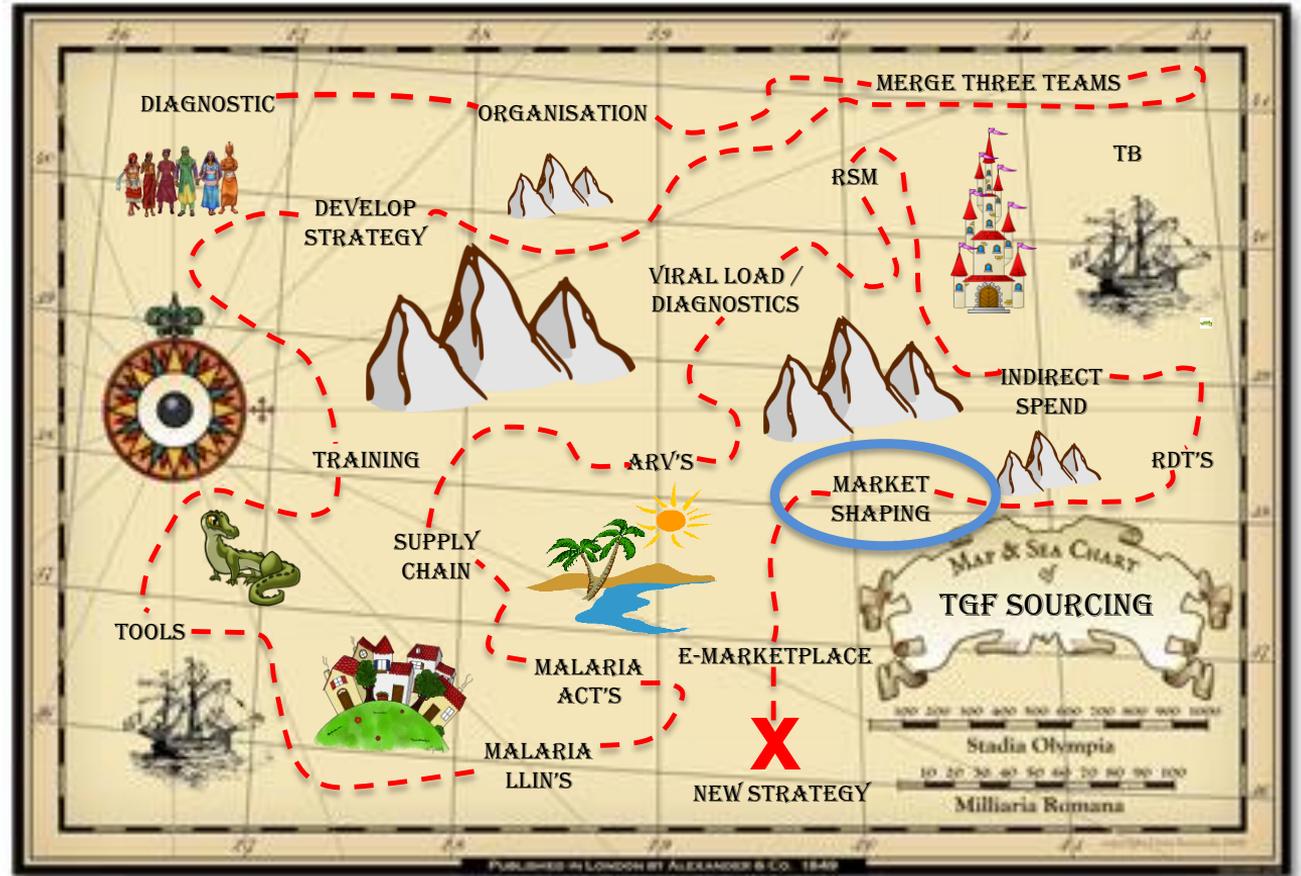
Building Knowledge : Rapid tests for HIV & Malaria



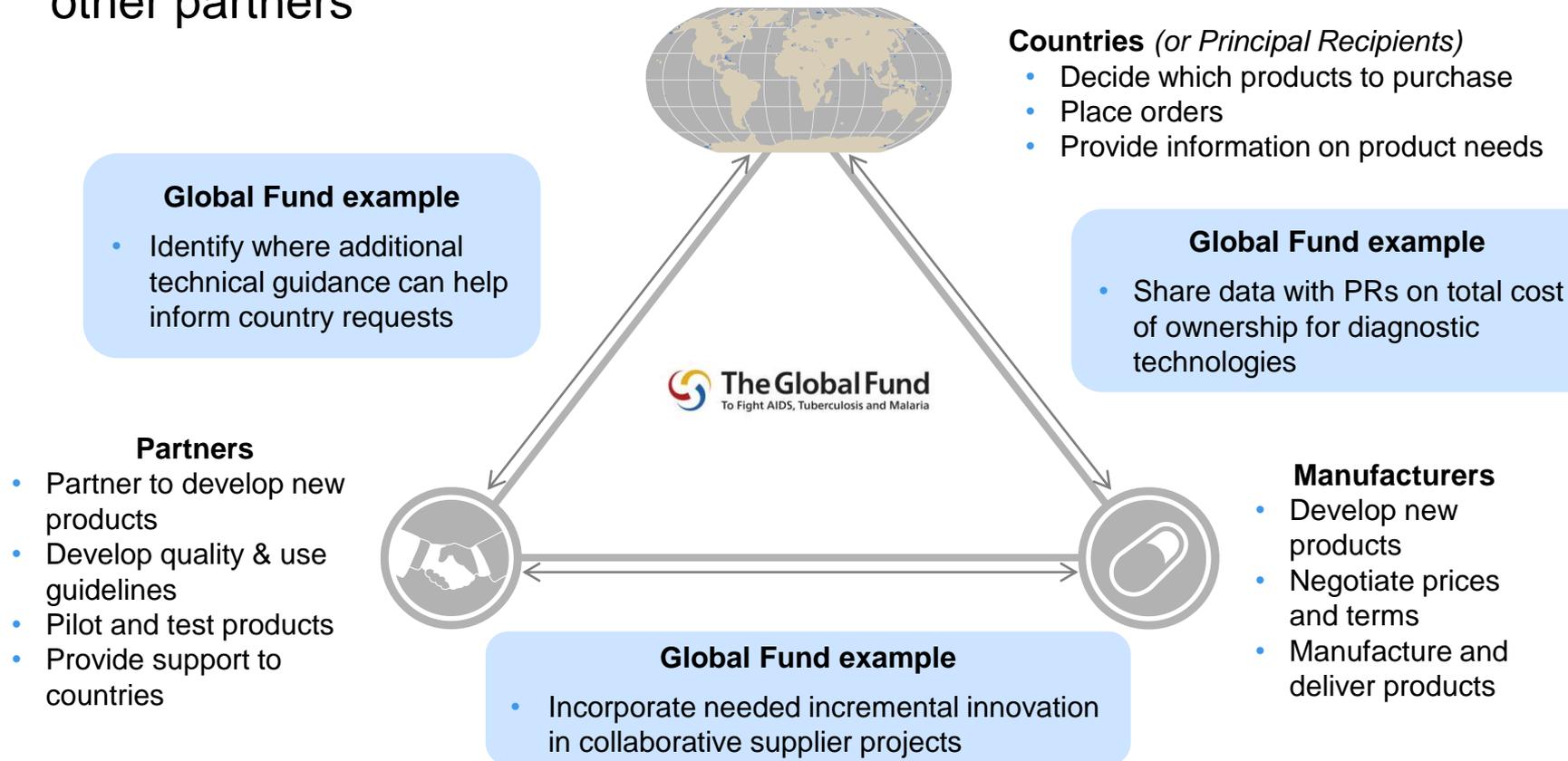
	Supplier X	Supplier Y	Supplier Z	Supplier J	Supplier Q	Supplier V
	India	USA		Japan	South Korea	China
HIV	Yes		Yes	Yes	Yes	Yes
Malaria	Yes	Yes			Yes	

Market analysis underway: data & visits
Visits to manufacturers with 80-90% volume almost done

Market Shaping & Dynamics



Global Fund can play a key role aligning countries, manufacturers and other partners



Our definition of “market shaping”

Market shaping supports health outcomes by...

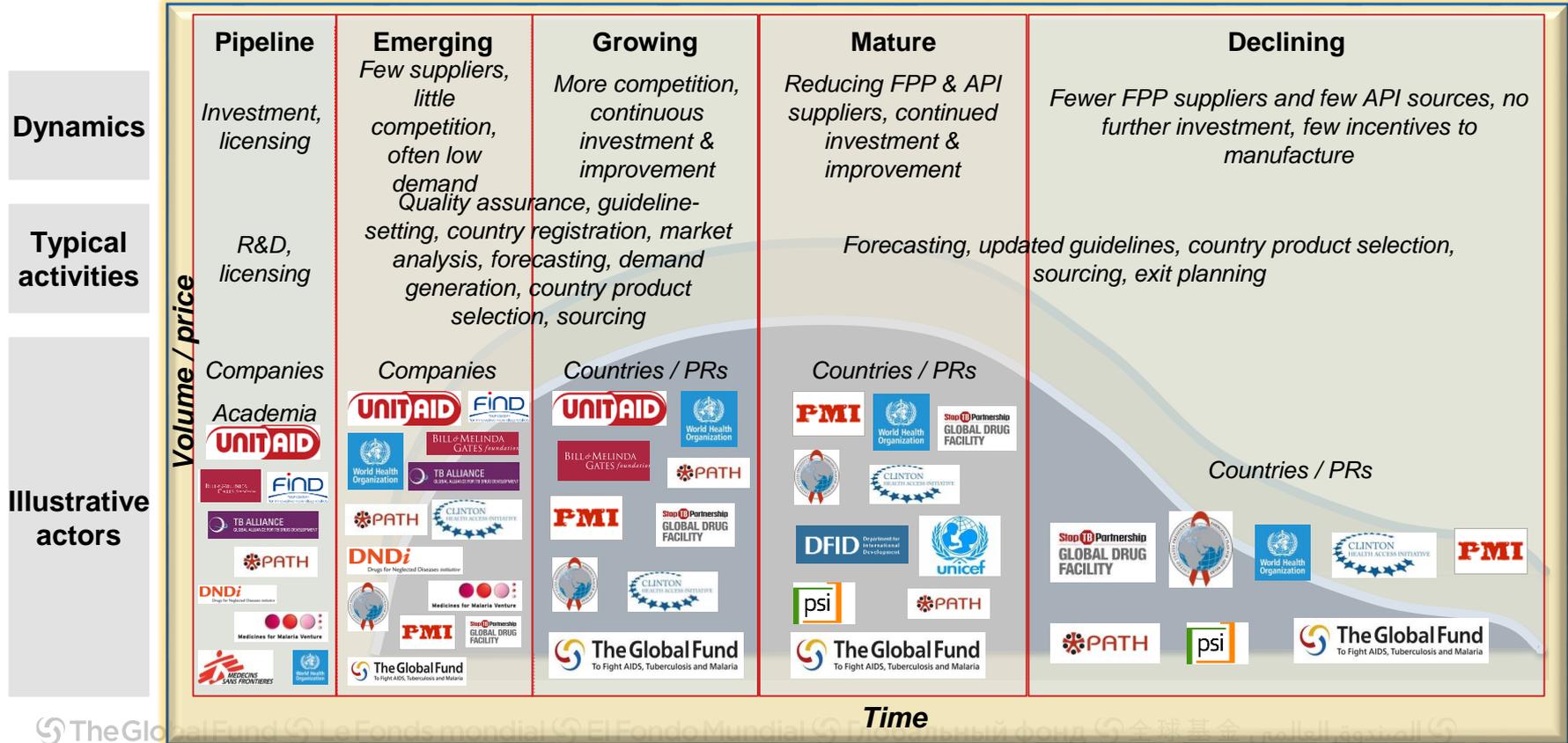
Implies proactive approach

Leveraging the Global Fund’s position to facilitate healthier global markets for health products, today and in the future

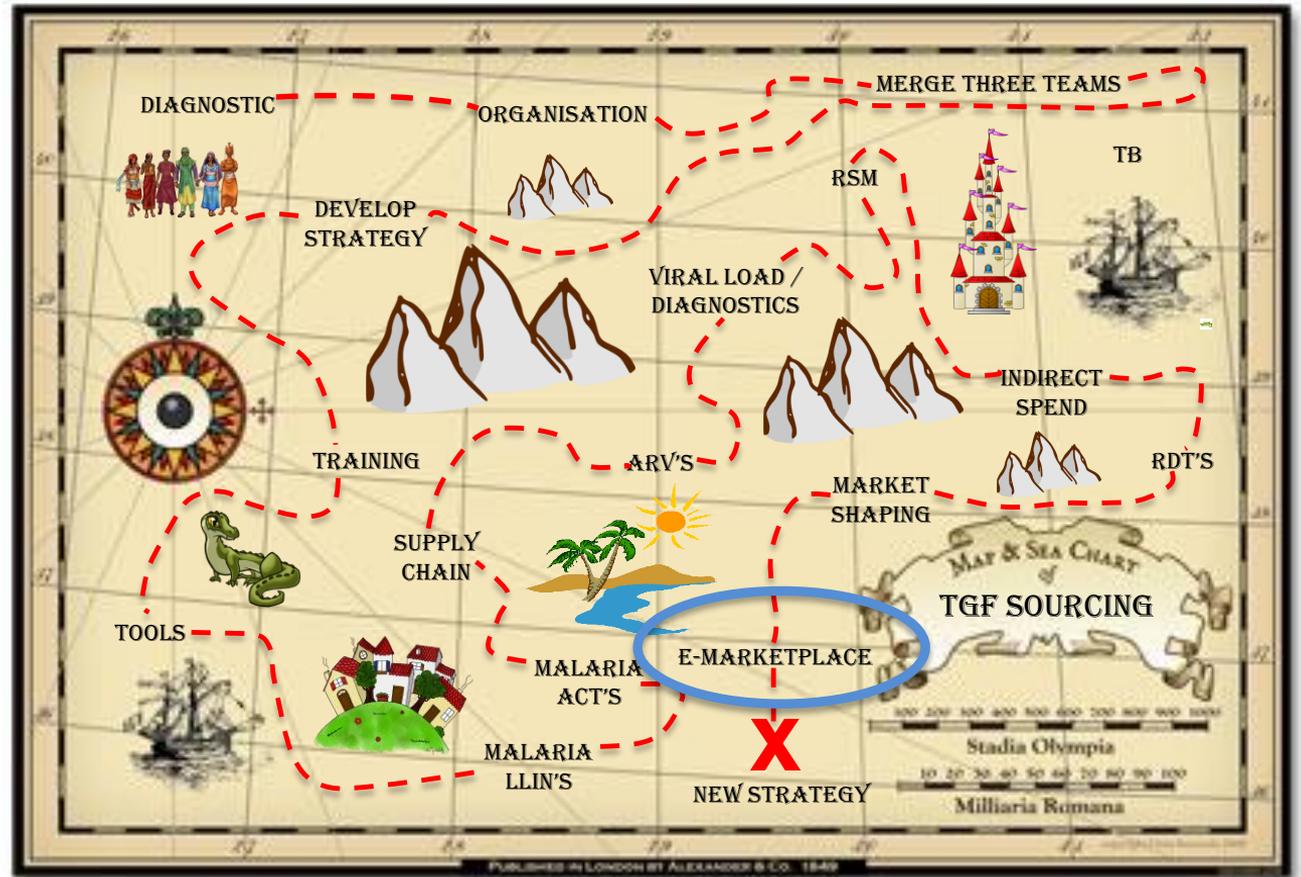
Focused on global market outcomes, not limited to outcomes for the Global Fund

Market shaping extends to future possibilities, not limited to current market conditions

Global Fund engages early in the product life cycle, but focuses on products as they begin to scale



E-Marketplace



Developing the E-Marketplace of the Future

MEC presentation

FISA Division
8th of July 2015

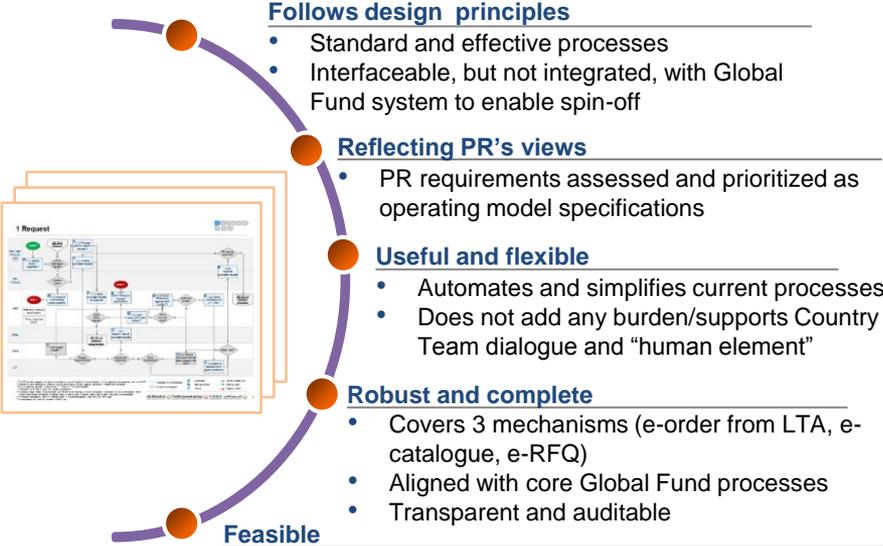


A detailed operating model for the e-marketplace has been developed and endorsed

Approach to operating model

- **Consult with PRs**
 - Consolidate PRs feedback into operating model requirements
 - 7 consultations to date, and ongoing
- **Consult with Global Fund teams**
 - Design operating model jointly with Sourcing, Finance, GMD, IT, legal (10+ functional/30+ individual workshops)
 - Fit with current processes
- **Consult with key suppliers** per product category to incorporate feedback into model
- Core operating model decisions made at **Design Authority**

Key characteristics of the e-marketplace operating model



- **Follows design principles**
 - Standard and effective processes
 - Interfaceable, but not integrated, with Global Fund system to enable spin-off
- **Reflecting PR's views**
 - PR requirements assessed and prioritized as operating model specifications
- **Useful and flexible**
 - Automates and simplifies current processes
 - Does not add any burden/supports Country Team dialogue and “human element”
- **Robust and complete**
 - Covers 3 mechanisms (e-order from LTA, e-catalogue, e-RFQ)
 - Aligned with core Global Fund processes
 - Transparent and auditable
- **Feasible**
 - Forms core of vendor choice process to ensure most requirements are implementable in solution

What we have heard from PRs as key benefits of e-marketplace

Key benefits of e-marketplace

Quotes by PRs



Visibility/Transparency

- Visibility in products & prices available
- Visibility/ability to track the process steps – especially after the issuance of the PO

“Seeing the full list of products with the relevant information will make our procurement decisions much easier”

– Procurement manager, Zambia



Access to a list of prequalified suppliers

“Quality is critical for us; having the list of suppliers already checked for quality is a big plus”

– Procurement officer, Senegal



Automation/acceleration of workflows leading to significant reduction of paperwork/gaining of time and audit trail

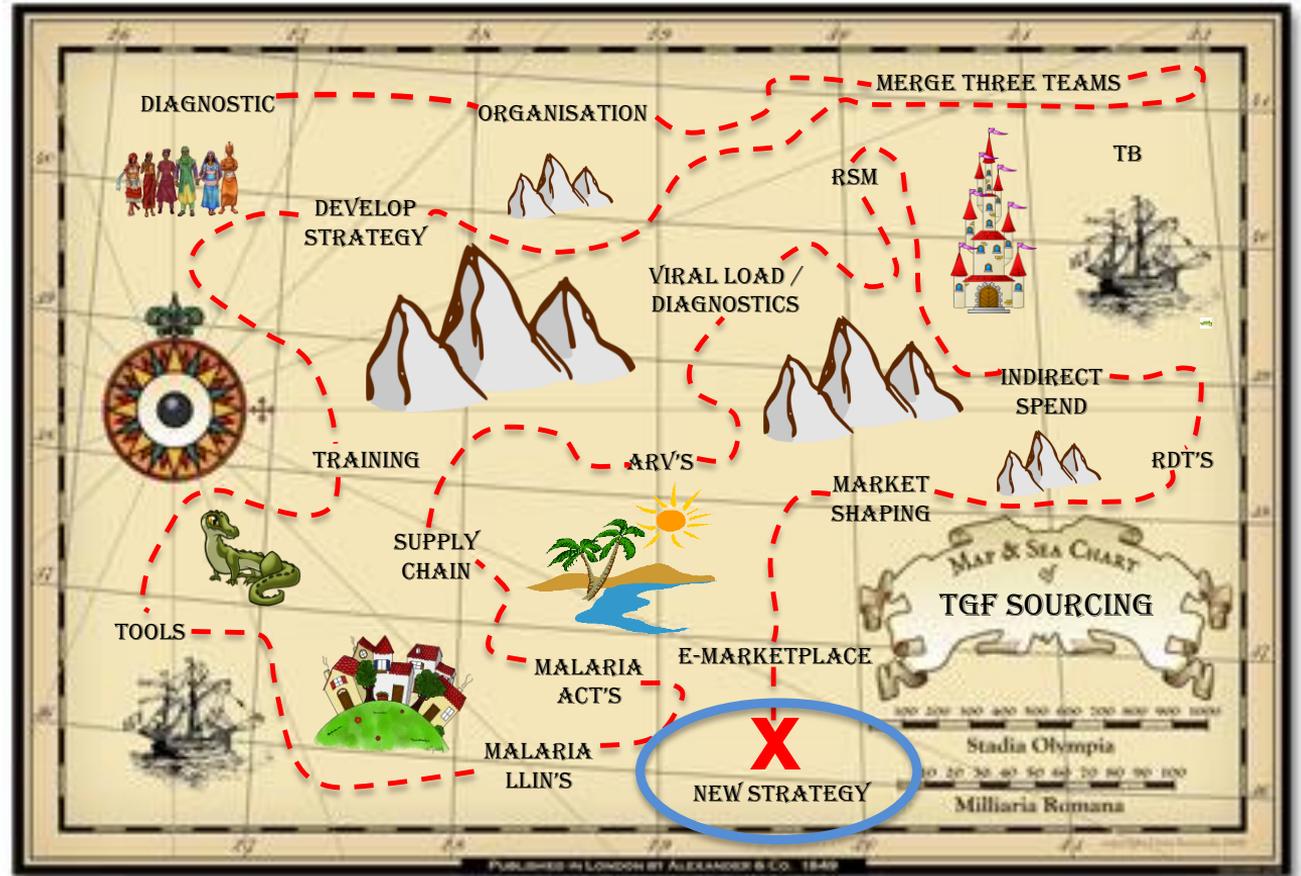
“An approval sometimes gets stuck for a month on someone’s desk, e-mp will speed up this process significantly”

– Head of procurement, Ghana



Generation of savings through access to larger variety of suppliers and long-term agreements for certain product categories

New Strategy



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

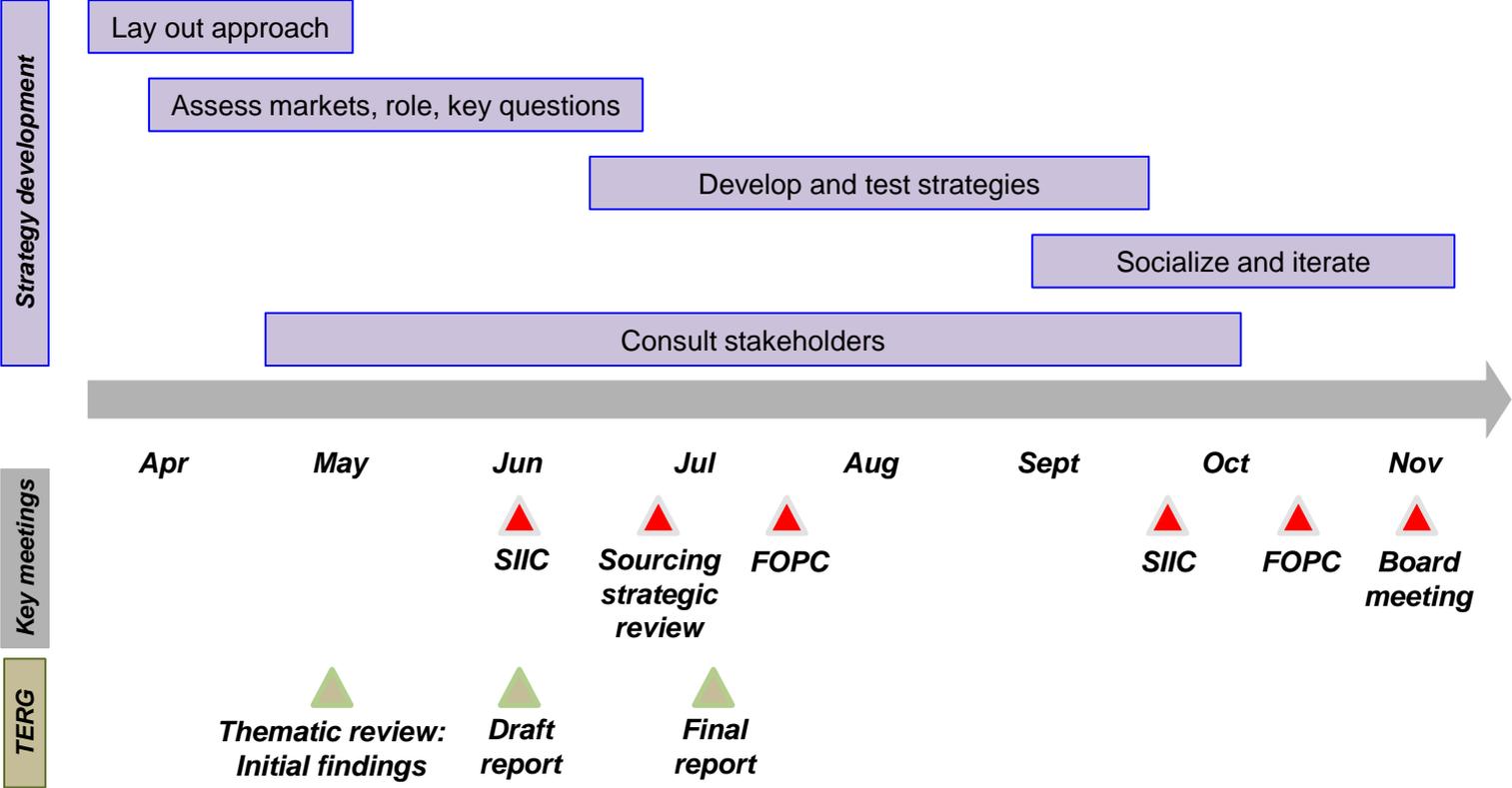
2 Identify opportunities for strategic cooperation in market intelligence activities

3 Measure market and public health impact.

Updated market shaping strategy will build on many past efforts and will be integrated with the Global Fund's 2017 – 2021 strategy

2004	ACT transition	<ul style="list-style-type: none"> Global Fund worked with WHO to facilitate countries to rapidly switch funding from suboptimal therapies to ACTs
2007	Initial market shaping strategy	<ul style="list-style-type: none"> Board decides that the Global Fund should play a “deliberate and strategic role in improving the impact of grants by influencing market dynamics” and endorses the creation of PQR and VPP
2007 - 2009	Creation of VPP and PQR	<ul style="list-style-type: none"> Based on the Board's 2007 decision, VPP became operational in mid-2009 with 40 countries and 74 grants by end 2010 PQR implemented to collect transaction-level procurement data
2011	Latest market shaping strategy	<ul style="list-style-type: none"> Board approved strategy “acknowledging the critical role of the Global Fund in shaping markets to maximize global access to health products...and further [emphasizing] its desire for the Global Fund to more actively shape markets...”
2013	Procurement 4 Impact	<ul style="list-style-type: none"> P4i transforms the way the Global Fund works across the supply chain, especially through the transition from VPP to PPM and the implementation of new long-term supplier agreements
2015 - 2016	2017 – 2021 strategy	<ul style="list-style-type: none"> Global Fund currently developing its strategy for 2017-2021, to be reviewed by the Board in March 2016

Sourcing is leading a refresh of the Global Fund's Market Shaping Strategy for the November Board meeting



Agenda

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Reminders

Please make sure to sign up for one of tomorrow's break-out sessions

- Space is limited – first come, first serve

Break-out rooms are also available for individual or small group meetings after our agenda finishes tomorrow at 1500

- Sign up for rooms on the same break-out session sign-up sheets

If you have questions or need anything, stop by the Registration Desk

For all your social media: #Procurement4impact

Update: Sourcing of Antiretroviral Medicines

Implementing The Global Fund's Framework Agreements: the first two quarters

Sourcing Strategic Review Meeting

9 July 2015

The new procurement approach was broad based and designed to address a range of objectives – it was not just about price

Sustainable Supply

- *Continued supply of all needed products through all stages of the lifecycle*
- *De-risk API supply chain*
- *Improved forecasting, payment and administrative processes*

On-Time Delivery

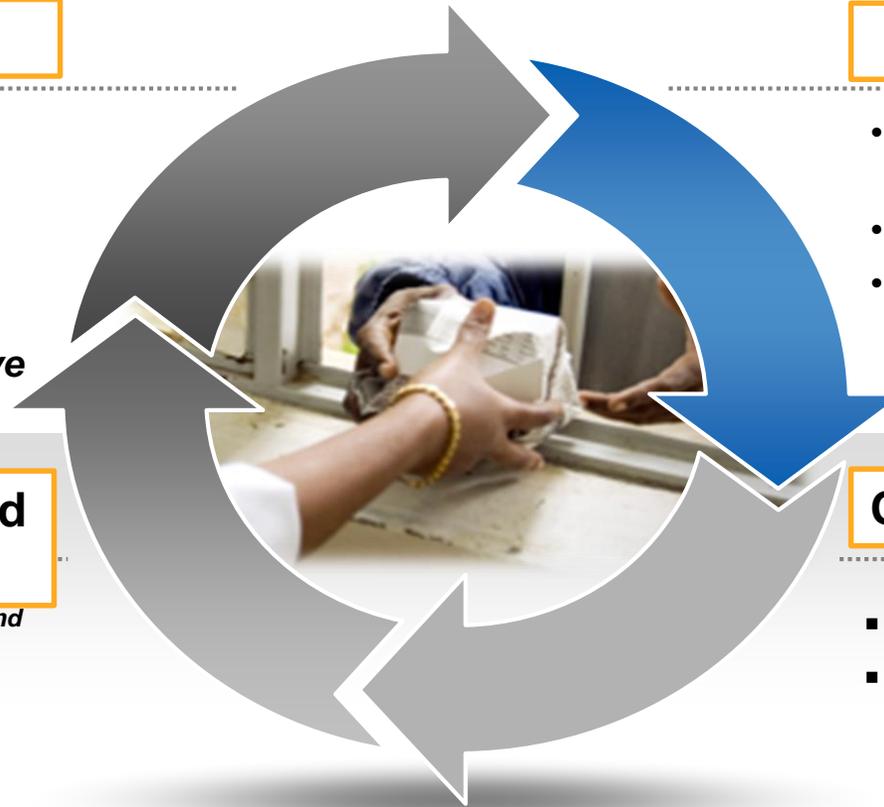
- *Improved delivery performance*
- *Shorter lead times*
- *Mitigate force majeure*

Competitive Pricing and Affordability

- *More affordable 1st and 2nd line regimens through leveraged volumes*
- *Improved planning and longer term contracts*
- *Use supplier expertise*
- *Collaboration to protect reasonable margins*

Quality and Regulatory

- *Longer shelf life*
- *Broader country registration footprints*



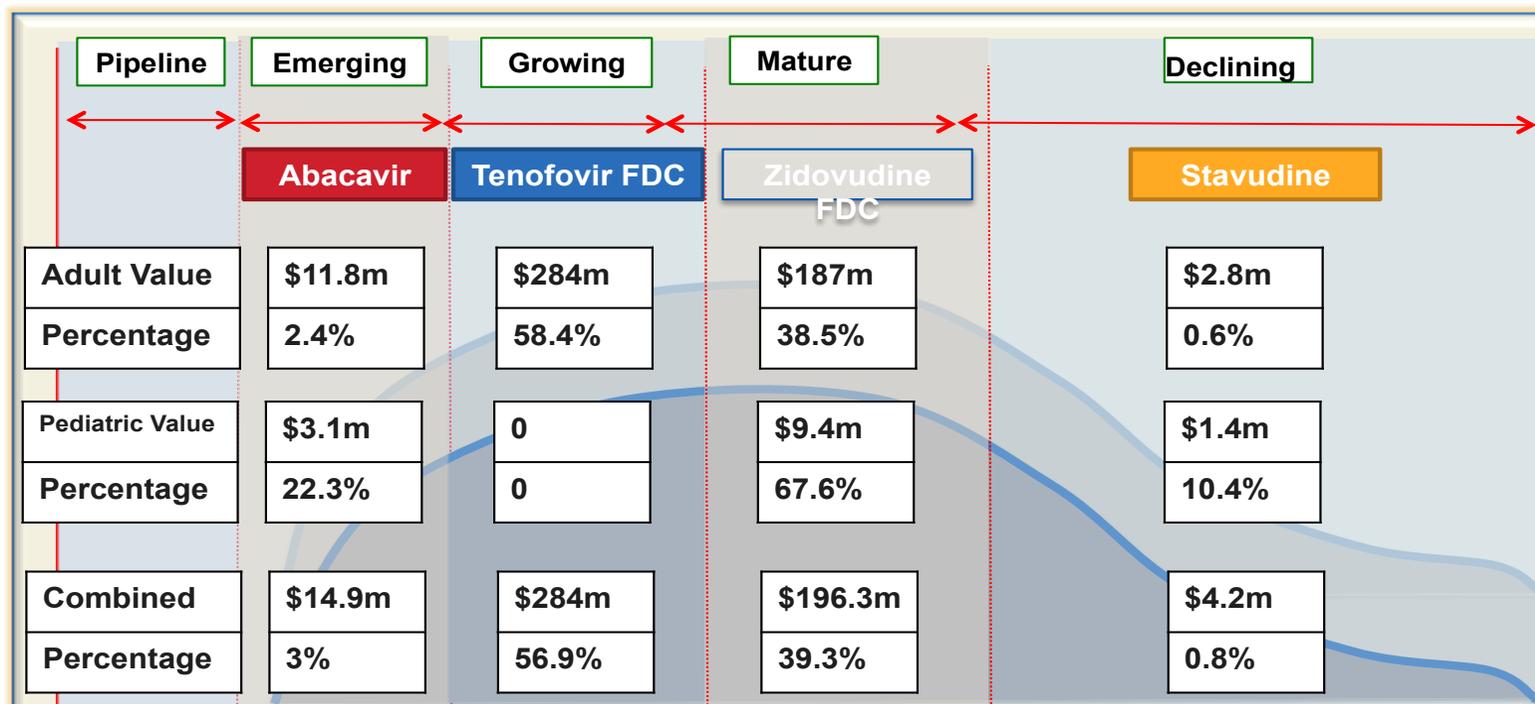
These objectives will result in a new form of supplier engagement

Key elements of the strategy: continuous supply

Challenge to address: ensuring availability of all 75 ARVs where some essential products have limited and intermittent demand

Solutions:

- Designed to support access according the product lifecycle stage attributes
- Evaluation of API supply security at the product level



Key element of the strategy: market and product sustainability

Challenge to Address: Ensuring ongoing and new supplier participation in a market associated with low returns.

Solution:

- Work with a panel of suppliers including developing long term supplier partnerships with collaborative projects and committed volumes over 3-5 years
- Mechanism to support new entrants and new products from existing players.

Schedule B3 Development Road Map

WORKED EXAMPLE
This worked example is based on a supplier whose objective is to reduce their lead time by changing their manufacturing process. All the activities and products are fictitious and the example is provided only to show how to fill in the template.

Page 1 Background Information

Client Name	ABC Pharma/Health	Initial Target	Lead time reduction from 6 months to 3 months at Phase 21 (Timeline)
Project Name	Lead Time Reduction Project	Target Date	2015-2016
Benefits Sharing Proposal	All lead time to the Global Fund, any additional financial benefits to be shared 50:50		
Initial Objective and Summarised Approach	Product Set Impacted	How Success(Value) is Measured	
Mapping of current supply chain and manufacturing processes followed by a joint cost analysis and the final implementation of new ways of working with both suppliers and The Global Fund	Various Active Ingredients and Formulations	Phase 1: Reduction from 6 to 3 months receipt at customer to date product is available for shipping	
Supplier Sponsorship and Resources Required	Actions Needed from the Global Fund	Actions Needed from Other Agencies	
Provide lead time reduction by financial, operational resources and 30% of PM, 100% for cost analysis. Operational resources are 30% of PM, 100% for cost analysis and 100% for data analysis, 20% of PM (see below)	Review and approve on-site activities. Assistance of project kick off, option review workshop. Internal investigation and implementation of internal process changes.	Internal investigation of changes or needed by the Global Fund. Independent PM to be advised of changes and any benefits from new way of working.	
Governance Model	Identified Risks	Additional Information Not Covered Above	
This project has been included as part of a portfolio alongside other projects processed. We will appoint 3PMs for all projects. Progress a monthly update and call and quarterly formal steering committee alternating VC and 2P. From our side Steering Committee will be sponsors and PM.	1. Complexity and regulatory requirements affecting manufacturing process changes.	This document has been prepared as an ongoing business development program. Results from the options workshop will be used in a series of phases.	

There is nothing below this line

Schedule B3 Development Road Map

WORKED EXAMPLE
This worked example is based on a supplier whose objective is to reduce their lead time by changing their manufacturing process. All the activities and products are fictitious and the example is provided only to show how to fill in the template.

Page 2 TimeLine

Active Name: Lead Time Reduction Project

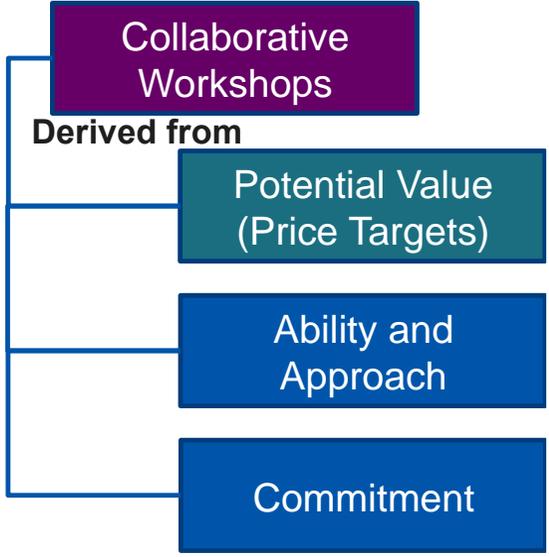
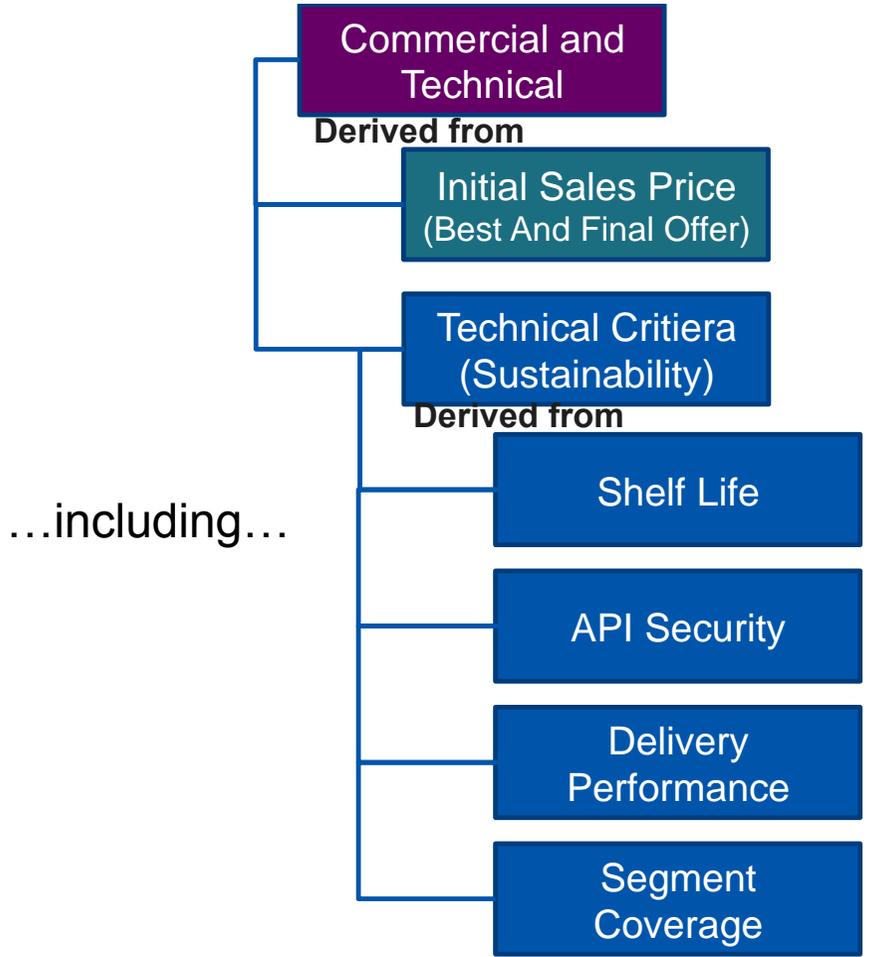
Section 3

Activity Name	Duration in Weeks	2015														
		January	February	March	April	May	June	July	August	September	October	November	December			
Team Mobilisation and Kick Off	2	1														
Internal Review and Mapping of Production Processes	9															
Identification of choke points in manufacturing process	7															
Analysis of supplier lead times and inventory policy	11															
Analysis of demand forecasts and provided lead times	9															
Workshop Preparation	3															
Option Workshop Delivering Prioritised Outputs	2															
Process Design for Priority Process Changes	4															
Training and Process Changes Piloting	4															
Full Roll Out Manufacturing Process Changes	6															
Roll out to demand management process changes	6															
Introduction of new stocking policy	4															
Final Review/Close out and Initiation of Phase 2	2															
Project Management Steers Meetings																
Phase 2 Roll Out																

Q1 Milestones		Q2 Milestones		Q3 Milestones		Q4 Milestones		Q1 Milestones	
Number	Milestone	Number	Milestone	Number	Milestone	Number	Milestone	Number	Milestone
1	Team mobilised and work plans agreed	2	Analysis Deliverables Complete	5	Pilots complete lessons learnt implemented	6	Close out meeting from Phase 1		
		3	Workshop Complete			7	Phase 2 commences (Provisional)		
		4	Training and roll out plans complete						

A broad range of factors were evaluated to meet the range of objectives

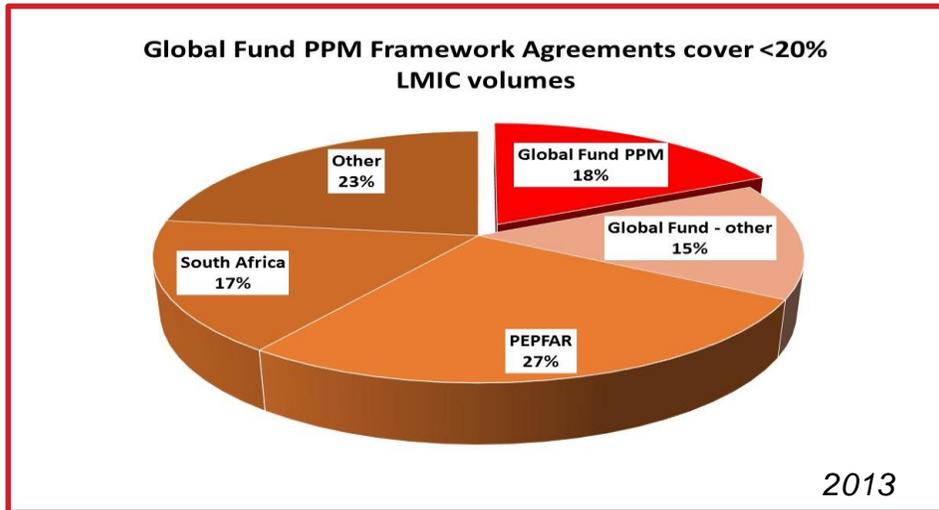
Schematically & illustratively



The overall weighting comprised

- 46 % price criteria
- 54 % other technical & value elements

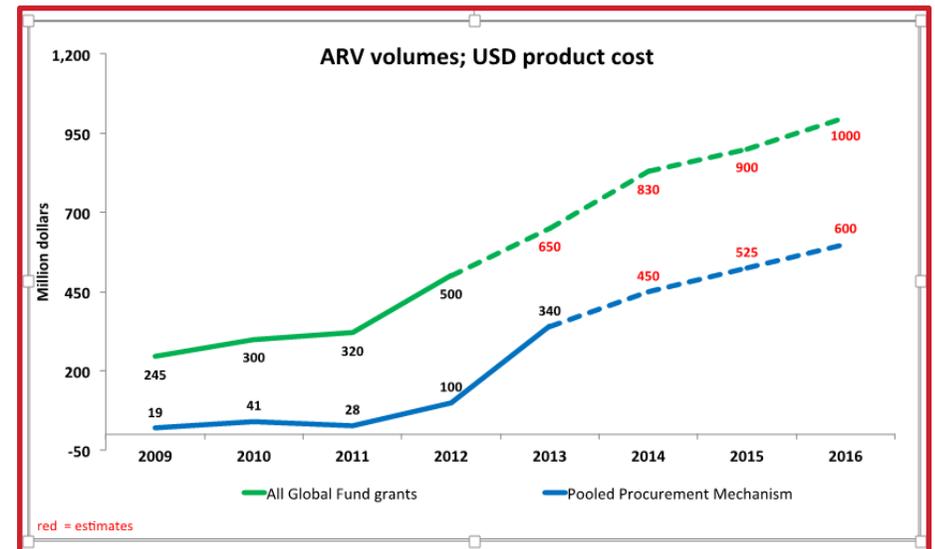
Recall: key numbers



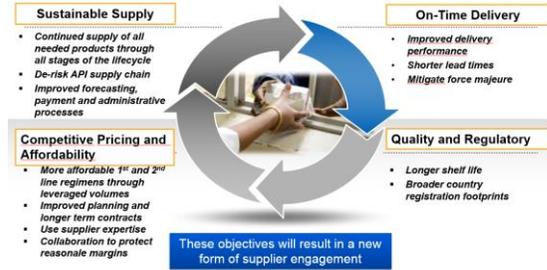
Products	Suppliers
110 products QA-approved	30 (10 originators; 20 generic)
Average 2.9 suppliers make each product (1 → 13)	15-20 suppliers participated in PPM 2010-13
20 products are made by 5 suppliers	Average 10.6 products produced by each supplier (1 → 50)
50 products are made by only 1 supplier	10 suppliers produce ≥ 10 products
75 products regularly procured	16 suppliers produce ≥ 5 products
Average 16 ARVs procured by GF-PR (1 → 38)	

2014

- High income market = 10x LMIC value
- Spend significantly skewed to high volume 1st line optimal treatments (85% of spend)
- In LMICs, ARVs are mostly supplied under licenses from originators
- South Africa has also entered into 3 year arrangement
- PPM + South Africa = 1/3 volumes that can encourage investment for scale for increasing numbers of people on treatment



The new procurement approach was broad based and designed to address a range of objectives – it was not just about price



Objective: sustainable supply: the first 2 quarters 2015

1. Continued supply of all needed products through all stages of the lifecycle

- Few challenges in obtaining ARVs including low volume products
 - Bundling low & high volume products; multiple awardees/ product ; diversification of API sources
- Procured from 13 ARV suppliers in first half of 2015 (including 8 with Framework Agreements)
- Coordinated procurement of paediatric ARVs with the PAPWG
- Commitments as a tool to support new product introduction
- Supply security improved for all buyers

2. De-risk API supply chain

- Evidence of more API sourcing diversification
- Finished dosage form suppliers establishing longer terms contracts with API suppliers
- Supplier partnership projects being implemented through objectivized annual business plans

3. Improved forecasting, payment and administrative processes

- Rolling monthly forecasts of demand and allocation provided to individual manufacturers for coming 6-12 months+
- Reduced administrative timelines (PSA, financing and PR approval) – 3 weeks less in 2014; working to reduce by a further 4 weeks by end 2015

The new procurement approach was broad based and designed to address a range of objectives – it was not just about price



Objective: On-time (reliable) delivery: the first 2 quarters 2015

1. Improved delivery performance

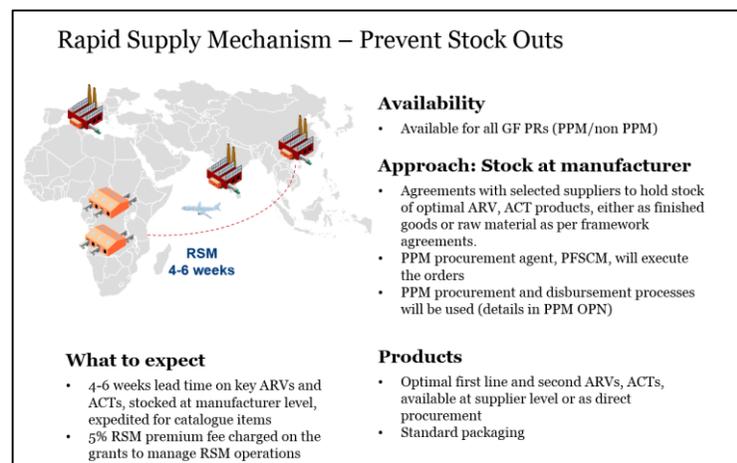
- Improved from +/- 40% OTIF in 2013/2014 to 70-80% by end Q2 2015

2. Shorter lead-times

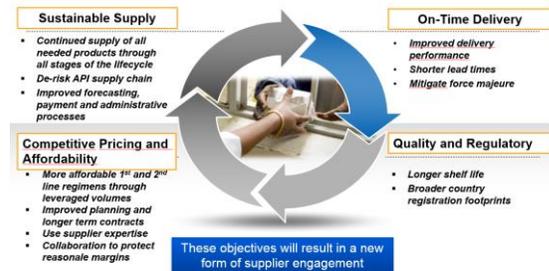
- Manufacturer lead-times reducing especially for high volume products

3. Mitigate force majeure

- Diversification of manufacturing locations: finished dosage forms; APIs; and key starting materials
 - Engagement with Indian, Chinese and African suppliers
- Vendor managed inventory linked to commitments as a viable solution to respond to stock-outs across the Global Fund portfolio
 - Initial target stocks held for 18 1st & 2nd line optimal ARVs for adults and children
 - ACTs



The new procurement approach was broad based and designed to address a range of objectives – it was not just about price



Objective: Competitive pricing and affordability: the first 2 quarters 2015

1. More affordable 1st and 2nd line regimens through leveraged volumes

- Cost reductions and changes in price dynamics for optimal 1st & 2nd line regimens for adults and children: immediate and over time: TDF FDCs; boosted-PI's; better paediatric products
- Cost avoidance through mitigation of proposed price increases for zidovudine-based regimens
- Enabling PAHO Strategic Fund to access Framework Agreement - including for non-GF financing
- Efficiency opportunities will be benefit all buyers

2. Improved planning and longer term contracts

- Rolling monthly forecasts of demand and allocation provided to individual manufacturers for coming 6-12 months+ resulting in more reliable on-time supply and shorter lead-times

3. Use supplier expertise

- Supplier partnership projects:
 - Price targets
 - API security & shelf life
 - New product introduction; dose reduction
 - Supply chain efficiency
 - Local manufacture

4. Collaboration to protect reasonable margins

- On target with price targets to pass on benefits of process efficiencies and improved API sourcing resulting from longer term contracts and commitments

The new procurement approach was broad based and designed to address a range of objectives – it was not just about price



Objective: Quality and Regulatory: the first 2 quarters 2015

1. Longer shelf life

- Longer shelf life rewarded in evaluation
- Supplier partnership project to extend shelf life
- Improved for all buyers

2. Broader country registration footprints

- Allocations linked to country registrations
- Regular reporting on registration status
- Country registration footprint monitored for expansion

3. Other

- Shorter and more focused list of priority products eligible for ERP mechanism

Further work is required to exploit all of the opportunities

- Better forecasting
- Earlier ordering from PRs: optimize production planning
- Exploiting the opportunities for using better products and enabling clinical choices to drive selection through price roadmaps for priority products
- Standardization and harmonization of packaging

In conclusion, we have a new form of supplier engagement with opportunities for further future value to be created and ultimately a more reliable and sustainable supply for more ARVs for more patients

Feature	Impact for Supplier
Longer term contracts: 2 - 5 years	Ability to secure financial resources and optimize API sourcing and production efficiencies
Financial volume commitments	Risk mitigation
A focus on total cost of ownership	Viability of inward investments
Search for value added services	Opportunity for innovation and investment
Regular performance review with focused KPIs <ul style="list-style-type: none"> • OTIF; lead-time; progress of projects including against target pricing 	Facilitates improvement and potential for additional volumes in new allocations
Key Quality Requirements	
<ul style="list-style-type: none"> • WHO PQ and/or SRA approvals • Country registrations 	GMP and supporting administrative processes for other products and markets

Further information

- Process, RFP documents, evaluation criteria, forecast, Framework Agreement templates: <http://www.theglobalfund.org/en/business/>
- Pretender strategy briefing: <http://www.theglobalfund.org/en/p4i/events/>
- PPM ARV Reference Prices: <http://www.theglobalfund.org/en/procurement/vpp/>
- Price and quality Reporting (PQR):
<http://www.theglobalfund.org/en/procurement/pqr/>
- More information to follow shortly

THANK YOU



Finished Pharmaceutical Product (FPP) Market Observations

1. Spend is significantly skewed towards high volume 1st line optimal treatments which form 85% of current spend.
2. In this space ARVs are mostly supplied by generic companies under license from originators in LMIC with a small number of suppliers supplying most of ARV requirements.
3. Low volume specialist adult and pediatric treatments form a long tail and supply chain integrity proves a major challenge owing to smaller order quantities and fragmented demand.
4. Relatively short product life combined with high regulatory burden adds complexity to managing the operation.
5. Sustainability becomes an emerging concern:
 - Some suppliers not participating in the tenders for some products
 - Competition for production between products of different margins
 - Poor supplier delivery performance

ARV FPPS are a high volume and complex business with a number of challenges

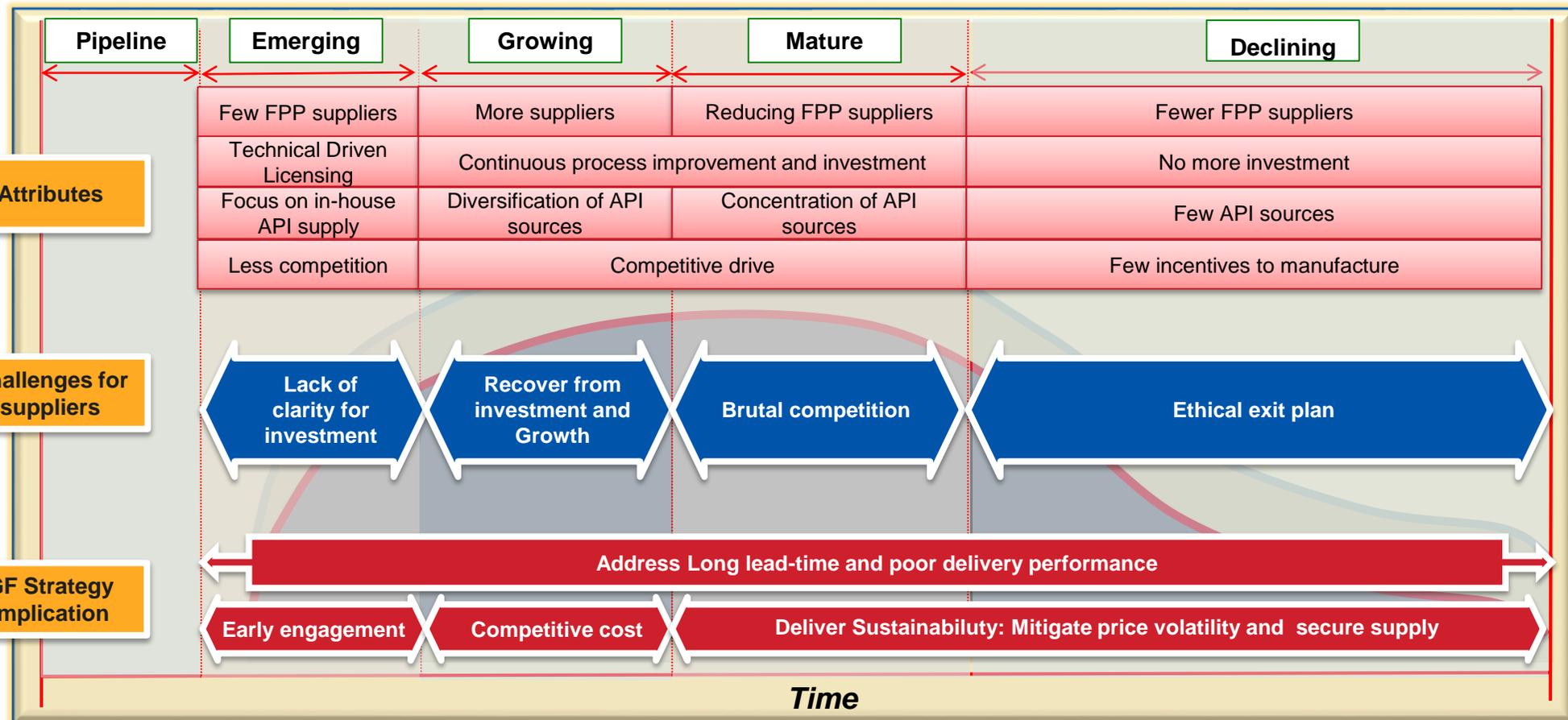
Active Pharmaceutical Ingredient (API) Market Observations

1. Despite sufficient oral solid finished dosage form capacity to meet forecast requirements for new products, active FPP suppliers could be limited by API availability.
2. Few generic suppliers are able to supply their entire API requirements and some of them rely on 100% external supply.
3. Some large, vertically integrated suppliers have made significant investment in API production to underwrite FPP supply. Others are taking a more selective approach with a focus on vertical integration in emerging products.
4. Opportunities for sourcing API for older products are reducing.
5. API supply interruption and price increase can be caused by Key Starting Material supply challenges.

API make or buy decisions are fundamental to determining cost competitiveness, supply security and long term FPP strategy.

Lifecycle Management and ARVs

We have overlaid the key ARV attributes to the lifecycle to determine the strategic priorities



Update: Sourcing of viral load & early infant diagnostic tests
Providing transparency in pricing, costs, acquisition and contracting options
Sourcing Strategic Review Meeting

9 July 2015
Geneva

The Global Fund is supporting the implementation of WHO Recommendations through programmatic, financing & procurement actions

1. Securing the Financing: Strategic Investment Notes: HIV & Health Systems Strengthening
2. Working with partners to support programmes scale-up: guidance and targeted support
3. Leveraging the Global Diagnostics Working Group – and - African Society for Laboratory Medicine (ASLM): QA; selection; systems strengthening
4. Policies for the procurement of health products including QA Policy & Expert Review Panel (with UNITAID)
5. Engaging with suppliers to understand the products and market (with PEPFAR, USAID, CDC)
6. Tender with objectives of transparency of pricing, total cost of ownership and contracting options

Working with partners to support scale-up



VL Strategy Workshop (Addis, Sept 2014)

Objectives

- The objective of the workshop was to develop country-specific plans for scaling-up HIV viral load testing using a network approach.

Main Outcomes

- Development of partnerships between countries, donors and IPs to develop country-specific viral load scale-up and implementation plans.
- Establishment of a taskforce to guide the implementation of the plans.

VL Toolkit

- Costing framework
- Training tools for Clinicians/Nurses
- M&E Framework
- Guidelines for Sample Referral Systems
- Quantification/Forecasting Tools
- Training Manual for Laboratorians



World Health Organization

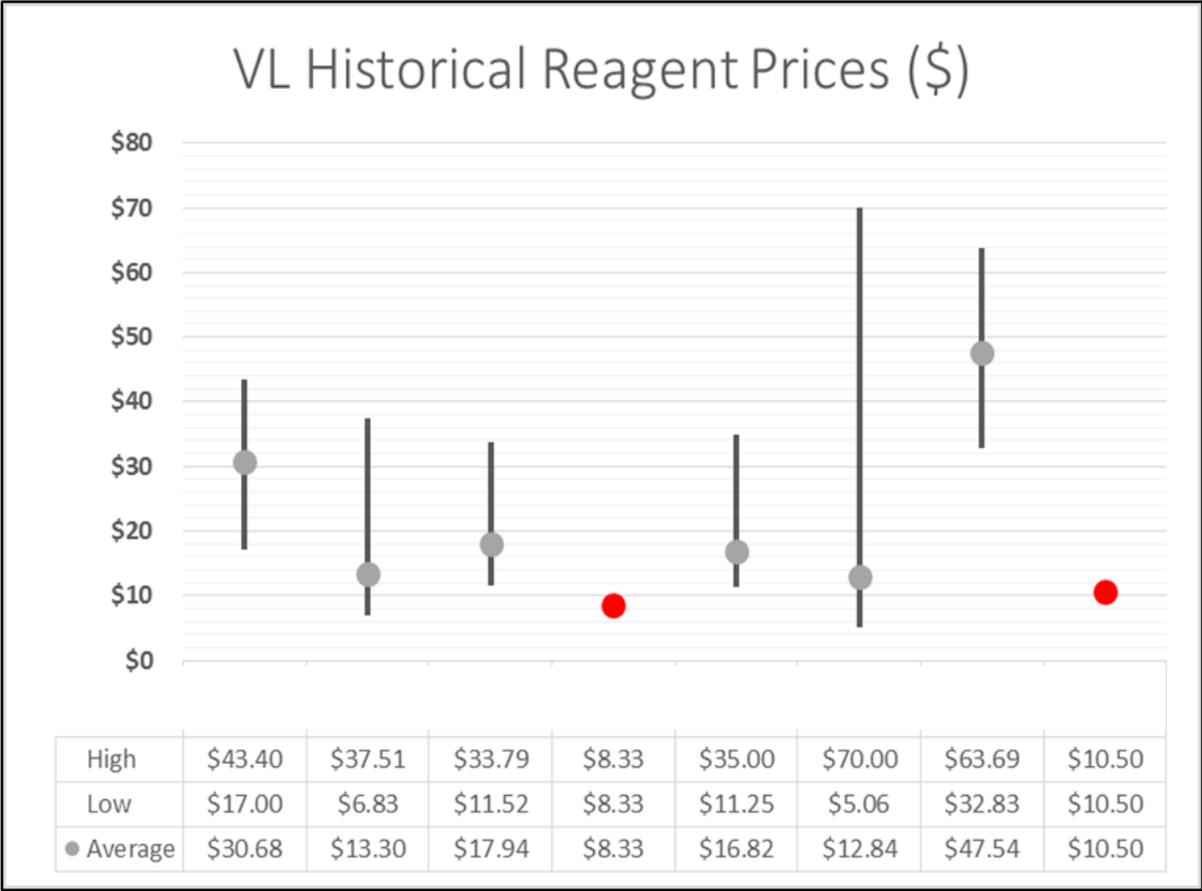


**DIAGNOSTICS
ACCESS INITIATIVE**
to achieve final HIV
treatment targets



Historically there has been little visibility in pricing with arrangements country-by- country or even machine-by-machine

Wide variability in pricing



Viral load & EID tender: completed June 2015

1. To select a panel of manufacturers to enter into Framework Agreements to supply PRs both through all procurement channels of Global Fund recipients
2. To improve transparency of cost and contracting elements to enable better selection, acquisition and procurement of analyzers, reagents and support services
3. Panel Suppliers are expected to enter into agreements that have the same terms, conditions and pricing with other public sector buyers



Tender process

Only bidders who were manufacturers of products in compliance with the Global Fund's Quality Assurance Policy on Diagnostics were eligible to participate

Stage 1

- > Preparation, submission, preliminary examination, screening and evaluation of proposals
- > Invitation of selected bidders to participate in Stage 2

Stage 2

- > Opportunity to discuss more detailed information and seek clarifications through dialogue and meetings
- > Review of assumptions for total cost of ownership model
- > Submission of Best and Final Offer (BAFO)

The same 2-stage process is available for new entrants when they meet the QA policy

Supplier panel

	Eligibility and Testing products	
	Regulatory status	
Abbott	WHO PQ	VL, EID
Alere	CE mark	EID
bioMérieux	WHO PQ	VL
Cepheid	CE mark	VL, EID
Hologic	CE mark	VL
Qiagen	CE mark	VL
Roche	WHO PQ	VL, EID



Outcome: a range of credible, cost-effective, competitive options with more transparent pricing and contracting: viral load & EID

Leveraged volumes	<ul style="list-style-type: none">✓ Enables volumes to be leveraged and promotes maximum up-time and throughput
Transparent contracting	<ul style="list-style-type: none">✓ Guides new selection and establish contracting modalities and templates✓ Benchmarks existing arrangements with forward-applicability in many cases✓ Delivers Framework Contracts and Transaction Agreements
Transparent costing	<ul style="list-style-type: none">✓ Provides standardized costing enabling easier and more transparent decision-making✓ Provides clear cost build-up to Total Cost of Ownership for a more meaningful and fair comparison
Additional acquisition models	<ul style="list-style-type: none">✓ Provides options of different acquisition models: purchase and reagent rental✓ “Reagent rental” now available from majority of suppliers that is comparable with the equivalent “all in” bottom up price – no or small “premium”✓ Identifies various value-added solutions available
Broader supplier base	<ul style="list-style-type: none">✓ Includes 2 new offerings for lab-based systems✓ Includes 2 new entrants for lower throughput/near-Point-of-Care offerings✓ Establishes process for new entrants with a clear target for pricing and contracting
Global visibility	<ul style="list-style-type: none">✓ Enables better global visibility and framework for performance management (rather than fragmented country-level) and sustained delivery✓ Includes agreement to make key elements of this RFP “available” in the public domain including TCO calculations

Transparency in pricing, total cost of ownership, contracting and acquisition options

<http://www.theglobalfund.org/en/procurement/viral-load-early-infant-diagnostics/>

TheGlobalFund English

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Home > Procurement and Supply Management > Viral Load / Early Infant Diagnosis

Procurement and Supply Management

Updates

Quality Assurance Information

Price and Quality Reporting

Procurement Support Services

Information for Suppliers

Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool

Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool

The information provided on this page is a summary of the results of a recent Request for Proposals (RFP) that will result in the establishment of Framework Agreements with seven diagnostic manufacturers that aim to make the market for HIV viral load testing more transparent and competitive.

We will be regularly updating the information and downloadable tool on this page and recommend that you regularly revisit the page to see the latest information. We are encourage feedback to enable us to improve the content- contact details are provided below.

Background

The 2013 WHO consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection recommend quantitative viral load testing as the preferred monitoring tool for diagnosing and confirming the failure of antiretroviral therapy (ART). Qualitative viral load is the recommended approach to early infant diagnosis (EID) of HIV. Testing for viral load and EID can sometimes use the same platforms with different reagents and protocols, which is why it often makes sense to consider planning and procurement together.

The purchase of viral load and/or EID machines can cost more than \$150,000. Reagents and other consumables needed to produce a test results may vary significantly in price with a range of \$10-85 per test for the reagents alone.

When equipment has been purchased, analyses by WHO and others have demonstrated low utilization of machines, frequent malfunctions, and other problems which limit the public health impact of these investments.

The Global Fund's Procurement Strategy for Viral Load and Early Infant Diagnosis therefore focuses on both optimizing existing equipment and investments as well as supporting scale-up - and was developed within the context that expanding VL and EID testing can be complex and requires, in addition to the investment in the products, significant investments in laboratory systems, sample transport networks and people.

The prime focus of the 'procurement' linked to the Strategy was to achieve simple, transparent and affordable pricing with optimal contracting models for analyzers and/or

Related Sections

- PSM Procurement and Supply Management
- P4i Procurement for Impact
- Private Sector Co-payment Mechanism
- Business Opportunities

Selection and Procurement Tool

The detailed information is presented in hyper-linked tool (currently presented as a PDF document) that can be [downloaded](#)

PDF - 4 MB | [English](#)

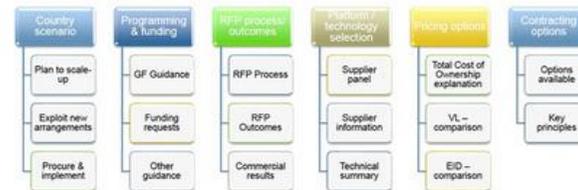
that enables navigation through the in-depth information according your needs (select Ctrl+L to view in full screen mode).

The high-level topic areas are:

- Country scenario – from looking to scale-up or to simply re-order
- Programming and funding – guidance for planning including Concept Notes and Grant Making
- RFP process and outcomes – the recent Global Fund RFP
- Platform /technology selection – suppliers on the supplier panel
- Pricing options – comparison of different costing models
- Contracting options

Viral Load and Early Infant Diagnosis (EID)

Navigation diagram – Home page



TheGlobalFund | Le Fonds mondial | El Fondo Mundial | Глобальный фонд | 全球基金 | الصندوق العالمي

Frequently Asked Questions (FAQ)

[download](#)

Global Fund Procurement
Strategy Review: HIV and Malaria RDTs
Aziz Jafarov



Developing the Sourcing Strategy in RDT

An approach that spanned two diseases, malaria and HIV, designed to understand the supply and demand side of both and any synergies (work in progress)

- Extensive supplier visits to manufacturers who account for > 80% of the combined \$145m spend a year.
- Started engagement with partner agencies to better understand challenges and opportunities
- Strategy development and refinement in progress



Supplier visits

Supplier	HIV RDTs	Malaria RDTs	Location
Access Bio	Developing	Yes	USA, South Korea, Ethiopia
Alere	Yes	Yes	Japan
Chembio	Yes	Developing	USA
KHB	Yes	Developing	China
Premier Medical	Yes	Yes	India
Standard Diagnostics	Yes	Yes	South Korea

Summarised Findings of the Analysis

Malaria

Demand

HIV

Sometimes brand specific demand

Complex algorithms

RDT Selection

Limited harmonization

Low acceptance

Evolving QA requirements

Supply

Significant over-capacity in manufacturing sector

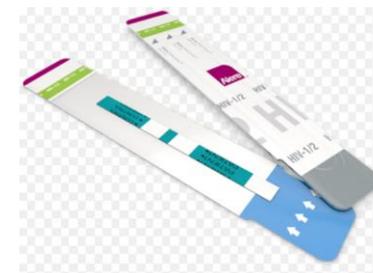
Perceived lower margin

Perceived higher margin

No test for elimination

Variable and generally short shelf life

Opportunities for improvements in product & packaging design

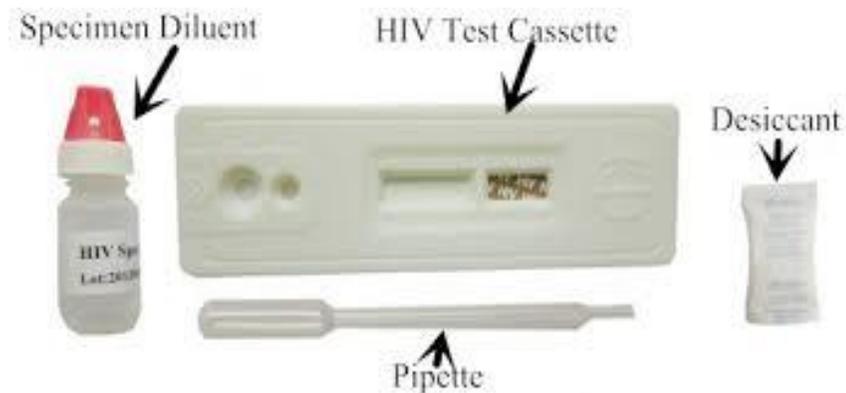


Product development / improvements

HIV

RDTs for self-testing:
saliva & blood

Next Generation Assays for the
detection of HIV Antibody and
Antigen



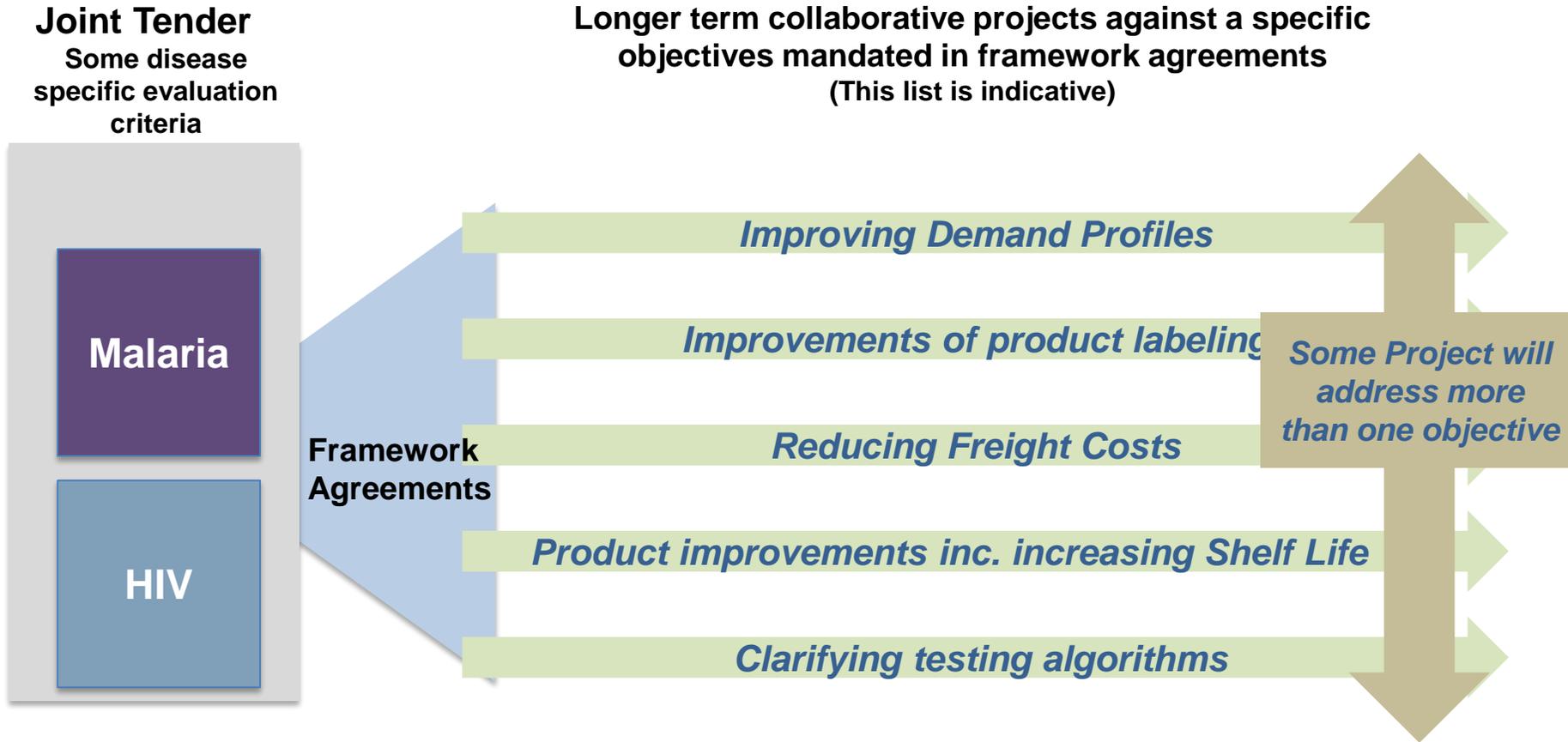
Malaria

Development more sensitive
malaria RDTs in collaboration with
BMGF to primarily apply in the
elimination stage

Introducing new single buffer
packaging materials to address
evaporation issue

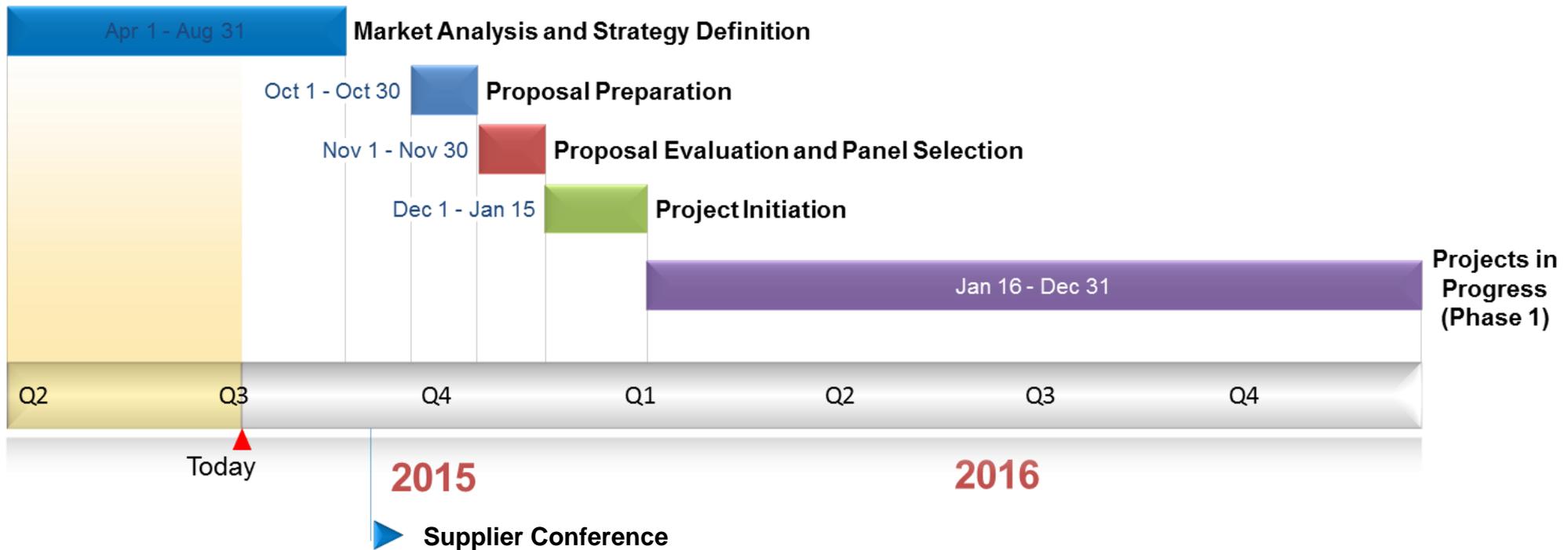
Reduced cassette size for
environmental and freight savings

Thoughts on Strategy



The Proposed Timeline

The Global Fund will issue the tender in Q4 and commence the improvement projects early in 2016

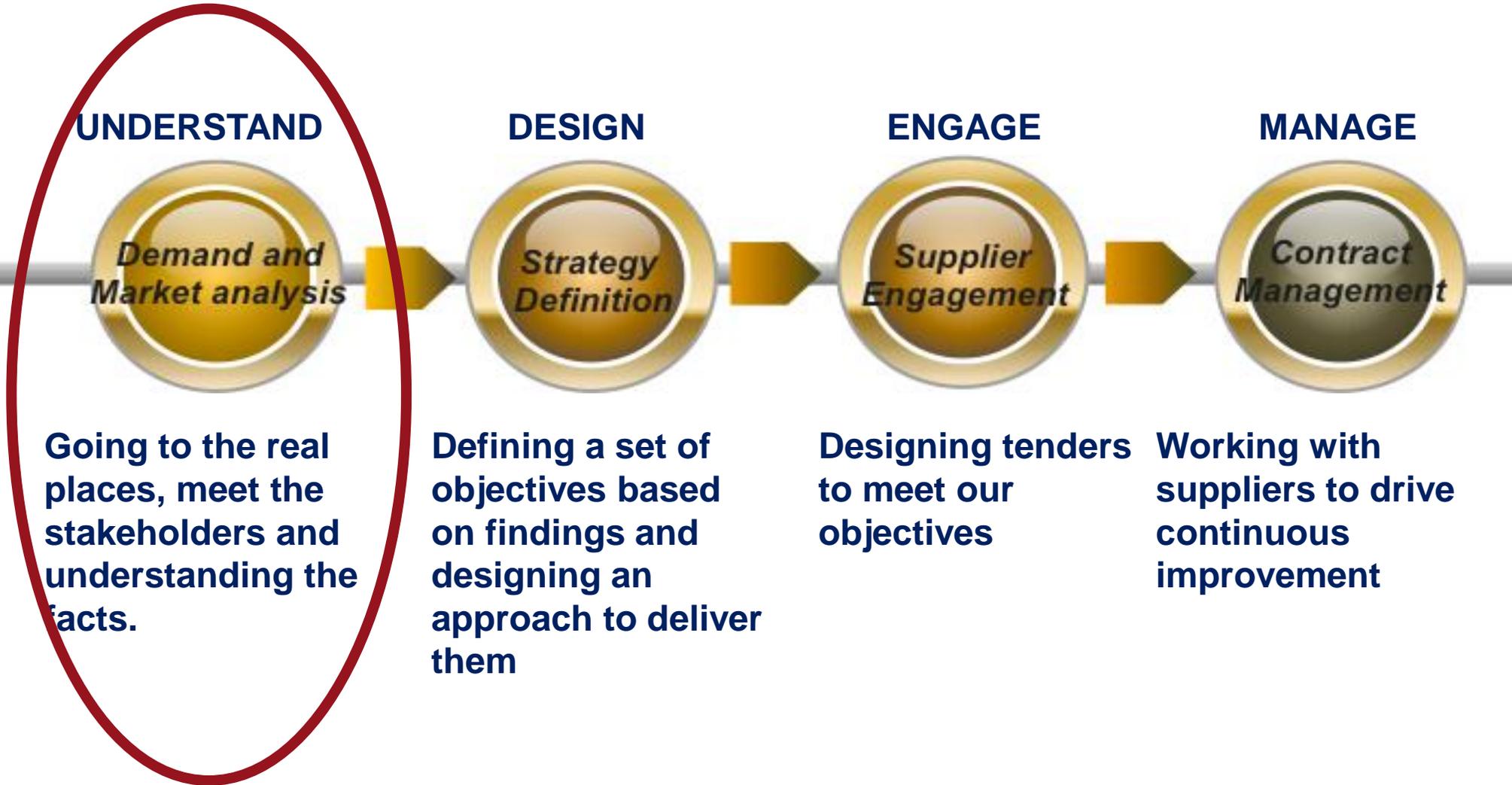


Global Fund Strategic Review Meeting Update on TB Strategy

09 July 2015



Strategy Development and Implementation



**Market analysis and
manufacturer
engagement**

**Understanding current
supply chain & GF demand**

Partner mapping

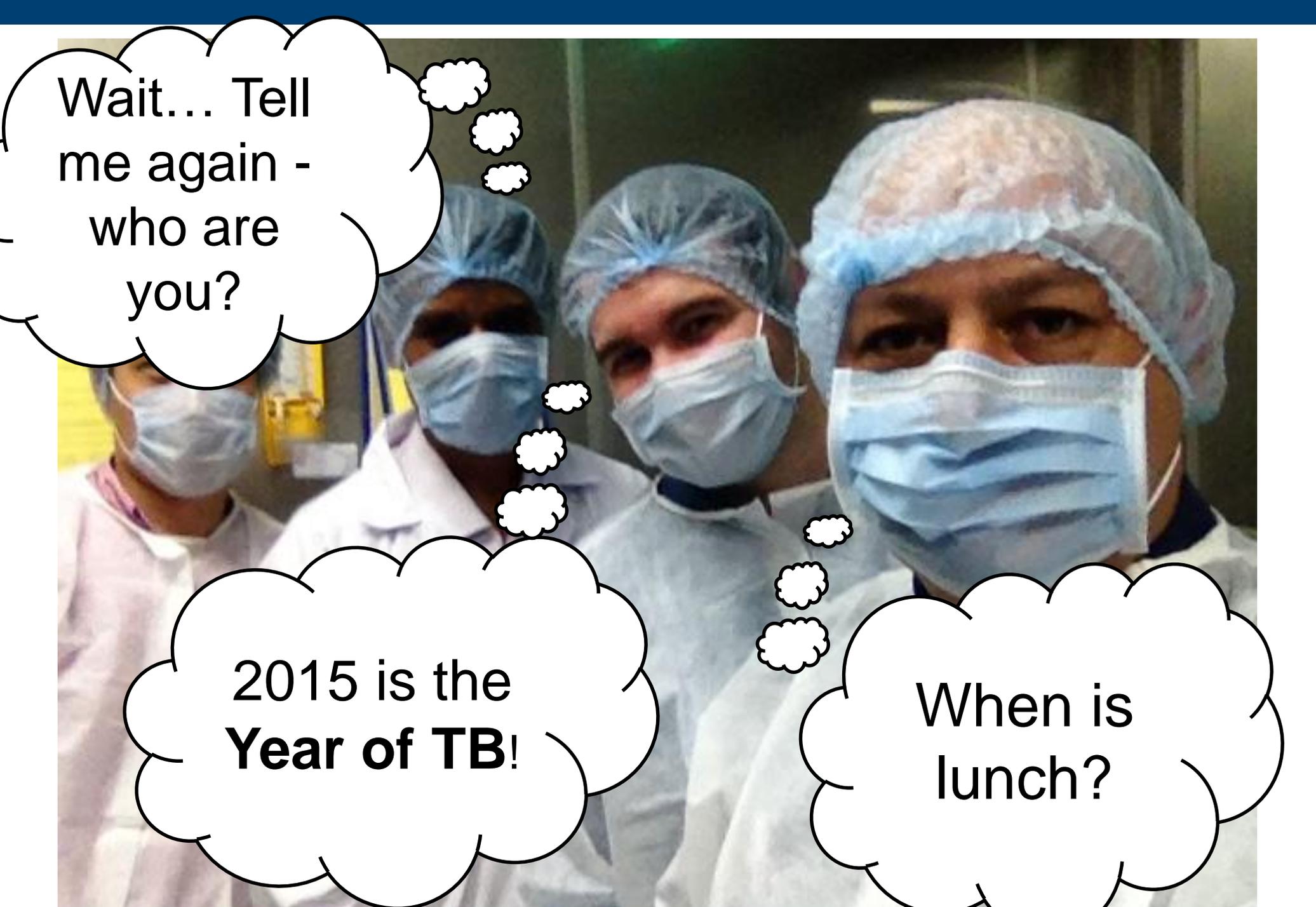
**Opportunities to increase GF
leverage**

**GF TB
Sourcing
Strategy**

Strengthening of GF/GDF relationship

Market analysis and manufacturer engagement





Wait... Tell
me again -
who are
you?

2015 is the
Year of TB!

When is
lunch?

**Market analysis and
manufacturer
engagement**

**Understanding current
supply chain & GF demand**

Partner mapping

**Opportunities to increase GF
leverage**

**GF TB
Sourcing
Strategy**

Strengthening of GF/GDF relationship

Emerging Themes

Demand management is key

- Understand volumes/timings
- Communicate with manufacturers (dialogue vs commitment)
- More explicit links to in-country activities, diagnostic scaleup, HIV/TB, adoption
- Tools to understand/nudge demand

PRs need new flexibilities

- Respond to reality on the ground
- Sustainable/reliable supply



Emerging Themes



TB market is dynamic

- New entrants, new products, growing competition
- Opportunities and interest in new ways of working
- Market still small; need for partnership with other large procurers

Harmonization opportunities

- New tools/mechanisms needed to advance this work

P4i approach and ARV tender

As the largest international funder of TB, what role should Global Fund play to address challenges and shape the TB market?



What lessons can be applied from malaria and HIV? Synergies? Risks?

Strategic Review Meeting

Market Shaping Strategy

9 July, 2015

Objectives

Recap the context for revising the Global Fund's Market Shaping Strategy

Provide an overview of our approach

Share elements of the revised strategy drafted so far

- > Harmonized framework for dimensions of market health, developed with UNITAID
- > Definition of Global Fund's role in market shaping
- > Strategic objectives
- > Guiding principles

Answer questions and get your input

What is “market shaping”?

Market shaping is an approach to maximizing public health impact by addressing market shortcomings which reduce access to health products

Common symptoms of market shortcomings

- ✗ High prices that are unaffordable for LMICs
- ✗ Low uptake of products, even if affordable or cost effective
- ✗ Unstable supply, with limited or volatile ability to meet global needs
- ✗ Unknown product quality
- ✗ Limited pipeline of new products or presentations

Root causes



Limited or asymmetric market information



High transaction costs



Risk imbalances between supply and demand

Illustrative interventions

- Demand forecasting
- Published quality assessments

- Pooled procurement
- Variant optimization
- Order coordination

- Volume guarantee
- Product development partnership

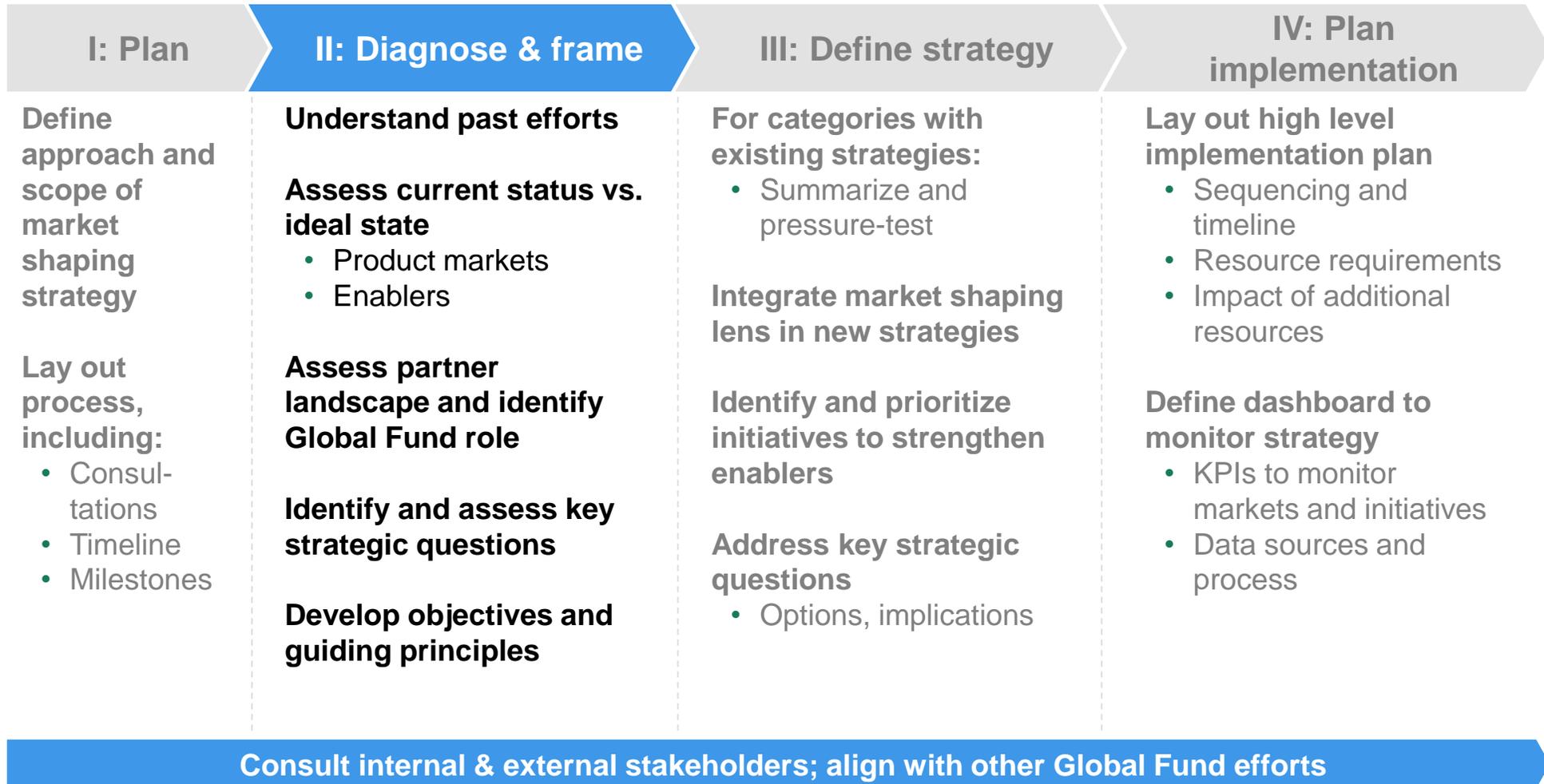
2011 Market Shaping Strategy emphasized a set of four objectives, applied to the ARV market

Designed to achieve an overall goal of dramatically expanding the Global Fund's impact on the three diseases by improving market outcomes of and therefore access to essential health products.

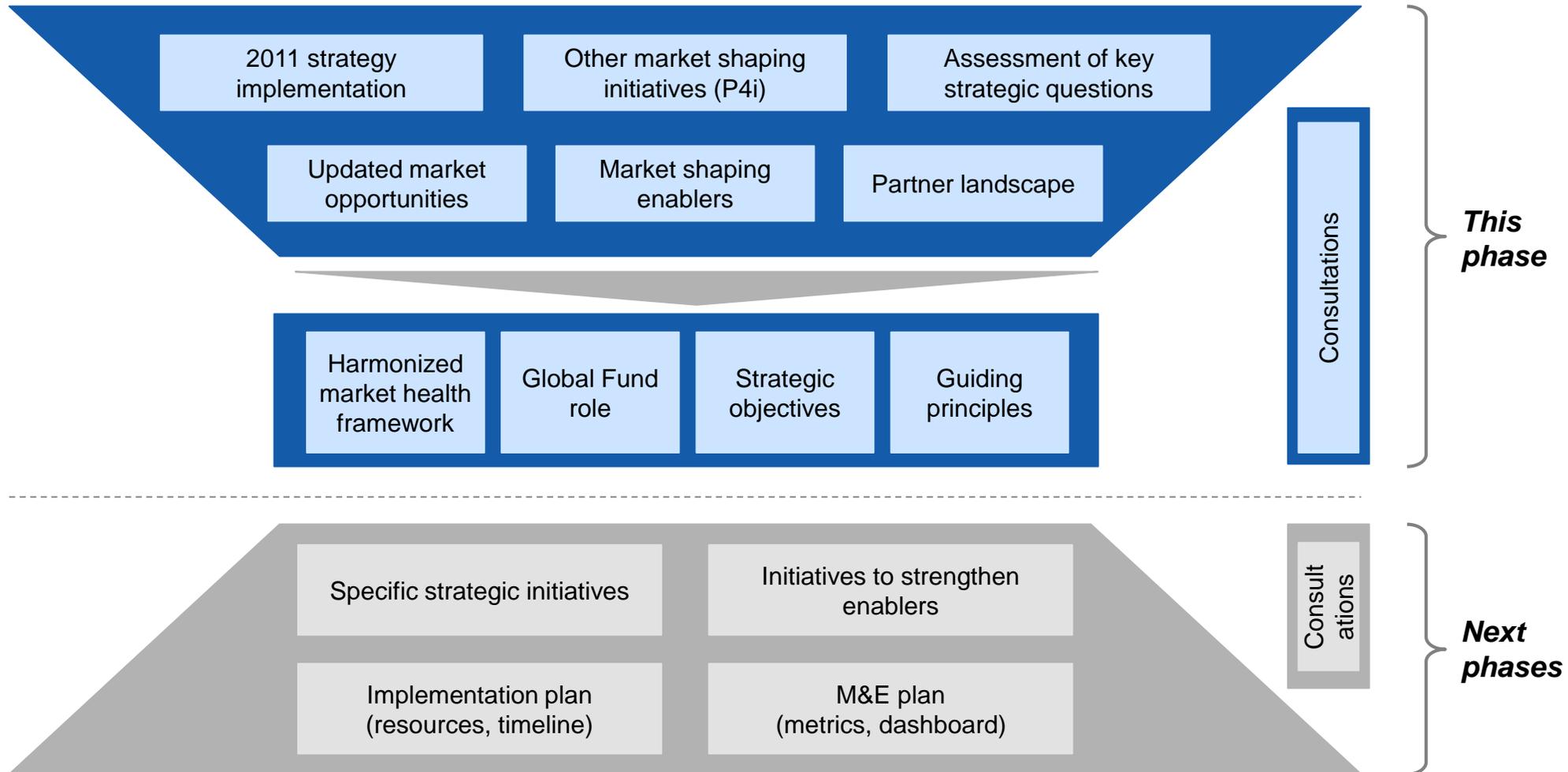
- i. Accelerate the introduction and maturation of new, more cost-effective products;
- ii. Ensure recipients procure the most cost-effective, WHO-recommended health products or regimens that meet the Global Fund's quality assurance policies;
- iii. Strengthen countries' capacity to implement strategic procurement practices; and
- iv. Ensure the continued availability, affordability, and innovation of products, including those where there are not currently sustainable market conditions

**-- Report of the Market Dynamics and Commodities Ad-Hoc Committee
GF/B23/9, May 2011**

Global Fund is taking a four-phase approach to revise Market Shaping Strategy



Recent work focused on a set of assessments to inform role, strategic objectives and guiding principles



Dimensions of market health harmonized with UNITAID

Current DRAFT

Applies to markets for medicines or technologies to effectively prevent, diagnose or treat a disease or condition.

Dimension	Description of healthy market
Innovation	<ul style="list-style-type: none">• There is a robust pipeline of new products, regimens or formulations intended to improve clinical efficacy, reduce cost, or better meet the needs of end users, providers or supply chain managers
Availability	<ul style="list-style-type: none">• New and/or superior evidence-supported, quality-assured products are rapidly introduced in the market and made available to those in LMICs. Adequate and sustainable supply exists to meet global needs
Demand and adoption	<ul style="list-style-type: none">• Countries, providers (e.g., healthcare providers, retailers) and end users rapidly introduce and adopt the most cost-effective products (within their local context)
Quality	<ul style="list-style-type: none">• Products are available at a high standard of quality and there is reliable information on the quality of the product. This includes not only the quality of the final, finished product, but also the quality of starting and intermediary materials used to manufacture the final product¹
Affordability	<ul style="list-style-type: none">• Products are offered at the lowest possible price that is sustainable for suppliers and does not impose an unreasonable financial burden on governments, donors, individuals or other payers
Delivery	<ul style="list-style-type: none">• Supply chain systems (including quantification, procurement, storage and distribution) function effectively to ensure that products reach end users in a reliable and timely way²

1. For the Global Fund, this is operationalized through the existing Quality Assurance Policies. 2. For the Global Fund, issues related to Delivery are typically handled by Health Product Managers in the Grant Management Division. This area is also being addressed through a supply chain strategy currently in development.

The Global Fund's role is complementary to its partners

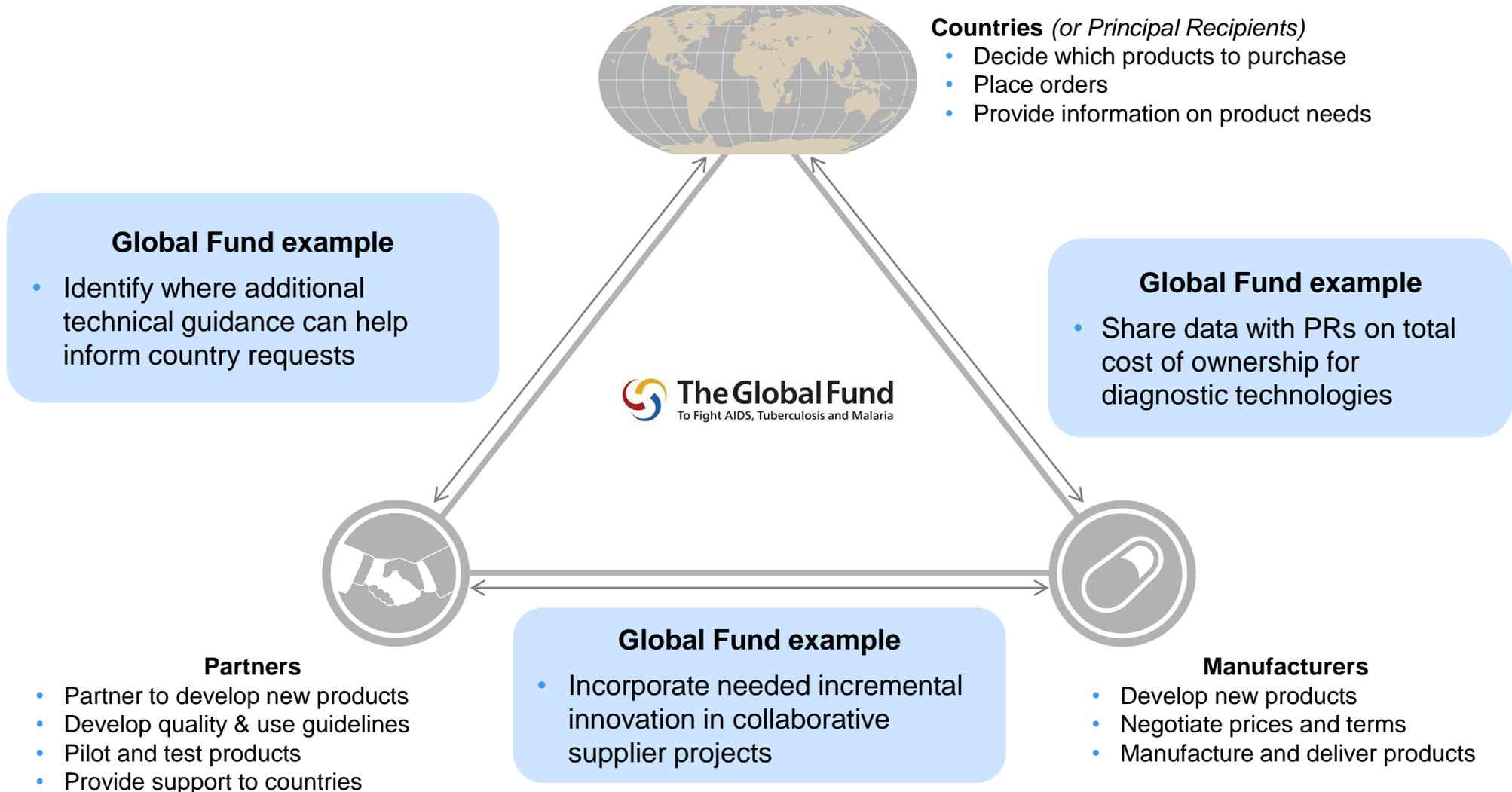
The Global Fund focuses on sourcing, product selection, market intelligence

- ✓ Sourcing products demanded by Global Fund Principal Recipients
- ✓ Informing product selection
- ✓ Gathering and analyzing market intelligence
- ✓ Scaling up new products, in close alignment with partners
- ✓ Facilitating alignment among partners, countries and manufacturers
- ✓ Providing input and supporting partners working on other areas of market shaping

Partners lead a core set of activities, especially early in the product life cycle

- ✓ Assessing user needs and developing target product profiles
- ✓ Investing in research and development
- ✓ Negotiating licensing arrangements
- ✓ Setting clinical or normative guidance
- ✓ Assuring product quality
- ✓ Supporting country registration and inclusion in treatment guidelines
- ✓ Piloting products and generating evidence

The Global Fund can play a key role aligning countries, manufacturers and other partners



Note: Other large buyers can play a similar role (eg, PEPFAR, PMI).

Strategic objectives will link directly to Global Fund strategy and market health dimensions

Global Fund strategy: Draft objectives

1. Differentiate for Impact Across the Development Continuum
2. Build Resilient and Sustainable Systems for Health
3. Respect and Promote Human Rights and Gender Equality
4. **Expand Access and Public Goods for Health**
 - Attract additional financial and programmatic resources from current and new public and private sources
 - Support countries to increase domestic resource mobilization for health
 - Shape markets to support innovation, sustainability, quality, affordability and availability
 - Support the rapid introduction and scale-up of cost effective current and new health technologies

Market shaping vision

Support health outcomes and access to products by leveraging the Global Fund's position to facilitate healthier global markets for health products, now and in the future

DRAFT strategic objectives

Strategy will further detail what would be entailed in each

Ensure the continued availability and affordability of health products

Promote consistent quality standards

Accelerate the adoption of new and/or more cost-effective products

Support efforts to stimulate innovation

Prepare for country transition and support long-term market viability

Strengthen key market shaping enablers

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Ensure the continued availability and affordability of health products

- a) Continue to facilitate market transparency
- b) Leverage strategic procurement practices in PPM sourcing
- c) Extend the benefits of PPM strategies to all PRs
- d) Respond to potential stock-outs and emergency orders

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- a) Coordinate with partners to develop and implement “roadmaps” for key product needs
- b) Engage with PRs on opportunities to optimize product selection within WHO guidance
- c) Utilize the Expert Review Panel to accelerate the availability of new quality-assured products

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Support efforts to stimulate innovation

- a) Coordinate with partners focused on innovation and lend GF capabilities to support their efforts
- b) Recognize the value of innovation in sourcing strategies and procurement policies, differentiating between radical and incremental innovation

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- a) Invest in strengthening in-country PSM and regulatory institutions
- b) Develop and implement the e-marketplace and accompanying mentorship program
- c) Assess additional transitioning country needs and strategies to support them

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Strengthen key market shaping enablers

- a) Through this strategy, ensure the Secretariat’s market shaping mandate is clearly articulated
- b) Strengthen the Global Fund’s tools and systems to support forecasting, market intelligence and data management
- c) Continue to strengthen and operationalize partnerships

Proposed guiding principles

Build from “benefits” cited in current Market Shaping Strategy

The Global Fund’s market shaping efforts will be...

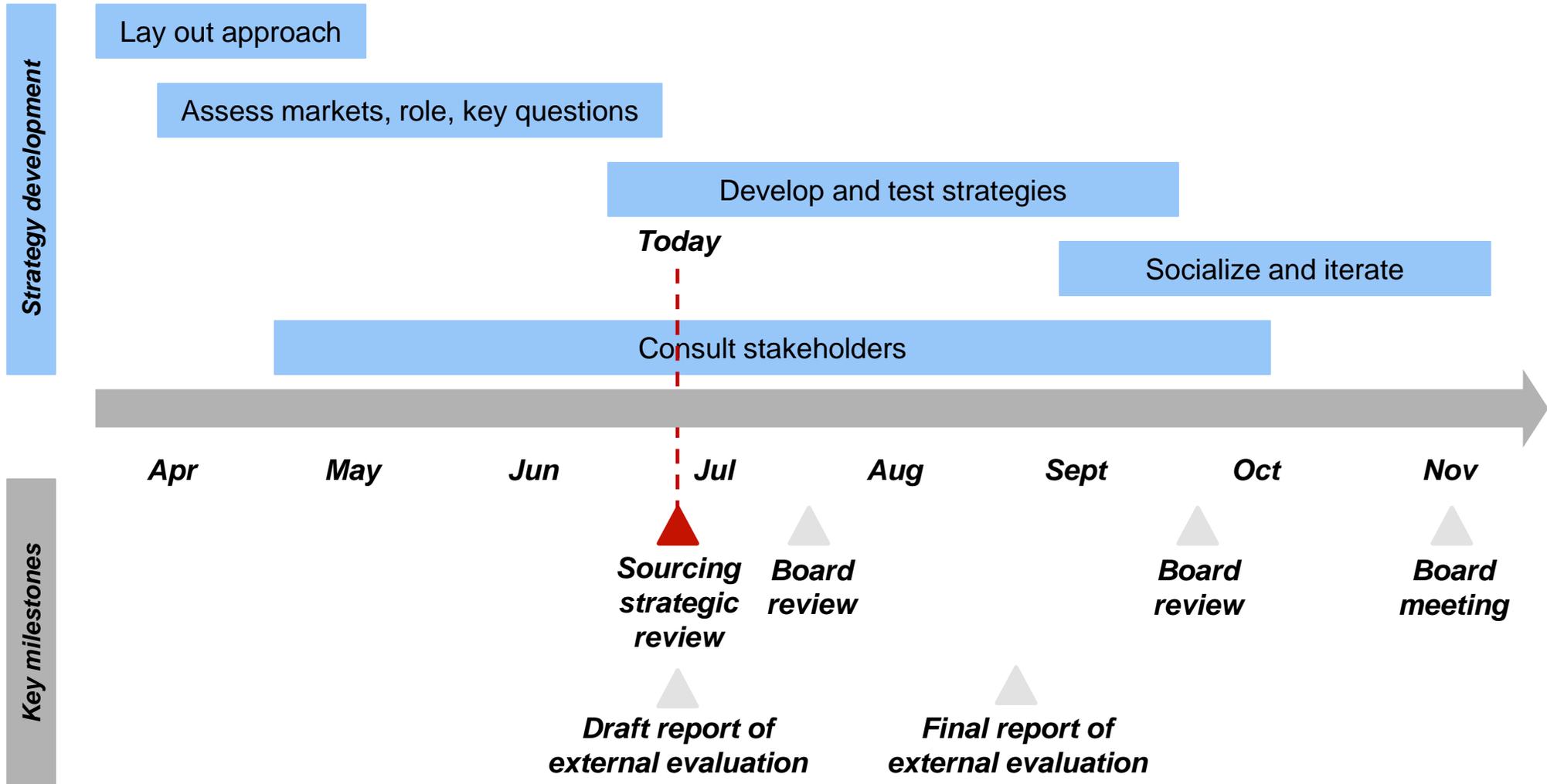
- > Focused
- > Sustainable
- > Flexible
- > Complementary
- > Balanced

The Global Fund will also...

- > Mitigate risks
- > Provide visibility
- > Solicit external expertise and perspectives
- > Prioritize

**Anchored to the Global Fund’s core principles of partnership,
country ownership and performance-based funding**

Several key milestones coming up as Market Shaping Strategy is revised for November Board meeting



We welcome your questions and feedback!

Strategic Review Meeting

Pooled Procurement Mechanism

9 July, 2015

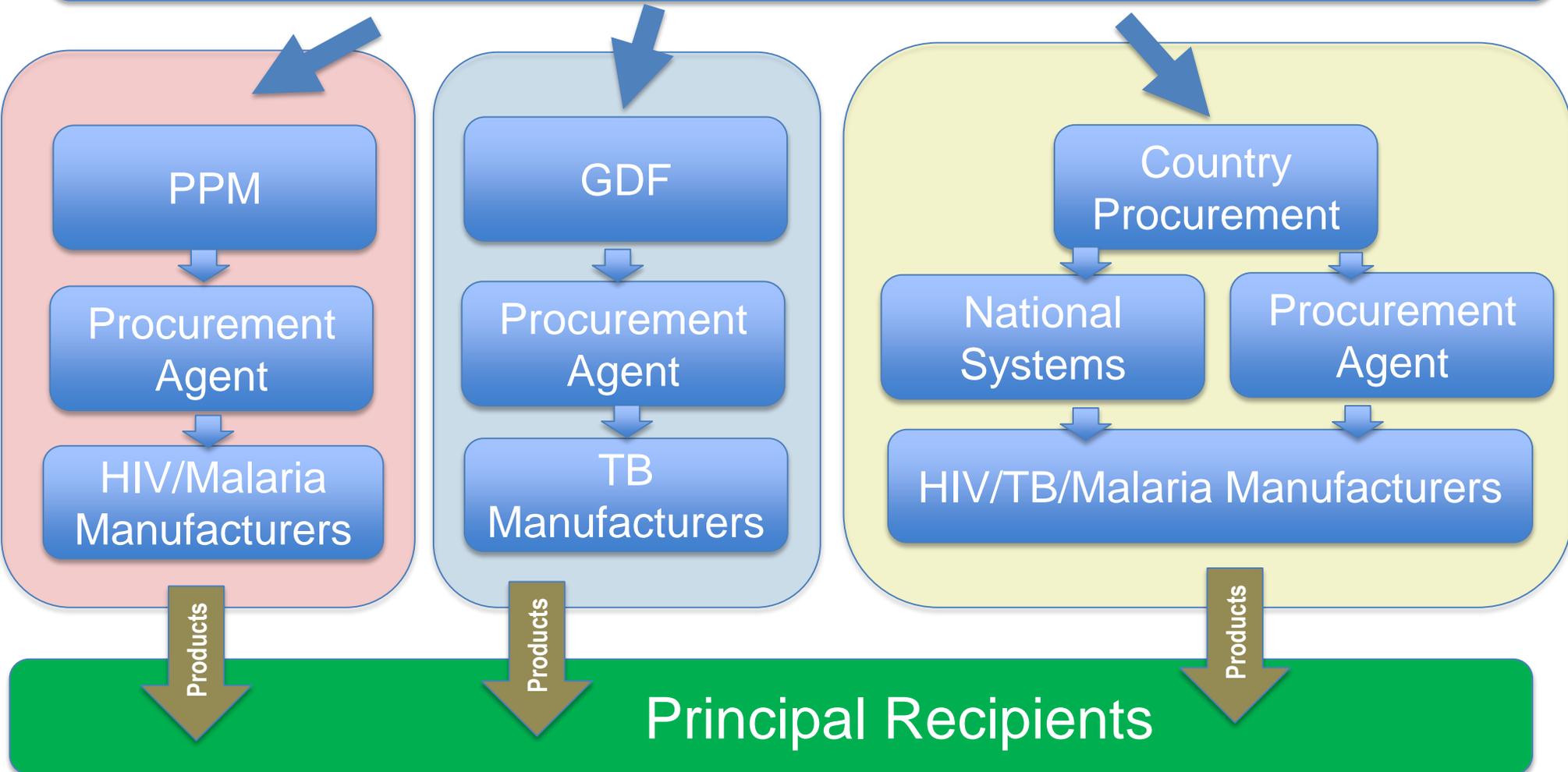
Pooled procurement is one of the Global Fund's primary tools to shape markets

Tool	Description
Price and Quality Reporting	Transaction-level procurement data on key health products gathered from Principal Recipients and made publicly available through a tool on the Global Fund's website
Quality Assurance policies	Guidelines to ensure that Global Fund-financed procurements are safe, effective and acceptable to patients
Pooled Procurement Mechanism	Mechanism to pool Global Fund-financed procurements, either on an opt-in basis by Principal Recipients or to manage grant-related risks

The Global Fund may also shape markets through specific procurement practices or country dialogue, but these are the primary tools at its disposal

Several channels for Global Fund-financed procurements

The Global Fund



Context: Pooled procurement is a key tool for the Global Fund to shape markets

2009: Voluntary Pooled Procurement (VPP) created

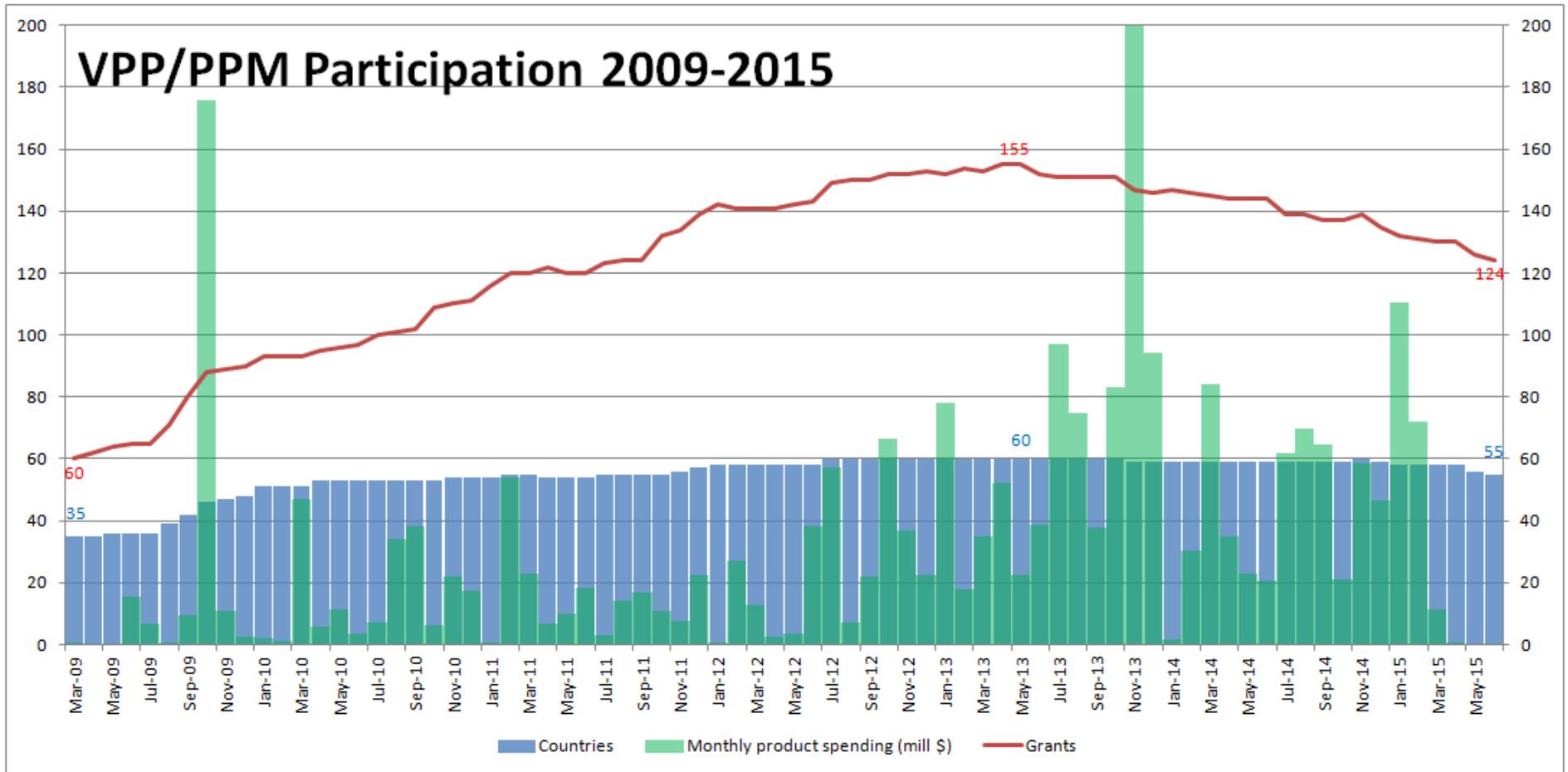
- Mechanism to centrally procure health products to impact markets
- Recognizing need to address common procurement and/or risk-related grant performance issues
- From 2009 – 2011, responsible for:
 - Over US\$ 700 million of health product orders from 47 countries
 - Savings of US\$ 57 million vs. budgets
- Constrained by procurement process and disbursement of grant funds

2013: Transition to Pooled Procurement Mechanism (PPM)

- Market Shaping Strategy calls for policy changes to enable true consolidation of volumes
- Grew to 60 countries and about US\$ 1 billion in 2013
- Global Fund can leverage pooled demand to shape markets, delivering benefits for countries and suppliers
 - Countries: improved value for money, risk reduction
 - Suppliers: greater visibility into demand, more predictable volume and lower transaction costs

Objective is to discuss the concerns raised as PPM has grown and address risks while maintaining its benefits

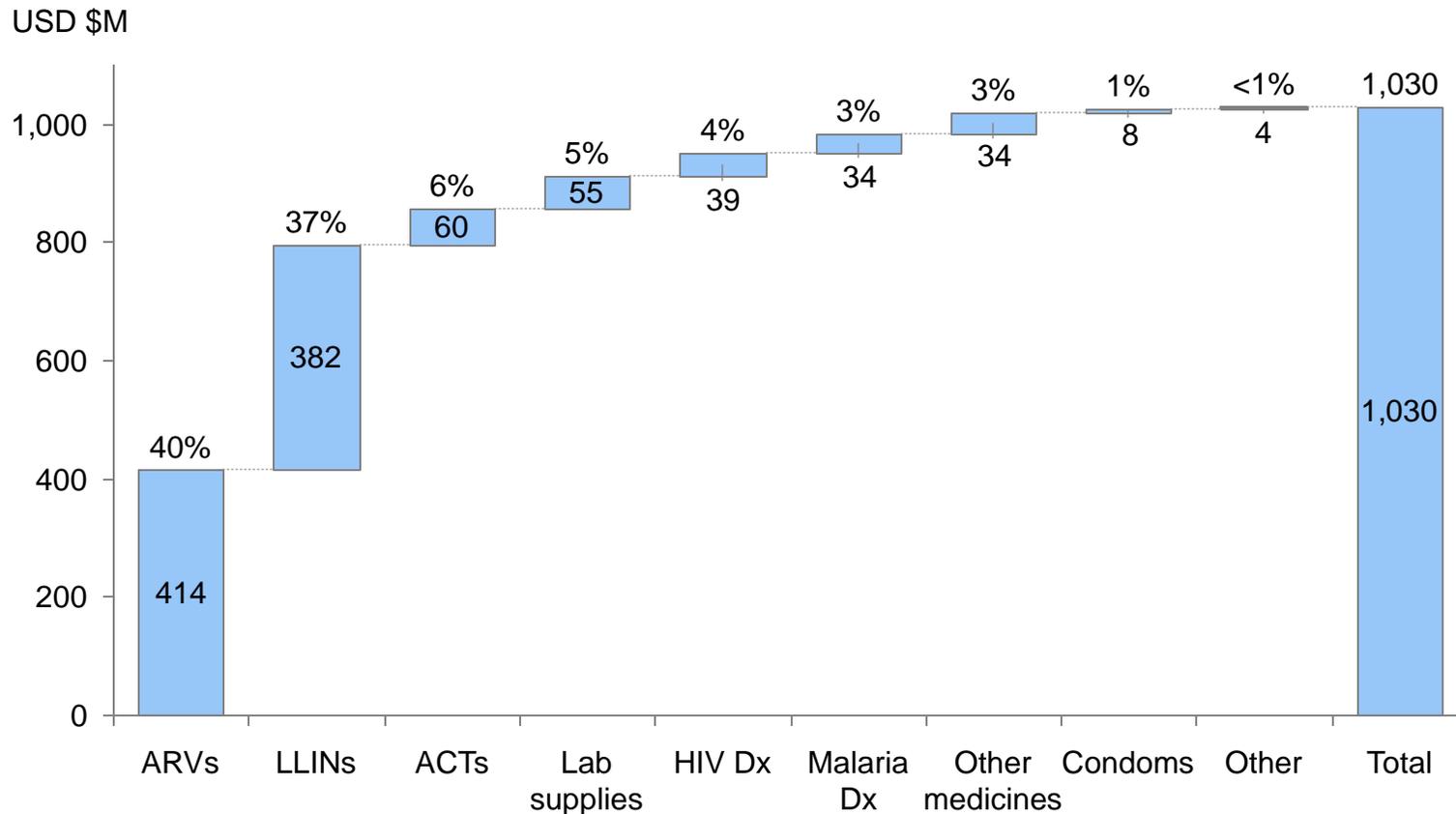
Participation in pooled procurement has grown from 35 countries to 55 countries since 2009



Source: Eurohealth Group analysis from Global Fund TERG Thematic Review, based on Global Fund PSA data and PQR.

ARVs and LLINs are largest categories purchased through the Global Fund's pooled procurement mechanism

Spend by category purchased through the Pooled Procurement Mechanism, 2013



Source: Global Fund pooled procurement data.

Pooled procurement has benefits for countries and suppliers

Country / PR benefits

For countries / PRs participating in pooled procurement:

- ✓ Provides better terms that they may not otherwise be able to access
- ✓ Ability to optimize across the PPM portfolio to achieve better outcomes
- ✓ Countries do not need to wait until grant disbursement to place orders

For all countries / PRs:

- ✓ Visibility on average reference prices negotiated by the Global Fund
- ✓ Global Fund sourcing strategies can have “spillover” benefits

Supplier benefits

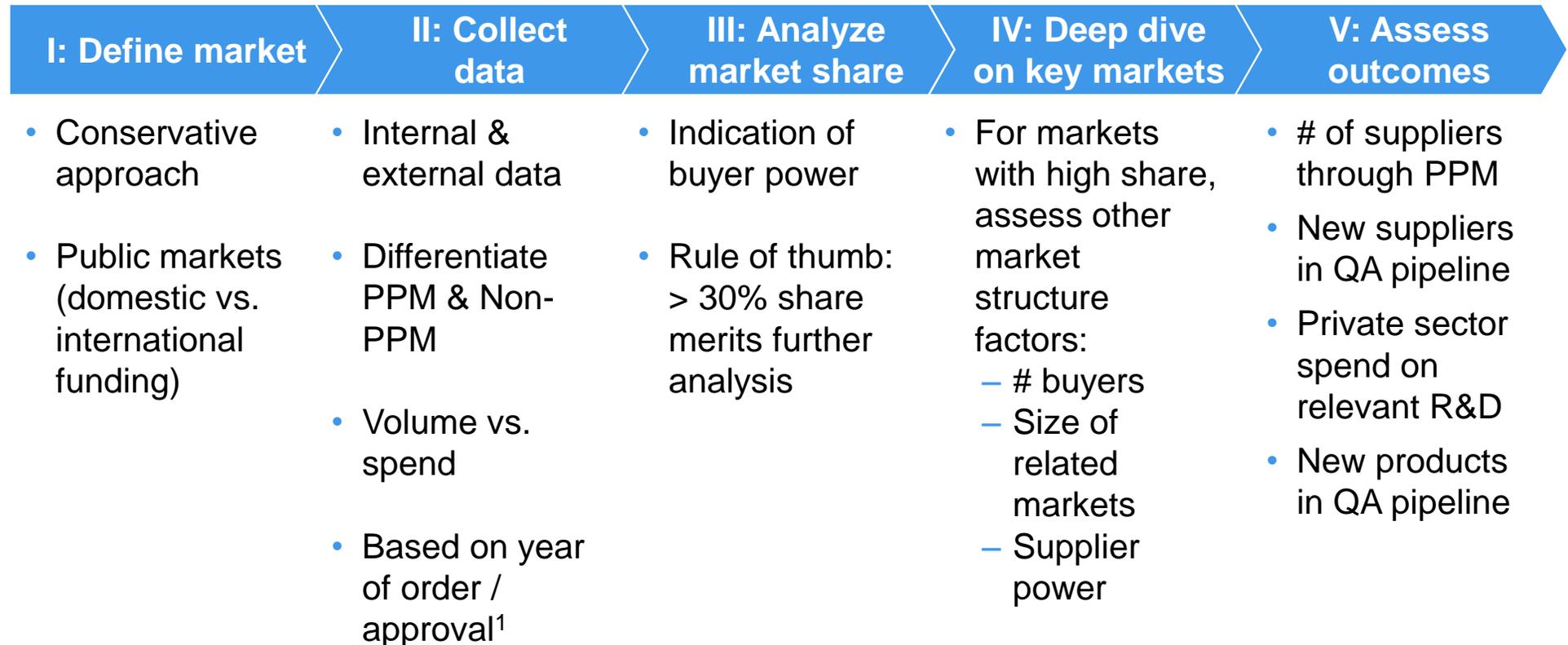
- ✓ Facilitates consolidated forecasting and greater visibility into demand
- ✓ Enables volume commitments, which provide stability and supports better planning
- ✓ Global Fund team can work with PRs to reduce unnecessary complexity in specifications
- ✓ Direct payment from the Global Fund speeds up payment
- ✓ Single, standardized tender and negotiation process with consistent messaging reduces transaction costs

Stakeholders sometimes cite risks associated with buyer power that results from pooled procurement

- 1 As a large buyer, the Global Fund may cause suppliers to exit the market, thus reducing supply security and potentially leading to higher long-term prices**
 - > Could focus too strongly on reducing prices, such that suppliers no longer have sufficient margin to stay in the market
 - > May not allocate volumes to a supplier, leaving the company without enough business to stay in the market
- 2 The Global Fund could also deter innovation if prices are reduced too far and companies are not able to recoup their investments**

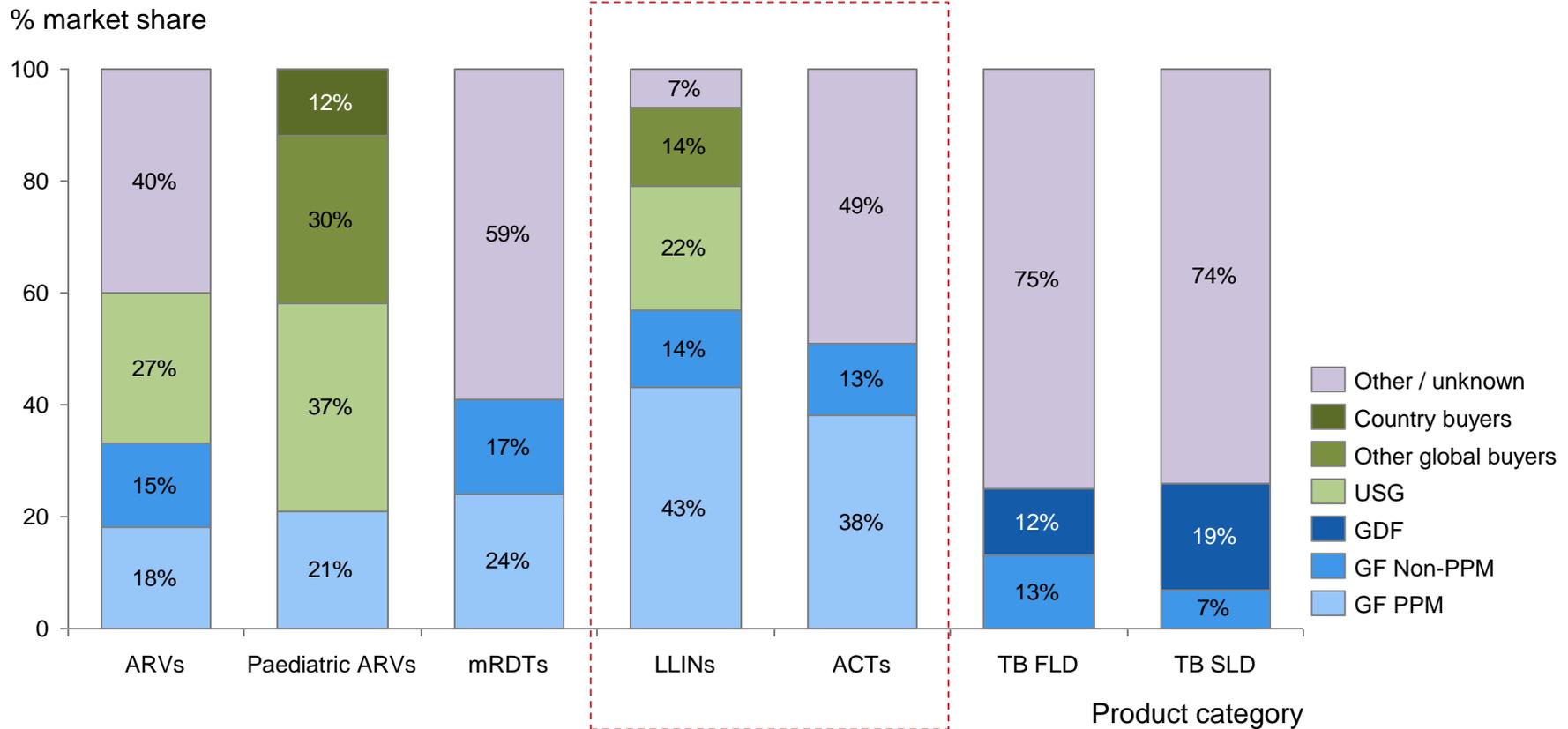
What can data tell us about the degree and level of these risks and whether they are materializing?

Approach: Examining the Global Fund's buyer power in key health product markets



1. Year of delivery used for paediatric ARVs.

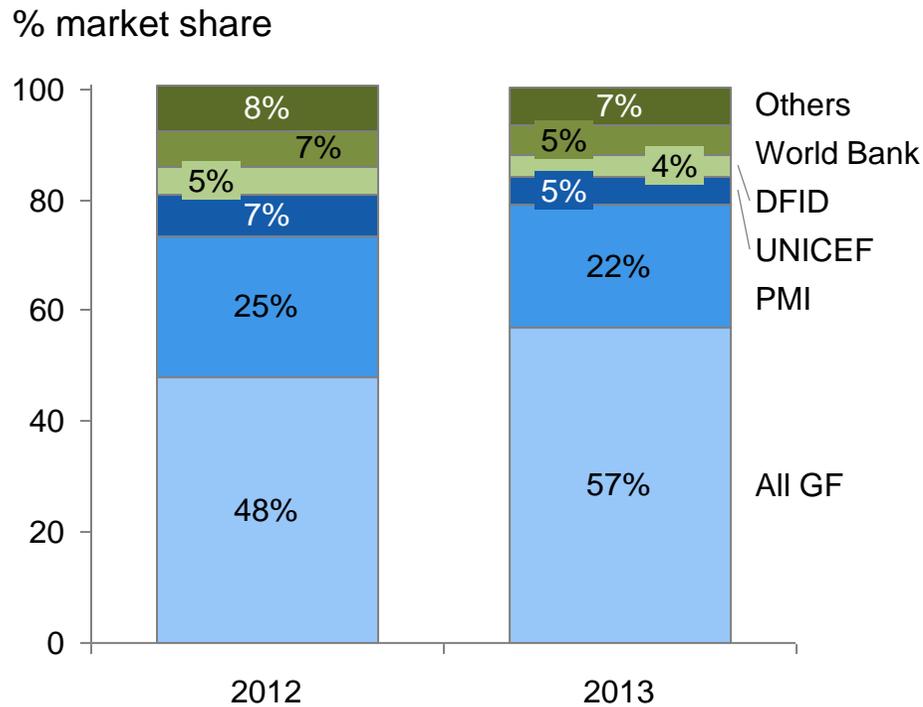
2013 public market share: LLINs and ACTs are only categories with PPM market share over 30%



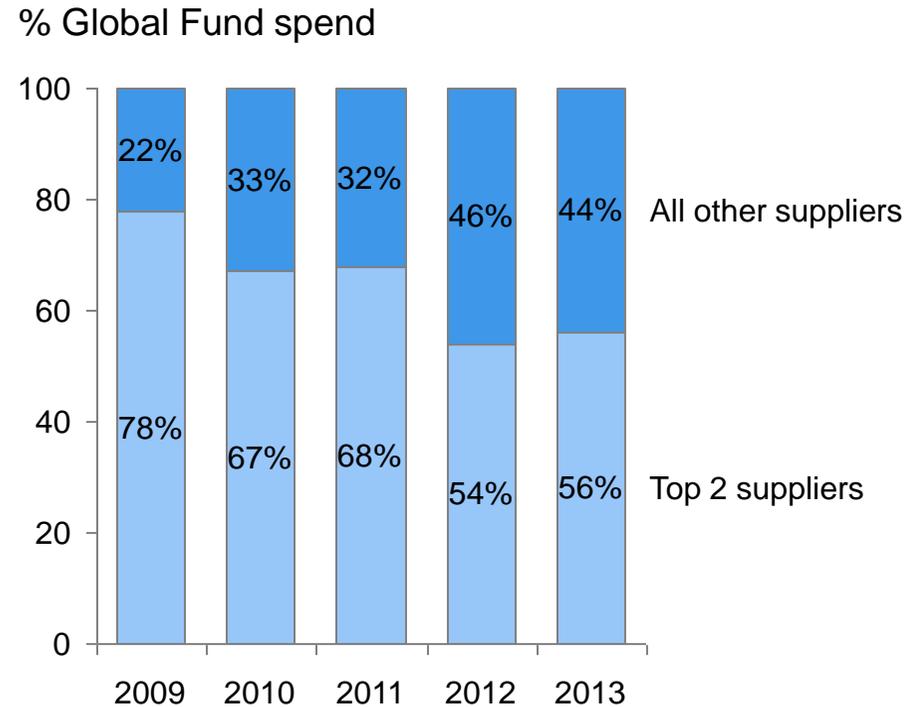
Market share in LLINs and ACTs merits further analysis

LLINs: Global Fund pricing pressure historically balanced by concentrated supplier base, but competition is increasing

PMI and other donors are smaller buyers, but significant market share



Volumes historically concentrated, but competition increasing



Risks to innovation may not be mitigated if GF or other donors are not able to support new products

ACTs: Presence of other buyers and supply concentration mitigate the Global Fund's buyer power

Presence of other buyers

- PMI and DFID are also substantial buyers in the ACT market
- Smaller volumes with UNICEF and MSF
- While Global Fund has large share, provides alternate business

Size of private market

- Also significant private market alternative for ACTs (QA and non QA)
 - Estimated 40% of patients seeking treatment in private sector
 - While the Global Fund provides significant financing for ACTs in the total market (private + public market), the PPM share is low

Supplier power

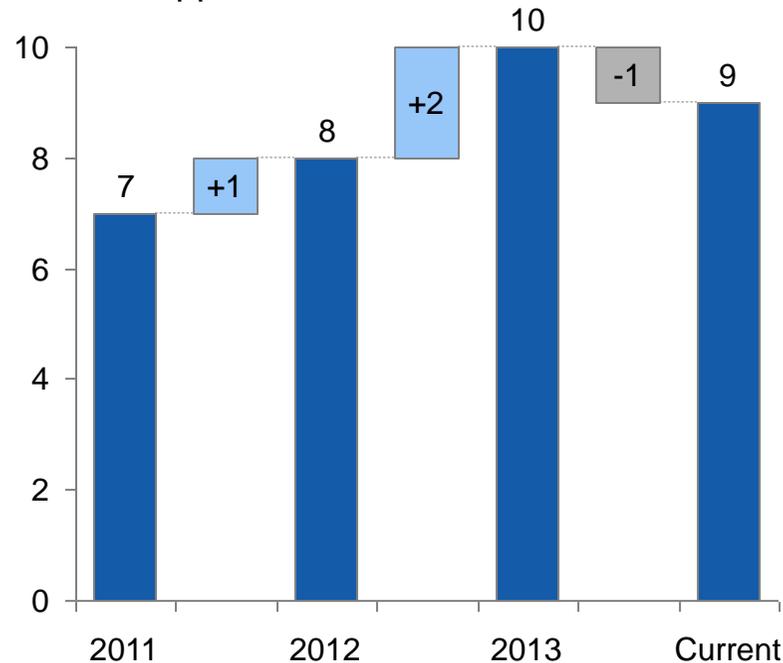
- As of 2012, supply concentrated with four manufacturers: Sanofi, Ajanta, Cipla and Novartis
 - Mix of generics and originators

Still significant supplier diversity through PPM for LLINs and ACTs

Fluctuation in number of suppliers occurred prior to recent tenders

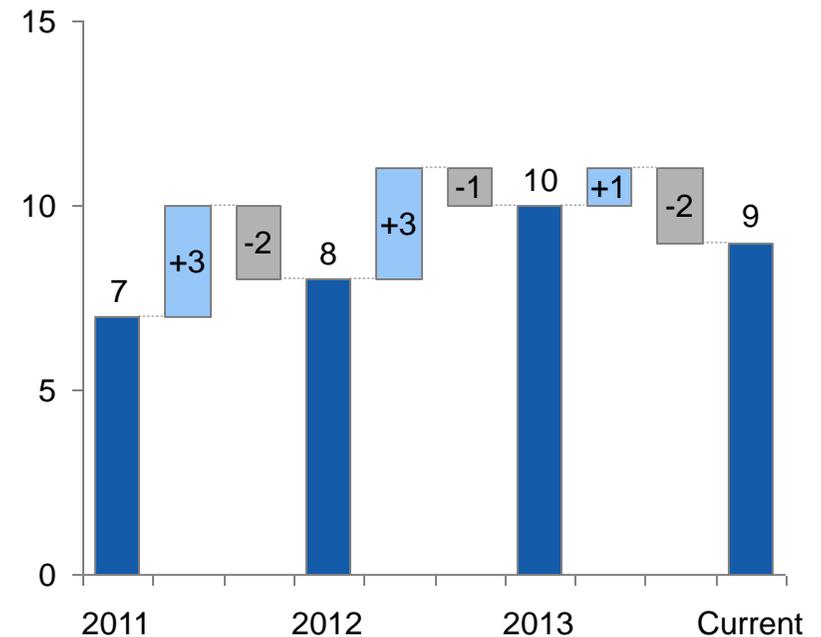
LLINs

PPM suppliers



ACTs

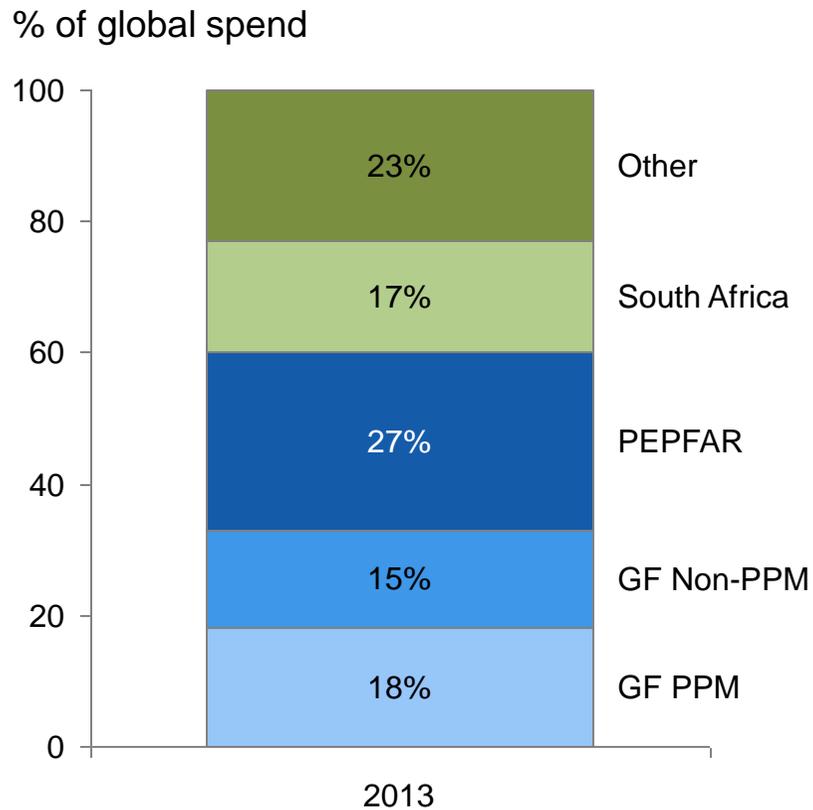
PPM suppliers



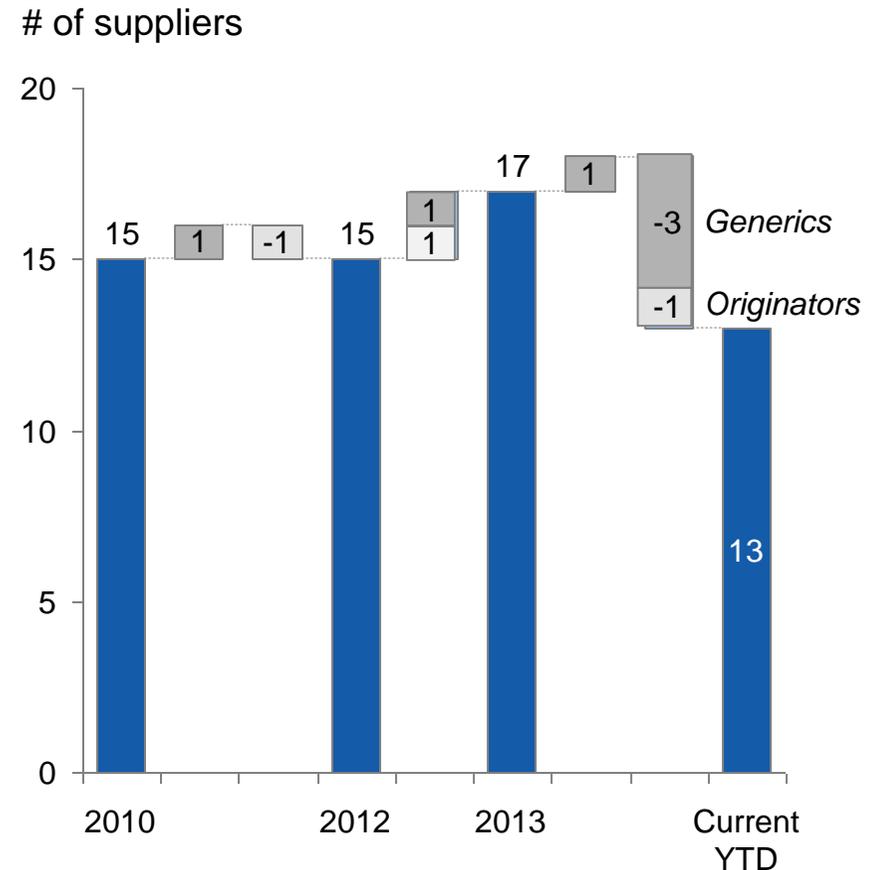
Includes all WHOPES-recommended suppliers

Number of ARV suppliers is lower year-to-date, but majority not included yet are originators with typically small volumes

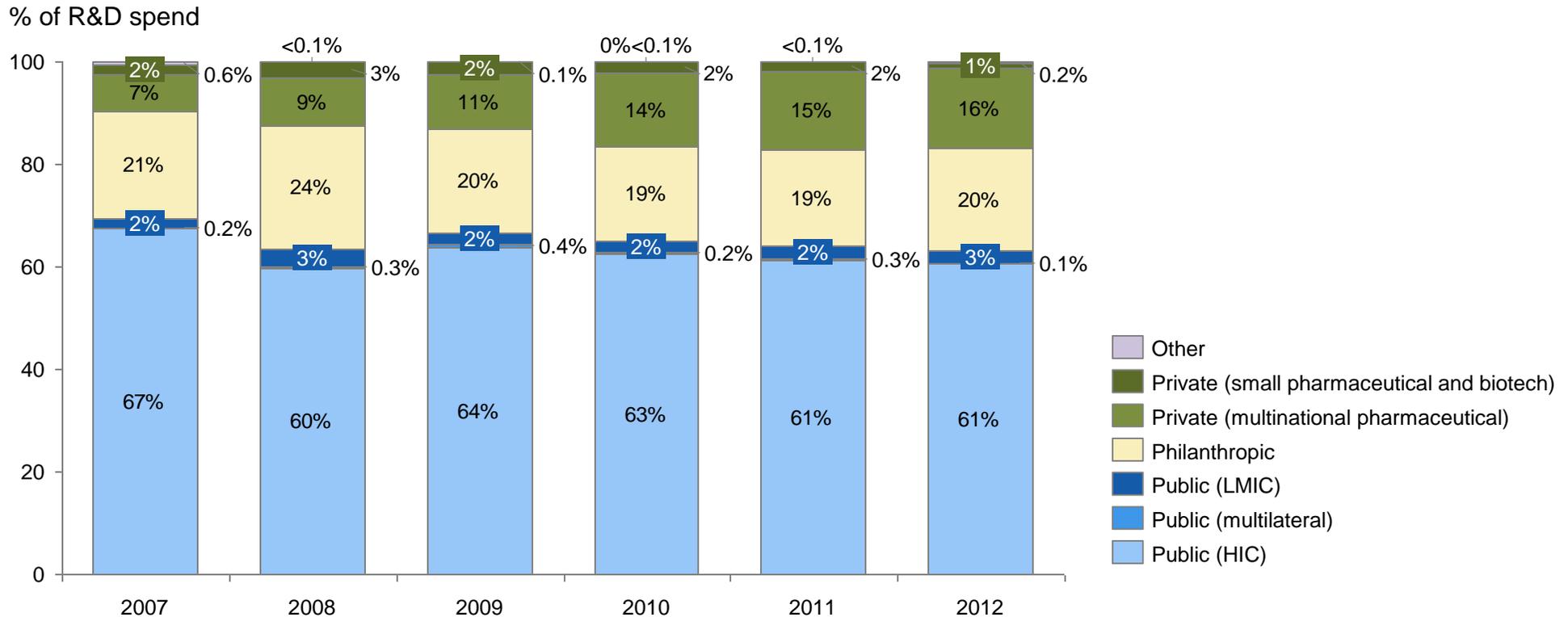
Recall: PPM is < 20% of market share



Number of PPM ARV suppliers



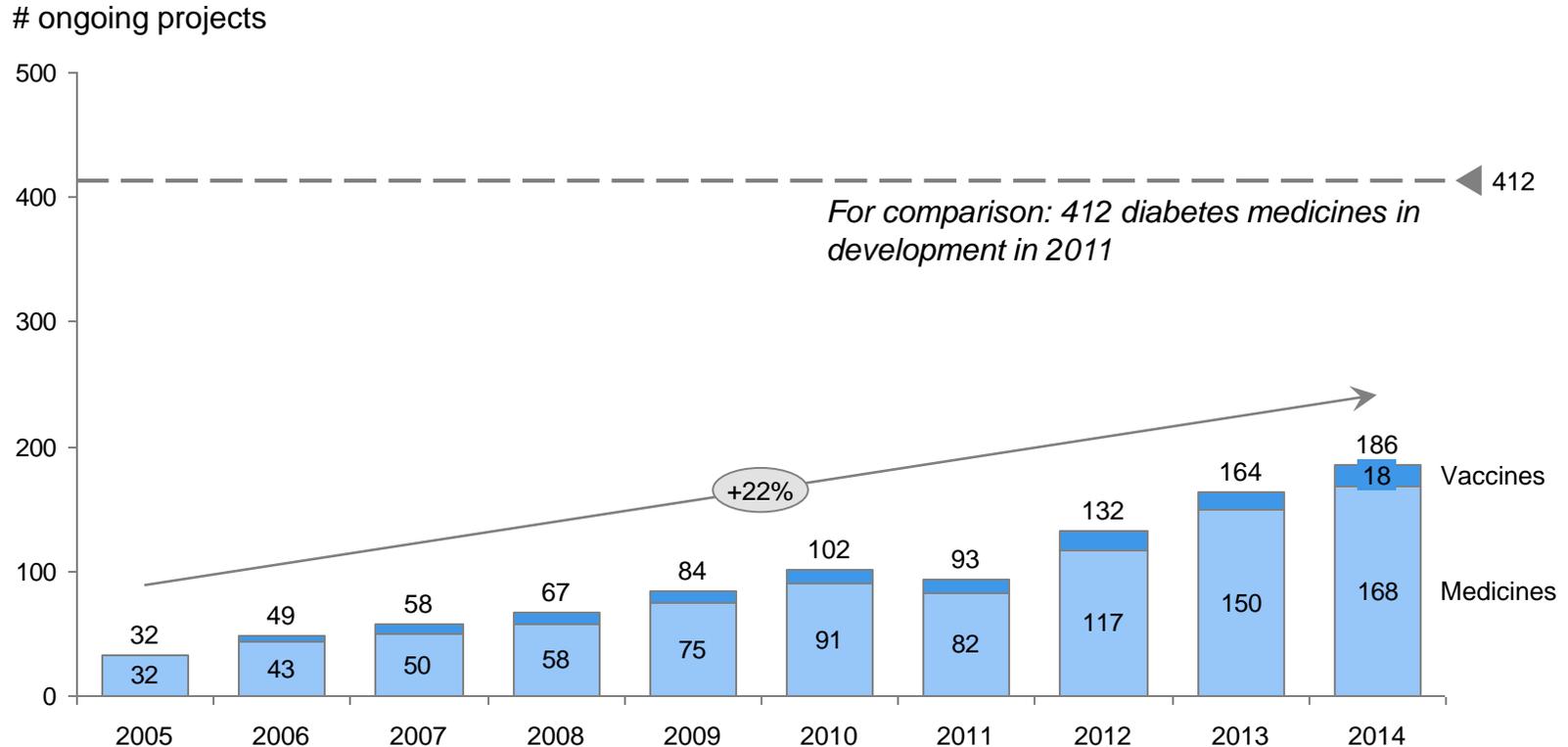
Private sector is ~17% of total R&D spend on “developing world diseases”, but share has doubled since 2007



Total spend on R&D for developing world diseases has increased during this time period

Note: Includes funding for diseases and product categories considered “neglected” in G-Finder Neglected Disease Research and Development survey. For HIV, includes vaccines, diagnostics, microbicides and select basic research and drugs.
Source: IFPMA.

Fewer ongoing R&D projects for “developing world diseases” than other diseases, but also increasing



Note: Developing world diseases include 17 neglected tropical diseases identified by the WHO. The majority of projects are focused on malaria or tuberculosis.
Source: IFPMA.

13 new LLIN products in the WHOPES review process

6 new manufacturers seeking WHOPES approval for LLINs

Phase	Product	Manufacturer
Stage I	Akanet	Kuselace
	SafeNet ¹	Mainpol GmbH
	Christiansen	Christiansen Sarl
Stage II	Panda Net 2.0	Life Ideas Textiles
	Veeralin	Vector Control Innovations
	Yahe	Fugian Yamei Co.

7 new products from existing manufacturers

Phase	Product	Manufacturer
Stage I	Interceptor G2	BASF
	Olyset Duo	Sumitomo Chemical
Stage II	MiraNet	A to Z Textile Mills
Stage III	DawaPlus 2.0 ²	Tana
	LifeNet ²	Bayer
	Olyset Plus ²	Sumitomo
	Permanet 3.0 ²	Vestergaard

1. Product for determination of equivalence. 2. Products have interim WHOPES recommendation.
Source: Pesticide products under WHOPES laboratory and/or field testing and evaluation, May 2015.

Global Fund is acting to manage risks that could result from buyer power due to pooled procurement

Risks identified

Drive suppliers out of the market

Deter innovation

Actions already taken

- Supplier base explicitly considered in global tenders
 - Volume preserved for new entrants
 - Maximum allocations based on total and available capacity
 - Balance of suppliers across geographies
 - Number of eligible or panel suppliers linked to global demand and supply
- Value of innovation also recognized in recent tenders
 - Innovation level considered in volume allocation criteria
 - In ARV tender, volume set aside for early lifecycle products and new entrants
 - Engagement with innovators to understand required volumes
 - Collaborative projects proposed by suppliers

Key questions for discussion

- ? Given the benefits of consolidating volume, how many suppliers is sufficient to maintain availability and competition in a market? Is there a baseline threshold?**
- ? If product availability is secure, what are the additional risks if a supplier exits the market? What is the Global Fund's responsibility for maintaining the supplier base?**
- ? What constitutes a healthy level of innovation? How should the Global Fund assess whether it needs to do more to support innovation?**
- ? Concretely, what other actions could the Global Fund take to realize further benefits of pooled procurement? Or mitigate risks?**