



PEPFAR

U.S. President's Emergency Plan for AIDS Relief



The Global Fund

To Fight AIDS, Tuberculosis and Malaria

**Meeting between the Global Fund,
PEPFAR and the manufacturers of
laboratory-based viral load
monitoring**

The Global Fund, Geneva

15- 16 January 2014



Plenary Agenda



Topic	Lead	Time
CPO welcome and perspective	CG	5
Introductions	MA	10
Agenda, objectives and outcome	MA	5
Global Fund and P4i –strategy and action	CG	20
USG procurement strategies/approach	BC	20
Strategic collaboration and context	MA	5
Development of programmatic, financing and procurement strategies		
<ul style="list-style-type: none"> - Consultation and engagement - Guiding Principles - Agreed actions plan - Initial forecasts 	MA	20
Initial comments / questions prior to 121 meetings	MA	5



Agenda – Wednesday 15th



08:30 - 09:00	Coffee, social introductions
09:00 - 10:30	Plenary Session
10:30 - 11:00	Break
121 meetings	
11:00 - 12:00	Abbott
12:00 - 13.00	Perkin-Elmer
13.00 - 13.30	Working lunch / review
13:30 - 14:30	Cavidi
14:30 - 14.45	Break
14:45 - 15:45	Roche
15:45 - 16:45	Qiagen



Agenda – Thursday 16th



08:30 - 09:00	Coffee
09:00 - 10:00	Hologic
10:00 - 11:00	Biocentric
11:00 - 11:15	Break
11:15 - 12.15	Biomerieux
12.15 - 13.15	Siemens
13:15 - 14:00	Working lunch / review
14:00 - 15.30	Open systems – OPP-ERA / MSF
15: 30 - 15:45	Break
15:45 - 16:30	De-brief and next steps



PEPFAR

Objective and outcome



Objective:

- Brief and receive inputs from manufacturers on the development of common Global Fund-PEPFAR strategies to support for the rational scale-up of laboratory monitoring of HIV (programmatic; financing; procurement)
- Understand specific supplier capability, motivation and high level strategic direction
- Understand current viral load technology capacity, country placement, constraints, challenges
- Begin dialogue to achieve more affordable viral load testing including comprehensive training, support and maintenance
- Discuss potential solutions to the challenges and next steps to support the development and implementation of the strategies

Outcome:

Agreed next steps on what needs to be done by the funders and manufacturers to collaborate to support rational scale-up of viral load testing.



Global Fund and PEPFAR presentations



 **The Global Fund**
To Fight AIDS, Tuberculosis and Malaria



The Global Fund: our new approach to collaboration with partners and supplier management

Christopher Game

PEPFAR's Strategies and Procurement Approach

Meeting between the Global Fund, PEPFAR and the manufacturers of laboratory-based viral load tests

 **PEPFAR**  **The Global Fund**
U.S. President's Emergency Plan for AIDS Relief To Fight AIDS, Tuberculosis and Malaria

William Coggin
Office of the Global AIDS Coordinator
U.S. President's Emergency Plan for AIDS Relief (PEPFAR)



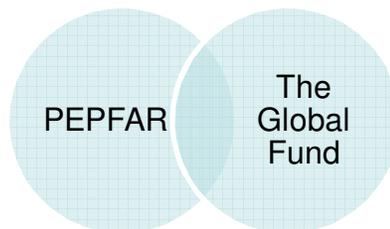
The challenge



- The WHO Consolidated ARV Guidelines recommend **increased viral load monitoring**, and **less CD4 monitoring** in HIV programmes...
-whilst programmes have invested and continue to scale-up CD4 monitoring.
- The expansion of laboratory monitoring for virologic monitoring, is complex and requires:
 - **significant investments** (planning, products, logistics and QA)
 - a **well-functioning laboratory network**, cross-cutting aspects such as human resources, information systems and infrastructure
 - **harmonized efforts** by the public health community - including HIV programmes, national governments, donors, industry, implementing partners, research institutions, healthcare workers and patients.



The Global Fund & PEPFAR: Strategic collaboration & context



Series of collaborative initiatives to maximise the efficiency of investments

better coordination of program planning
and allocation of funds

leveraging scale in commodity
procurement.

Most recent focus on laboratory monitoring of HIV treatment

Multi-party consultation on November 18-19, 2013 in Washington

Key action: *“Engage directly with suppliers, with an initial focus on all manufacturers of lab-based viral load diagnostic equipment with a scene-setting call in December 2013 and a subsequent supplier meeting in January 2014.”*

Scene-setting call held December 19th, 2013



Consultation Nov 18th -19th: Objectives and participants



Objective

To outline programmatic, financing and procurement strategies for operationalizing the rational scale-up of laboratory monitoring of HIV treatment and infant diagnosis recommended in the 2013 WHO Consolidated HIV Guidelines in the context of Global Fund and PEPFAR programmes.

Global Fund

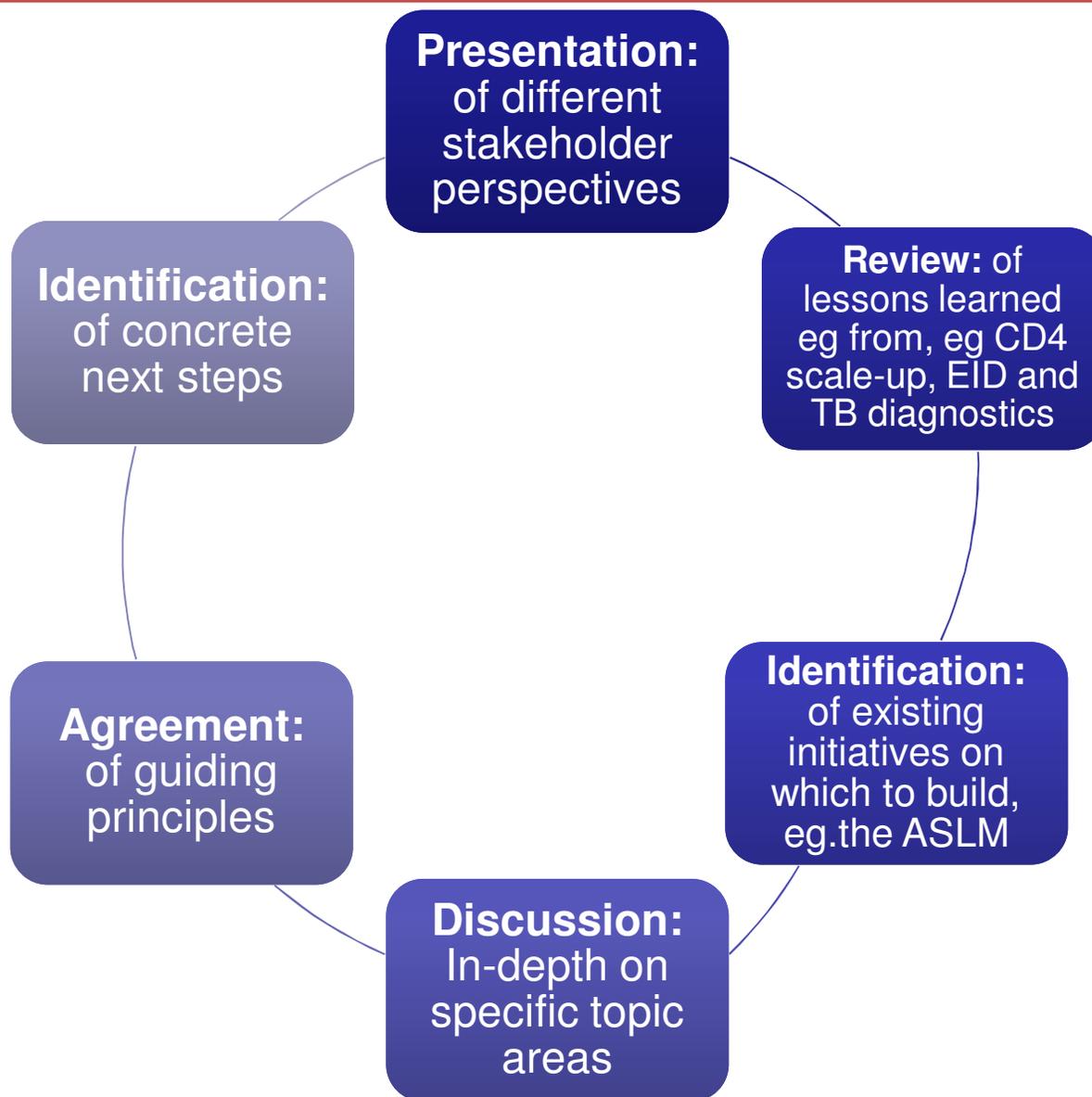
(Grant Management Division, Strategy Investment & Impact Division, Sourcing and Supply Management Department)

PEPFAR

(Office of the U.S. Global AIDS Coordinator, United States Agency for International Development, Centers for Disease Control and Prevention)

Stakeholder groups:
African Society for Laboratory Medicine (**ASLM**), Clinton Health Access Initiative (**CHAI**), **Bill and Melinda Gates Foundation**, Médecins Sans Frontières (**MSF**), South African National Health Laboratory Service (**SANHLS**), **NIH**, **UNICEF**, **UNITAID**, and **WHO**.

Consultation meeting





Guiding Principles



Both the Global Fund and PEPFAR support the WHO recommendations citing viral load testing as the preferred method of monitoring patients on ART.

To optimize investments in HIV programs and recognising diagnostic point of care pipeline, the process should move forward cognizant of the following principles:

- 1. Do no harm to existing programs.*
- 2. Analyse the impact of scale-up on existing budgets.*
- 3. Optimize existing equipment and investments.*
- 4. Understand the current diagnostic marketplace.*
- 5. Develop a quality assurance program that supports scale-up, and*
- 6. Consider the context of the host country partner program as introduction and scale-up-takes place.*



Agreed priority actions for H1 2014: Programmatic and financing



1. Collect and review existing country data on the current status of planning for introduction of viral load
2. Liaise with Global HIV Diagnostics Working Group and ASLM to leverage their previous work and to their involvement on key aspects of implementation at country-level.
3. Country-level: Develop and disseminate recommendations, scenarios, and templates for developing rational country-specific viral load deployment plans to support Q1 2014 scale up.
4. Headquarters: Disseminate all recommendations and tools among technical, procurement and other staff directly overseeing grants in both the Global Fund and PEPFAR (within Q1 of 2014).
5. Develop decision criteria to facilitate the development and evaluation of requests for financing; integration of these into the Global Fund and PEPFAR's respective funding guidance.
6. Develop a monitoring and evaluation framework.



Agreed priority actions for H1 2014: Procurement options



The Global Fund
To Fight AIDS, Tuberculosis and Malaria

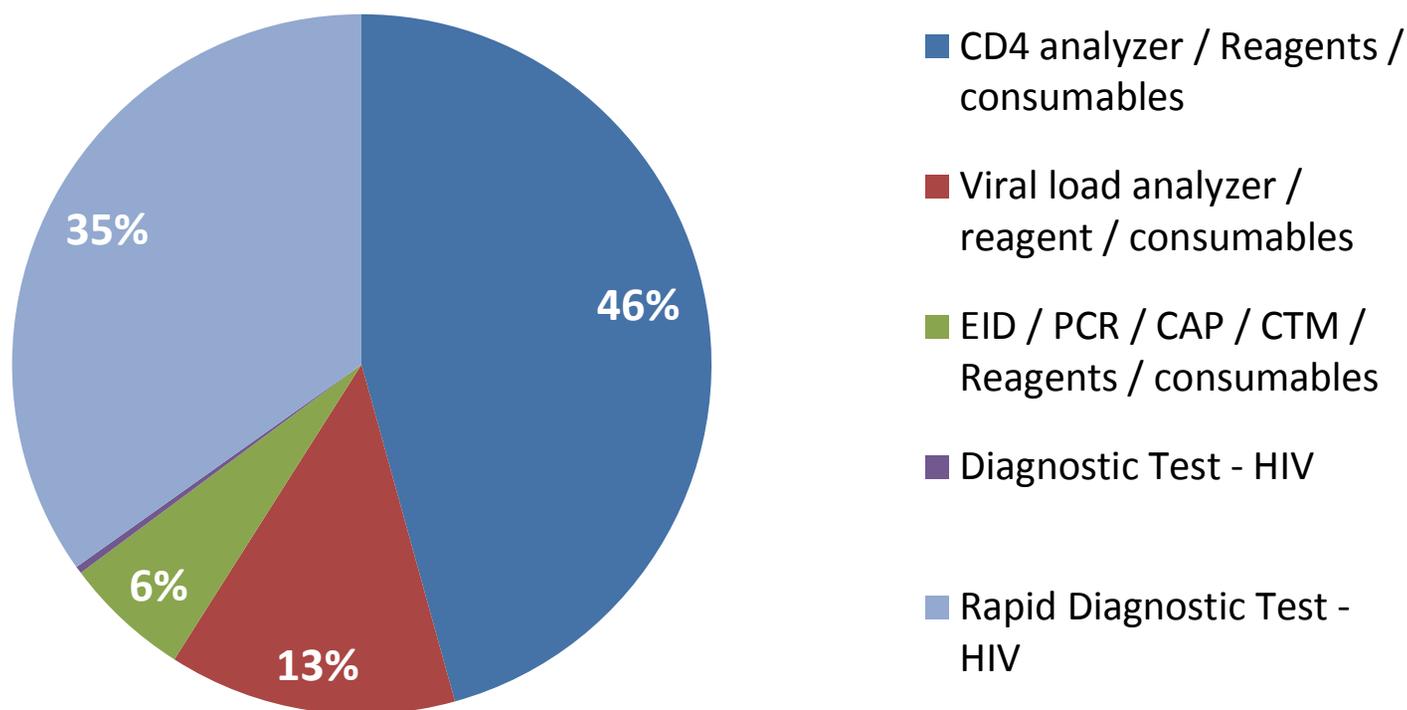
1. Engage directly with suppliers, with an initial focus on all manufacturers of lab-based viral load diagnostic equipment with a scene-setting call in December 2013 and a subsequent supplier meeting in January 2014.
2. Define procurement modalities that will include procurement/rental options (including buy/lease guidance), training and maintenance support, reagents, equipment utilisation and sample applicability.
3. Identify and engage approximately five priority countries for concerted engagement and as potential participants in a regional market shaping activity.
 - Through consolidating planned country demand, this activity will leverage the respective volumes of the Global Fund and PEPFAR, increasing testing capacity/throughput and value for money.
4. Evaluate and document outcomes of joint Global Fund-PEPFAR engagement with suppliers and consider applicability in other diagnostic and commodities' areas.



Forecast 2014 GF spend HIV Diagnostics



2014 HIV Diagnostics (\$80m)



Source: Forecasted from consolidation of current country PSM Plans end 2013

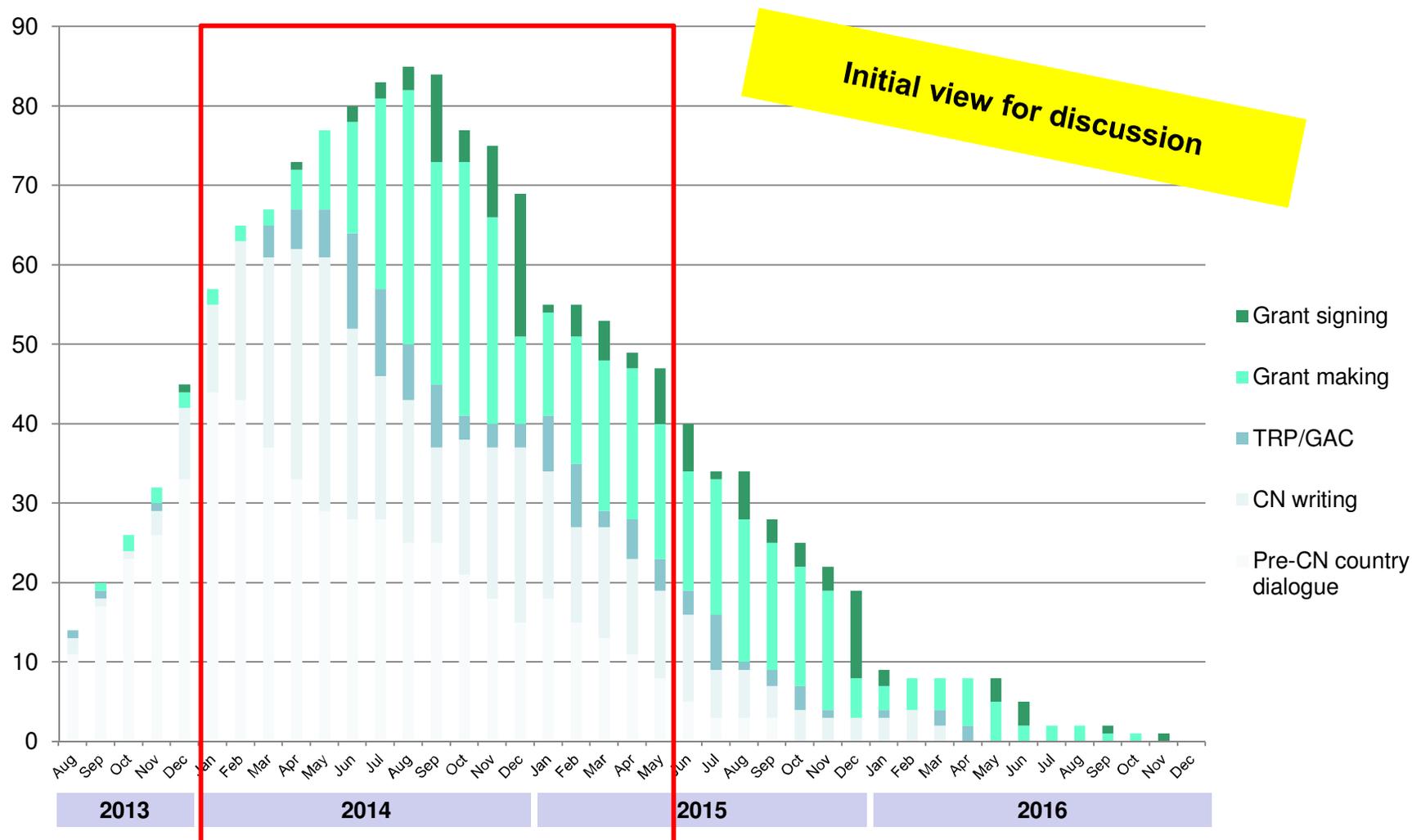
The updated WHO guidelines, New Funding Model, and the Global Fund VL procurement strategy is expected to have a significant impact on future country demand level and type



GF NFM application peak forecast to occur in 2014 to mid-2015



Number of HIV/AIDS applications in each stage, by month for ALL REGIONS





Countries coming to access GF funding in early and late 2014



	Scheduled for Early 2014	Scheduled for Late 2014
Middle East and Africa Anglophone Countries	<ul style="list-style-type: none"> • Botswana • Ethiopia • Gambia • Ghana • Iraq • Malawi • Mozambique • Somalia • South Sudan • Sudan • Swaziland • Tanzania • West Bank and Gaza Strip • Yemen • Zambia • South Africa 	<ul style="list-style-type: none"> • Angola • Egypt • Eritrea • Kenya • Lesotho • Liberia • Multicountry Mid.East - N.Africa (MENAHR) • Nigeria • Rwanda • Syria • Uganda • Mauritius
African Francophone Countries	<ul style="list-style-type: none"> • Burkina Faso • Djibouti • Tunisia • Congo (Democratic Republic) 	<ul style="list-style-type: none"> • Benin • Burundi • Cameroon • Cape Verde • Chad • Guinea • Guinea-Bissau • Mauritania • Morocco • Niger • Senegal • Gabon



Initial comments / questions prior to 121 meetings





PEPFAR

U.S. President's Emergency Plan for AIDS Relief



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To Fight AIDS, Tuberculosis and Malaria

Back-up slides

Guiding Principles

Details

“Do No Harm”

- “Do No Harm”: The transition should not jeopardize scale-up of ART services to those currently eligible under WHO normative guidance. This will need to take into account levels of ART coverage and existing guidelines. It is expected that not all countries will move towards adoption at the same rate. Additionally, the introduction of virologic monitoring should not detract from roll-out of EID testing.

“Minimize Impacts on Budgets”

- “Minimize Impacts on Budgets”: We aim for the transition to have as little impact on laboratory and treatment budgets as possible. This will involve careful consideration of a variety of trade-offs involving clinical monitoring protocols, machine placement and choice of technology. Consideration of budgetary impacts for virologic testing should span several years, as initial costs may be higher, with benefits accruing in subsequent years.

“Optimize Existing Investments”

- “Optimize Existing Investments”: Increasing the capacity for virologic monitoring will require optimal use of current diagnostics and maximizing return on previous investments. Innovative approaches to support laboratories, transfer specimens and communicate results should be encouraged to fit the needs of current and future investments.

“Optimize Markets”

- “Optimize Markets”: The introduction of new laboratory technologies to improve laboratory systems, should take place in a rational manner, optimizing the efficiencies gained through pooled procurement while allowing for some competition. An optimal market may favor no more than 2-4 specific technologies in a given country, though differences in lab systems between countries make selection of specific technologies inappropriate at the global level.

“With Quality Assurance”

- “Quality Assurance”: The platforms, testing algorithms and lab systems set up for virologic testing should be embedded within an appropriate system for quality assurance.

“Within Local Context”

- “Within Local Context”: The transition process should take into consideration local HIV treatment guidelines and epidemiology. Virologic testing could be phased-in through prioritization of special populations or geographic areas; the role and amount of donor supported CD4 testing needs to be considered, both in the short and long terms.



The Global Fund: our new approach to collaboration with partners and supplier management

Christopher Game

What is The Global Fund ?



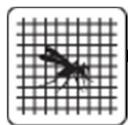
600 Employees



6.1 Million People currently receiving ARV therapy



11.2 Million New smear-positive TB cases detected and treated



360 Million Insecticide-treated nets distributed

\$3Bn+

Since its inception in 2002, the Global Fund to Fight AIDS, Tuberculosis and Malaria has become the main multilateral funder in global health . It channels 82 percent of the international financing for TB, 50 percent for malaria, and 21 percent of the international financing against AIDS. It also funds health systems strengthening, as inadequate health systems are one of the main obstacles to scaling up interventions to secure better health outcomes for HIV, TB and malaria.

The Global Fund Strategy



Based on 5 core principals

Invest more strategically in areas with high potential for impact and strong value for money, and fund based on countries' national strategies;

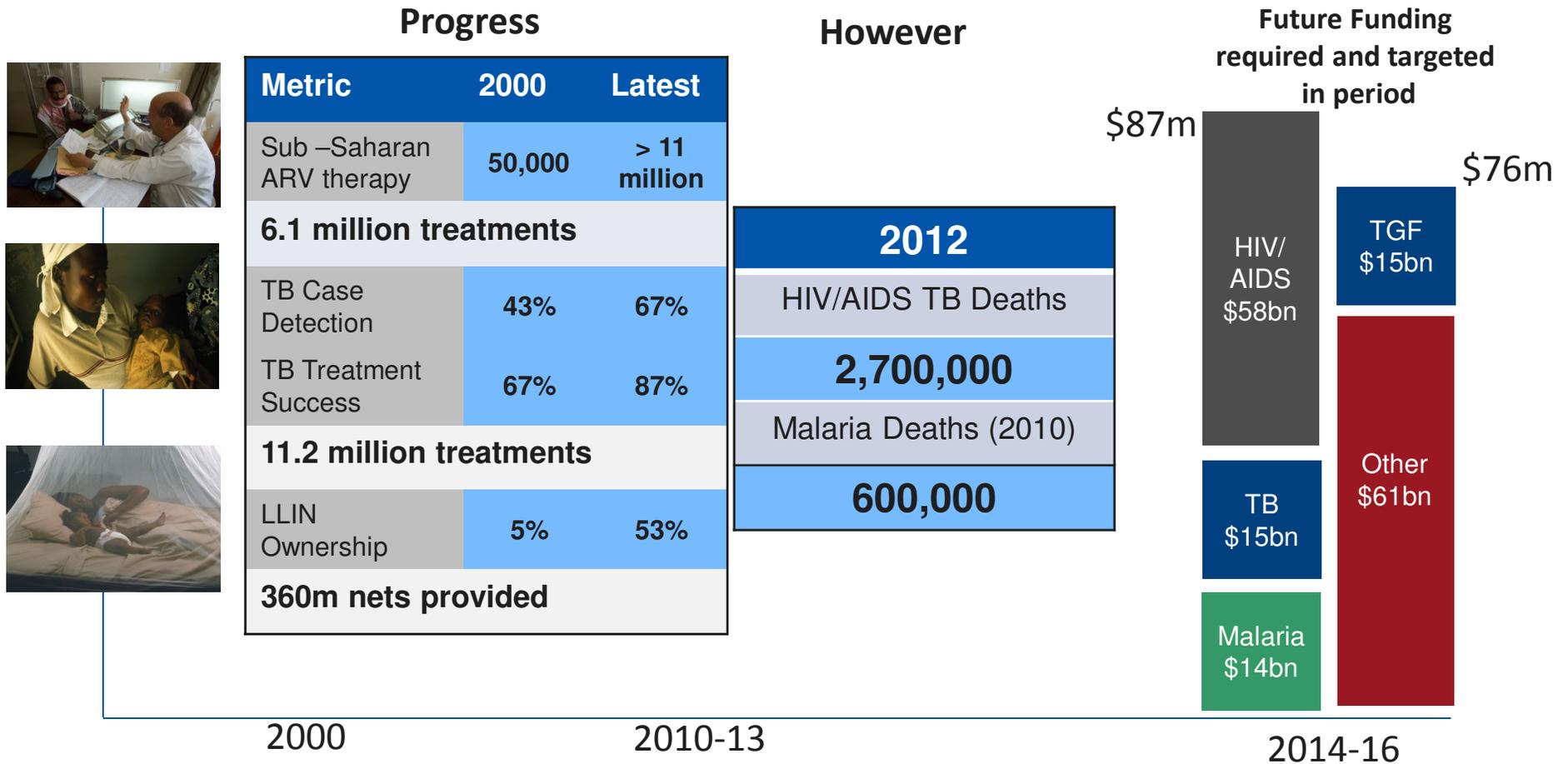
Evolve the funding model to provide funding in a more proactive, flexible, predictable and effective way;

Actively support grant implementation success through more active grant management and better engagement with partners;

Promote and protect human rights in the context of the three diseases; and

Sustains the gains, mobilize resources – by increasing the sustainability of supported programs and attracting additional funding from current and new sources.

The fight goes on



Maximising the value from procurement will contribute to the number of lives saved

Procurement 4 Impact: Our Objectives

Are directly 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

With measurable performance in value and lives saved



Minimising waste and eliminating non value adding activities

Ensuring effective governance and watertight compliance

Building collaborative relationships with partner agencies suppliers and donors

The Principles of Our Approach

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



Earlier involvement and closer collaboration with partners & manufacturers

Improving our purchasing capability and changing our contracting models

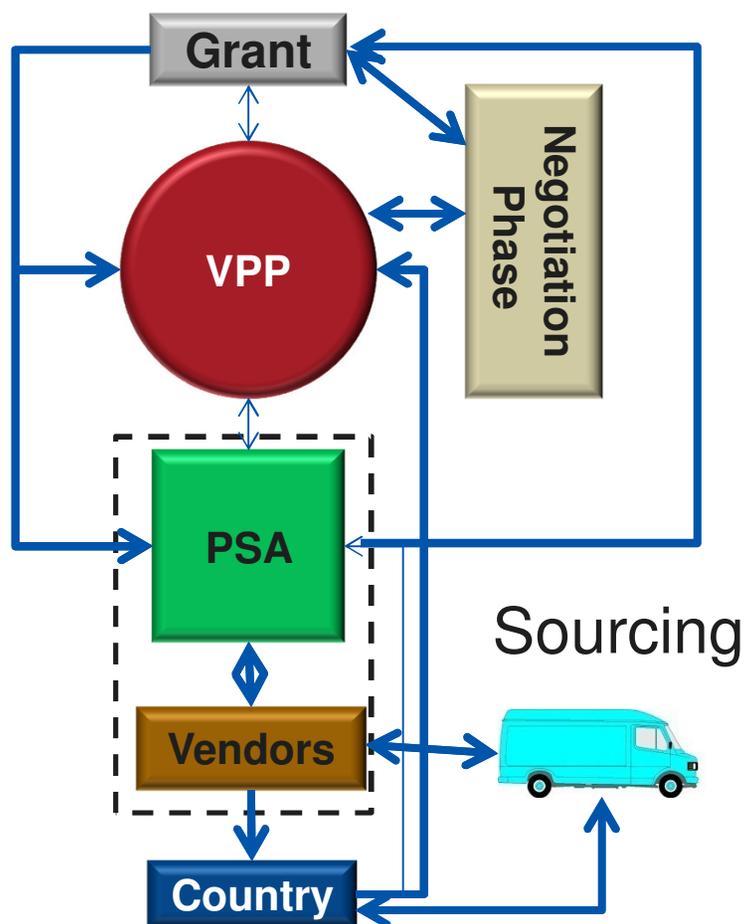
Optimising the international supply chain to reduce cost

Better planning and scheduling to support continuity of supply

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

....why transform ?

Old State Health Products:



What needed to improve :

- Poor Penetration (Punitive / Voluntary)
- Lack of Control
- High Agency Costs
- Wrong Agency Incentive model
- Agency 'local versus Global' expertise
- Poor visibility of innovation
- Lack of ownership / supplier relationships
- Poor funds flow
- Time / difficult to plan
- Mediocre internal customer service
- Little competition in pricing
- Role of Global Fund largely executorial
- No volume leverage/Many spot purchases

'It felt as though the roles were reversed and we had the agencies performing the sourcing, and the Global Fund was executing'

The Impact on the Ground



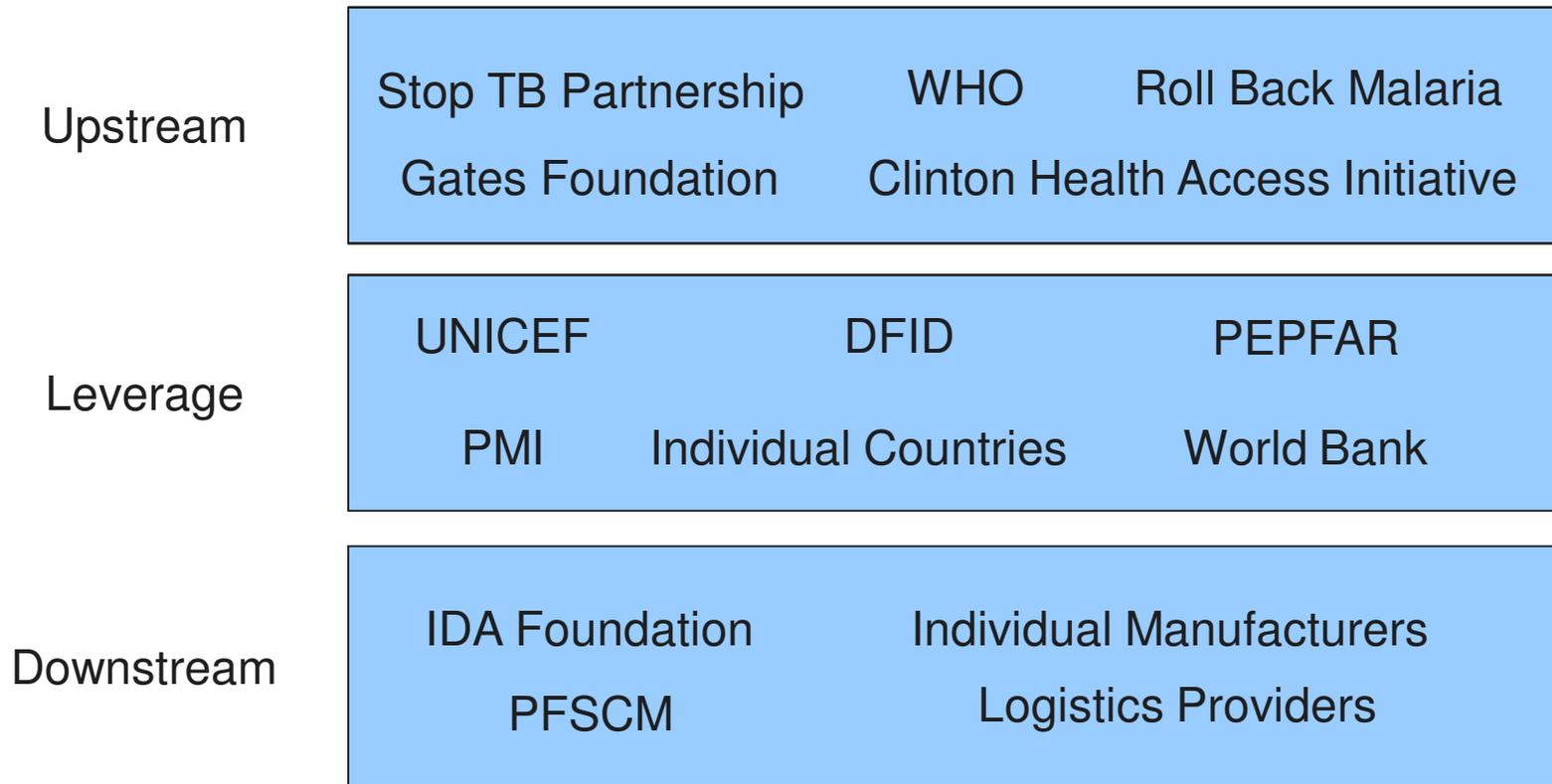
Improving our forecasting accuracy

To support our new planning process we will change the way we interact with countries. This approach will also be facilitated by the new funding proposals

Today	The Future
<p>Demands are triggered by PSM plans which are presented in an inconsistent format.</p>	<p>Overall demand will be calculated from available funding</p>
<p>Overall demand is calculated reactively by hand</p>	<p>This demand will be placed on manufacturers as an underwritten volume</p>
<p>Orders are placed on PSA for onward transmission to manufacturers</p>	<p>Detailed PR requirements will be presented in a consistent format</p>
	<p>We will use a planning tool to convert our forecast in to specific orders by type</p>



The Partner Landscape



Laying the foundations for collaboration 2013

Organisation

- Organization created by merging Amfm, Corporate & Voluntary Pooled Procurement
- New capabilities created, Business Planning and analysis, Active Pharmaceutical Ingredients and Formulation

Process

- Sourcing in-sourced from the Procurement Agents
- Procurement Agents re-purposed as Logistics Agents and placed in-house. New contracts to KPI Logistics agents further downstream and increase accountability

Market Dynamics

- All outstanding Market Dynamics performance issues resolved (WHO ARV guidelines & Paed. ARV's)
- Coalitions / consortiums formed with other donors and funders to leverage spend, specification and demand
- Indirect spend control initiated with grant teams (vehicles, civil works, IT & Lab supplies)

Performance

- 131 Million value / savings delivered in year to-date
- Lead-times reduced from 9 to 6 months
- LLIN global strategy successfully rolled out with tender savings of \$ 70Mil/annum)
- Training produced and delivered to FPM's and PSM's

Supply Chain

- Supply Chain capabilities :
 - Ability to forecast
 - Track and trace system up and running
 - Ability to measure delivery performance (OTIF)
 - In country supply mapping for hi-impact countries under-way
 - Rapid Supply Mechanism defined for all three diseases and in process

Collaboration Opportunities 2014

Organisation

- Integrate Purchasing and Supply Managers(PSM's) into Sourcing organization
- Re-structure to segregate operations from strategy
- Strengthen Indirect spend area

Process

- Launch E-Procurement toolset (reverse auctions etc.)Amazon.com for aid
- Launch country catalogue / application tool and implement in High-Impact countries (with APP functionality)
- Launch pooled disbursement

Market Dynamics

- Complete market strategy for Tenofovir combination drugs
- Leverage Indirect spend into partner organizations
- Introduce new Chinese and Indian vendors to the Aid sector

Performance

- Deliver 8% value / savings
- Achieve 60% OTIF
- Lead-times reduced from 6 to 5 months
- Roll out Global strategies on ACT's, Diagnostics & ARV's
- Implement Rapid Supply Mechanism

Supply Chain

- Complete Supply Chain mapping for High-Impact Countries
- Establish common platforms for traceability at beneficiary level (Counterfeit /theft /diversion)
- Create base level training for in-country partners

What changes with the Commercial Relationship

To ensure we maintain a competitive price in a longer term contractual framework we will need to change our commercial model.



What does this mean for our Suppliers?



1 We want a new style of relationship that brings links the public and private sector financing

2 We are prepared to enter into longer term contracts with forecast volumes that will allow you to run your businesses more effectively.

3 In return we will require a more open and collaborative style which means working with us in a straightforward, honest fashion.

4 We will adjust our level of business with you dependent on your performance with us and our buying partners.

5 Zero tolerance of non compliance with Global Fund policies

Back-up slides

What does this mean.....

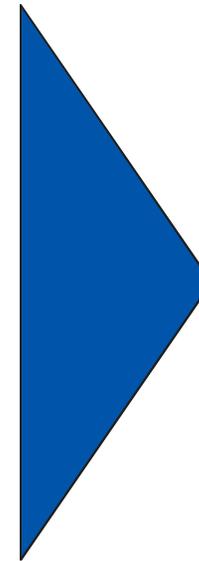


Insourcing of Sourcing

Pooled disbursement

Scale & Leverage

Organization and Tools



**Become a
customer
Of choice**

Insourcing of Sourcing



- Voluntary Pooled Procurement has evolved into a 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
- i-Fund
- Reference App.
- Tender and E-Procurement capability
- Rapid response mechanism

PEPFAR's Strategies and Procurement Approach

Meeting between the Global Fund, PEPFAR and the manufacturers of laboratory-based viral load tests



PEPFAR
U.S. President's Emergency Plan for AIDS Relief



The Global Fund
To Fight AIDS, Tuberculosis and Malaria

William Coggin

Office of the Global AIDS Coordinator

U.S. President's Emergency Plan for AIDS Relief
(PEPFAR)



PEPFAR Results



- As of September 30, 2013:
 - life-saving antiretroviral treatment for 6.7 million people
 - HIV testing and counseling for more than 57.7 million people, providing a critical entry point to prevention, treatment, and care.
 - HIV testing and counseling for more than 12.8 million pregnant women.
 - For 780,000 of these women who tested positive for HIV, PEPFAR provided ARVs to prevent mother-to-child transmission (PMTCT) of the virus
 - supported more than 4.2 million voluntary medical male circumcision (VMMC) procedures
 - supported 17 million people with care and support, including more than 5 million orphans and vulnerable children



AIDS-free GENERATION

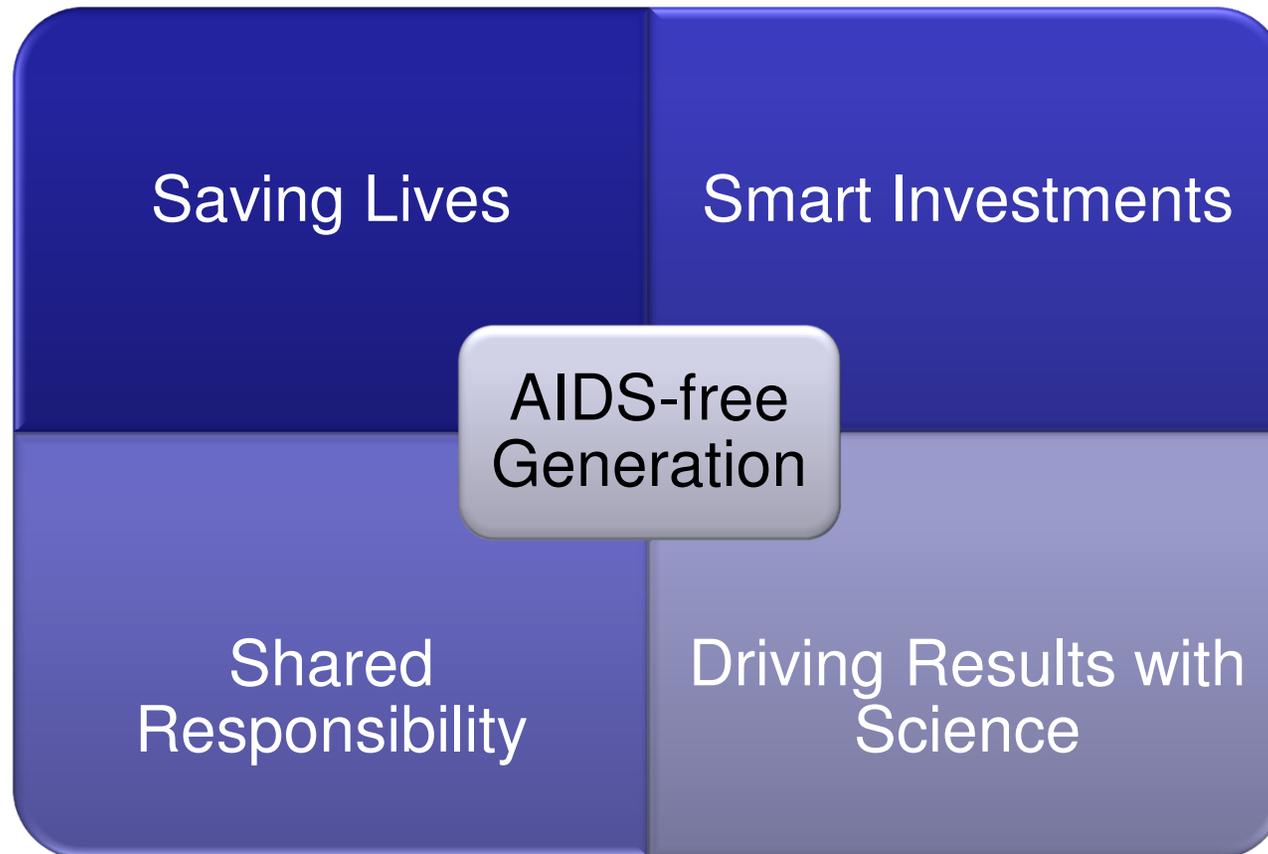


VISION STATEMENT OF PEPFAR BLUEPRINT

*Scientific advances and their successful implementation have brought the world to a **tipping point** in the fight against AIDS. The United States believes that by making **smart investments** based on **sound science**, and a **shared global responsibility**, we can **save millions of lives** and achieve an AIDS-free generation.*



PEPFAR Blueprint: Four Roadmaps



Each road map contains **specific goals and comprehensive action** and implementation steps on how PEPFAR will support partner countries' efforts to meet the goal of an AIDS-free generation



Road Map for Saving Lives



Goal:

Scale-Up Combination Prevention and Treatment

Action Steps (relating to treatment):

- 1. PMTCT & MCH:** Work toward the elimination of new HIV infections among children by 2015 and keeping their mothers alive
- 2. Treatment:** Increase coverage of HIV treatment both to reduce AIDS-related mortality and to enhance HIV prevention, especially to MSM, IDUs, Transgender, and Commercial Sex Workers
- 3. Circumcision:** Increase the number of males who are circumcised for HIV prevention
- 4. Prevention:** Increase access to HIV testing and counseling and condoms and other evidence based-targeted prevention interventions.



New WHO Consolidated Guidelines on use of ARVs for Treating and Preventing HIV



- Hasten progress to the “tipping point,” where the annual increase in adults on treatment is greater than the number of annual new adult HIV infections
- Ambassador Eric Goosby, M.D.:
 - *“The new consolidated guidelines will continue to propel us even closer to achieving an AIDS-free generation.*
 - *The guidelines are visionary as they close gaps between north and south, and promote quality and equity. We endorse the bold direction of the new guidelines and want to underscore the importance they hold for helping us address some of the most significant challenges we face in treatment and prevention.*
 - *Fourth, it is critical that we strengthen durable viral suppression. Rational expansion of viral load monitoring will improve the quality of treatment for people living with HIV, prevent the development of HIV drug resistance and maximize efforts to prevent HIV transmission.”*



PEPFAR resource allocations & procurement (*in brief...*)



Overall:

- Annual country planning levels for entire portfolio
- Country-level consultation with agencies, MOH & partners
- Allocation across prevention, care & treatment in op plan
- HQ review and approval

Specific to laboratories:

- CDC evaluation of new assays requisite for inclusion on USAID waiver list
- WHO prequalification
- Integration into countries national strategic laboratory plans
- VL based on 8 guiding principles



Procurement flexibilities & country footprint



- Pooled procurement of major drugs & diagnostics encouraged
 - use of procurement agent (SCMS) to leverage volume purchases and best value, increase flexibility, and facilitate hedging strategies
- Technical footprint in countries
 - Technical expertise in country: labs, treatment, supply chain among others



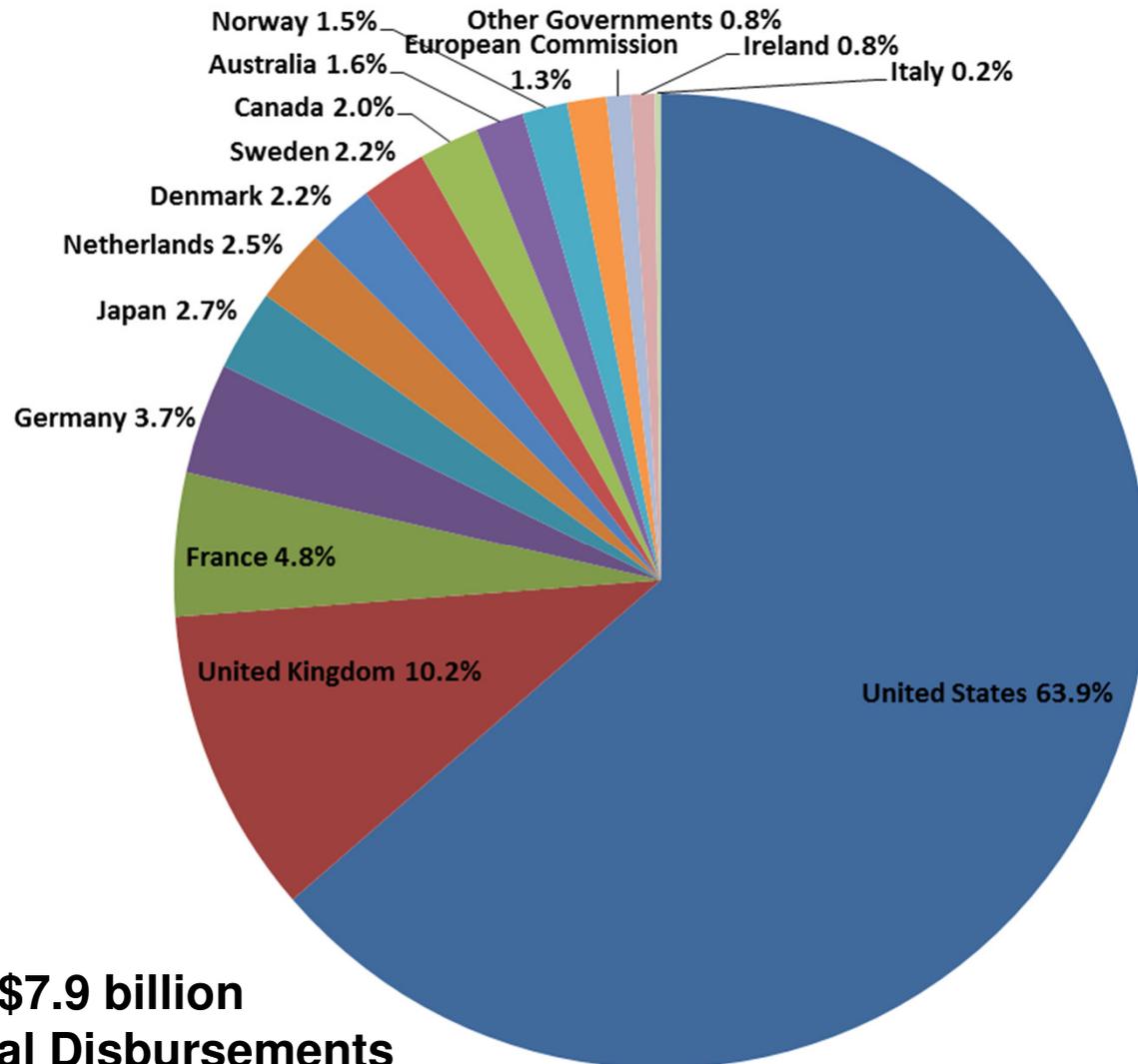
Multiple streams of engagement in Viral Load



- Policy, financing and demand issues
- Programmatic issues
- Regulatory and quality assurance requirements
- Procurement & best value



A Shared Global Responsibility



In 2012, the US accounted for **64%** of all bilateral commitments by donor governments (\$5B).

\$7.9 billion
Bilateral Disbursements

Source: Adapted from Kaiser Family Foundation/UNAIDS: Financing the Response to HIV in Low- and Middle-Income Countries, Sept 2013



A Key Partner: The Global Fund



The Global Fund
Replenishment
\$12 billion for
2014-2016

- US contributing \$1.65 billion in 2013
- US hosted replenishment conference in Washington, December 2-3, 2013

Global Fund
new funding
model

- Country dialogue, key-affected populations, science-based interventions, flexible application timeline
- Expanded WHO treatment guidelines and robust replenishment will stimulate ARV demand



Conclusion



-
- PEPFAR continues to deploy substantial resources and is working closely with national governments and the Global Fund to ensure coordination and maximum impact for our collective investments
 - Increased focus on evidence-based interventions including treatment, PMTCT, VMMC and condoms
 - PEPFAR plans to accelerate treatment to close coverage gaps & achieve “tipping points” in high-burden/low-resourced partner countries, and to maintain the scale-up in others in coordination with other donor partners
 - Continued attention to efficiency of our service delivery operations will enable even greater health impacts in the future.
 - Access to new diagnostics and monitoring tools essential.



Thank You!



For further information, please visit:

www.PEPPFAR.gov

www.facebook.com/PEPPFAR

<http://twitter.com/USPEPPFAR>