Making Interventions Scalable and Cost-Effective

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USAID

MTN Meeting
Cape Town, October 6, 2015

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Programmatic Context

- UNAIDS Targets for 2020
  - 90-90-90
- PEPFAR Targets for 2017
  - DREAMS – 40% reduction in HIV incidence
  - VMMC – 13 million (cumulative)
  - ART – 18.5 million (jointly with other efforts)
- New WHO Guidance, September 2015
  - Treat **ALL** – all adults living with HIV (at any CD4)
  - PrEP as a prevention option for people at substantial risk of HIV

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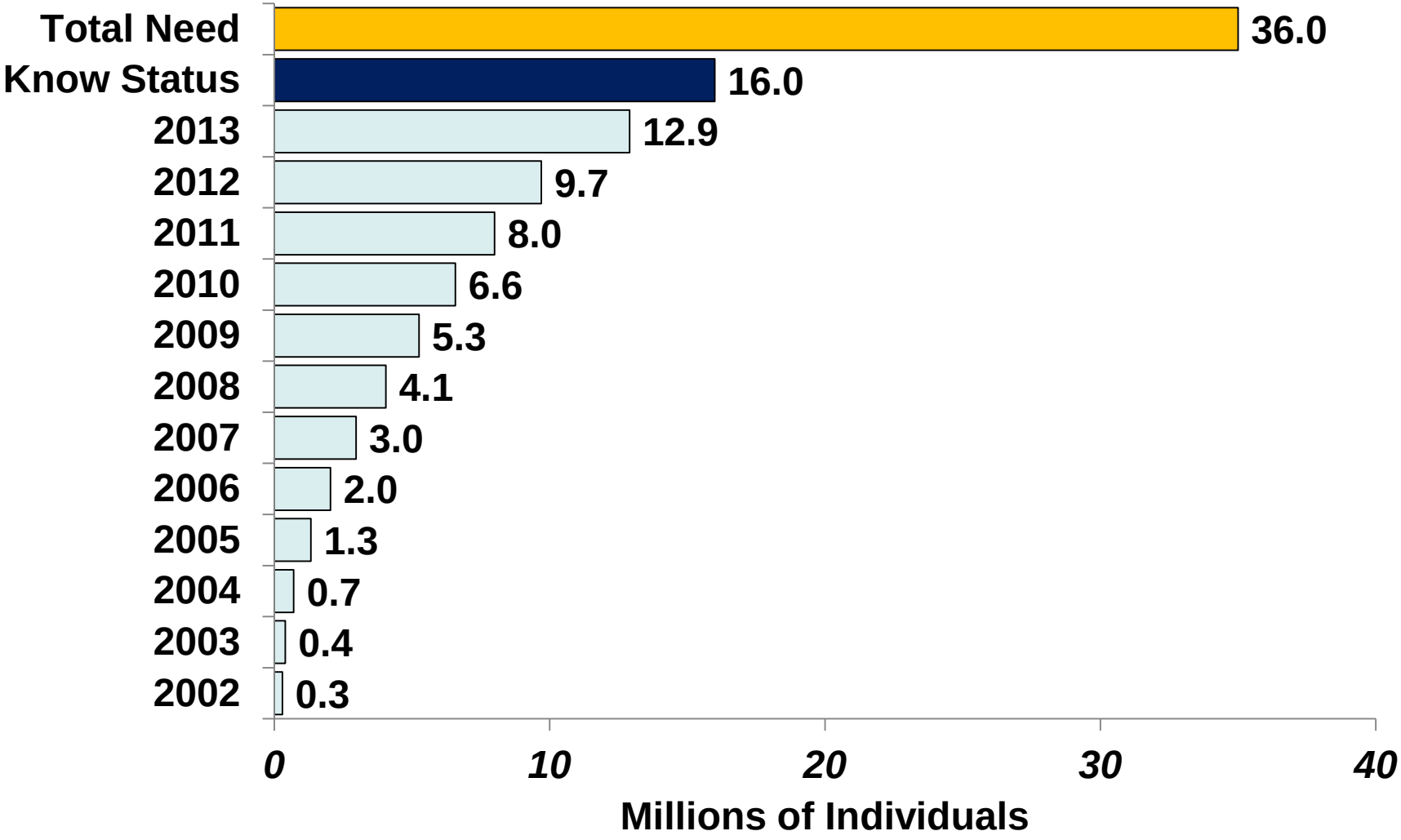
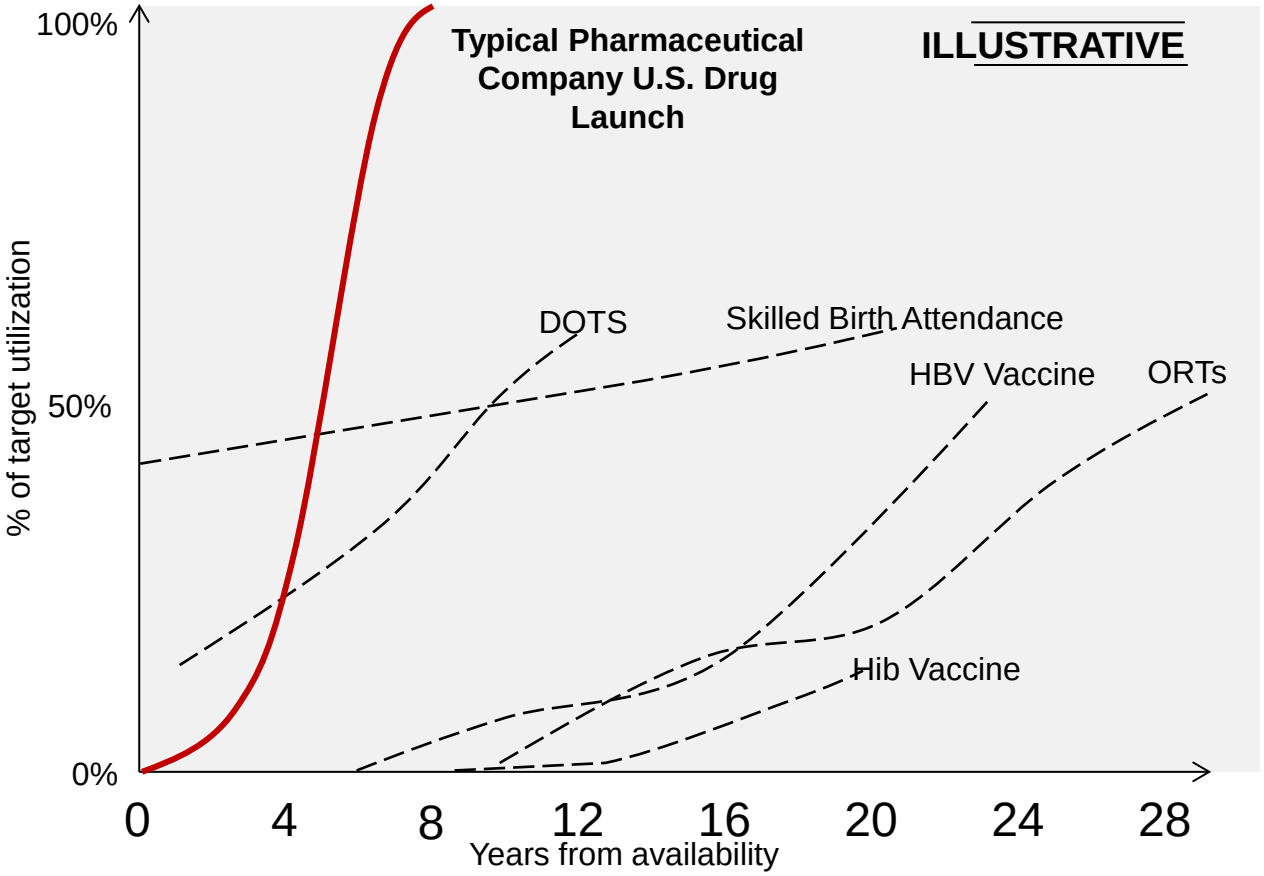
ART Scale-Up: What We Need to Achieve



Critical interventions have historically faced slow uptake and low coverage

Global Health Scale-up Illustration[1]

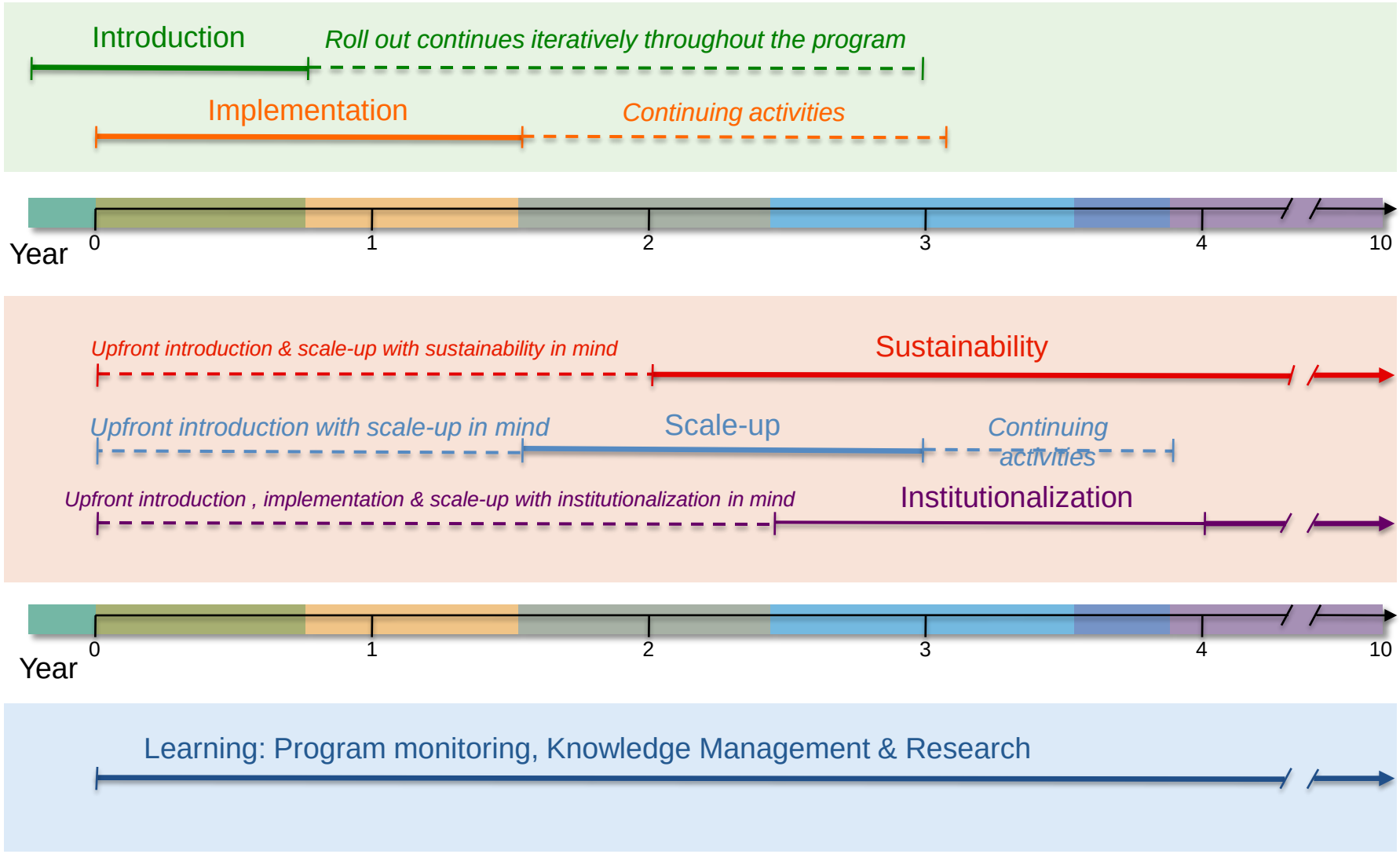


Global health launches face many challenges:

- Often take decades to reach significant numbers of end-users
- Disproportionately affects the poor
- Successes to learn from – child mortality has been cut in half over the past decade

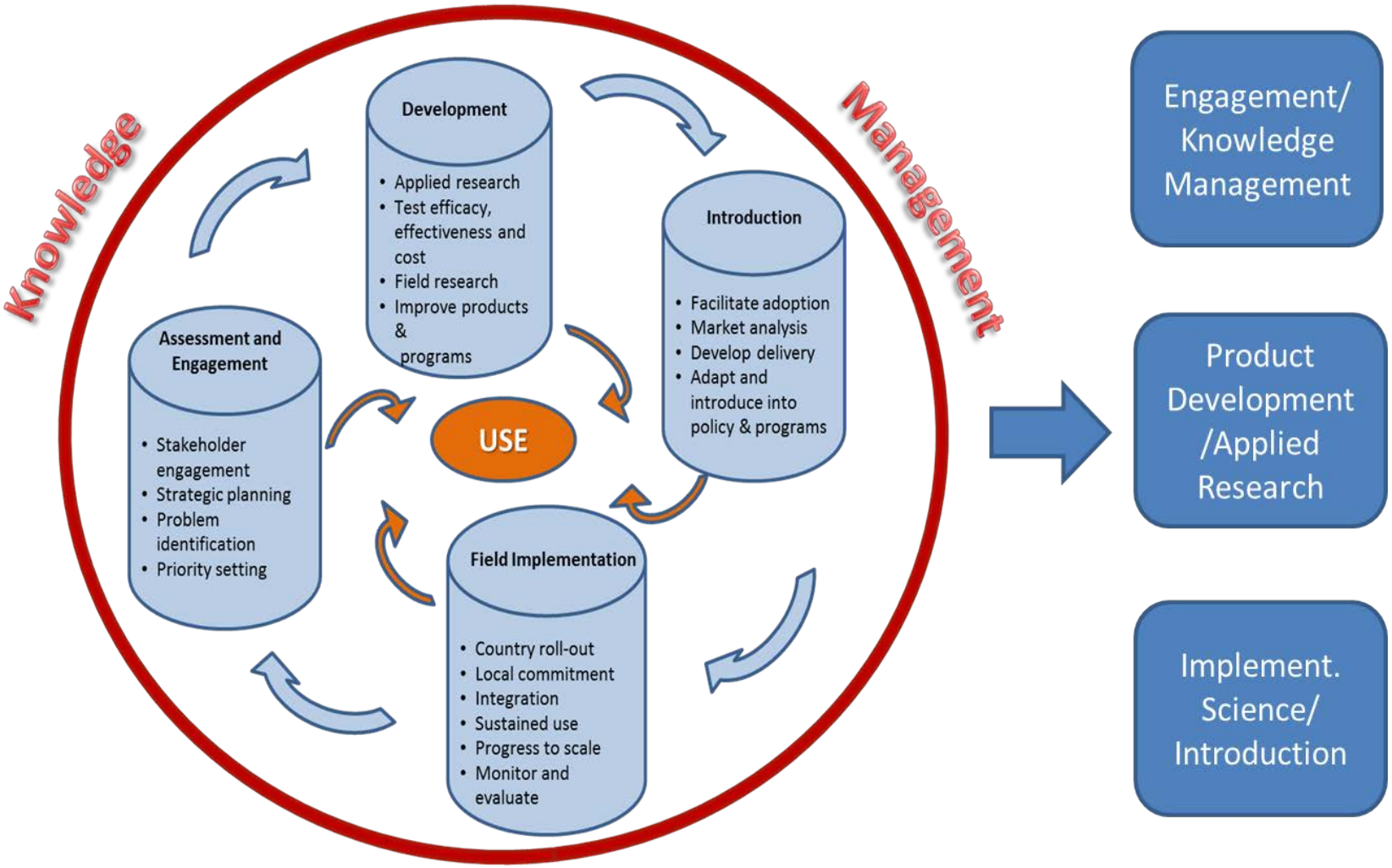
1) Adapted from Bill & Melinda Gates Foundation and Boston Consulting Group analysis

Integrated Delivery – Theoretical Model



Courtesy - Rashad Massoud, URC, 2014

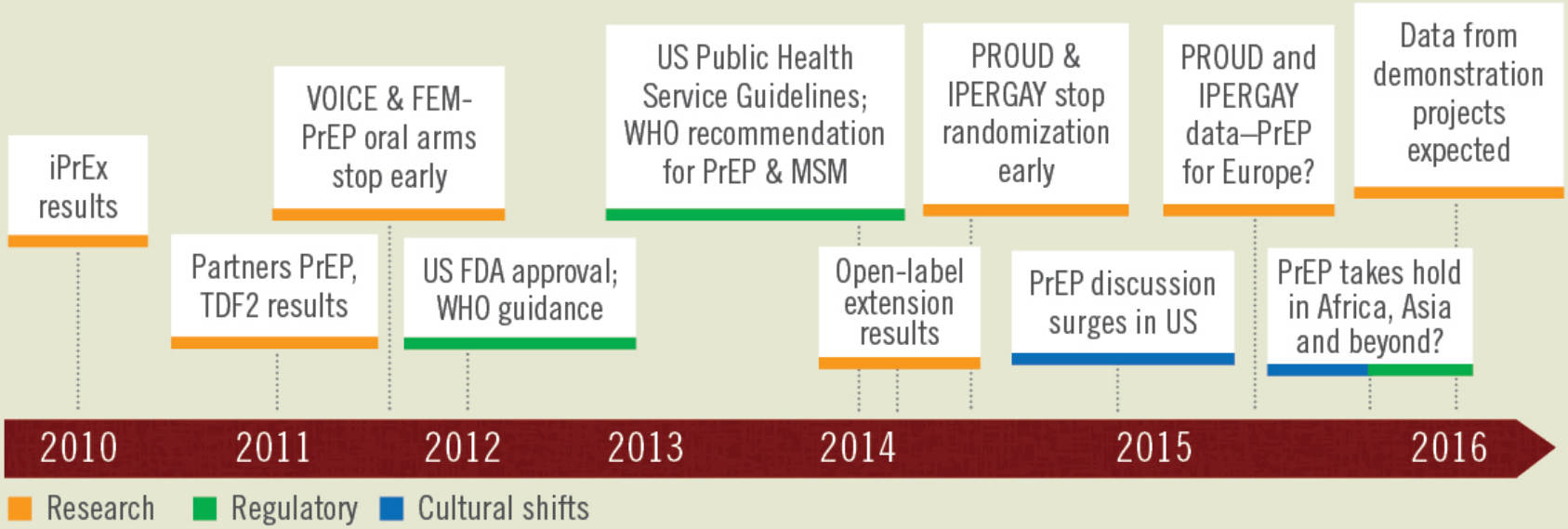
Product R&D, Introduction and Field Implementation



Courtesy – Neal Brandes, USAID

Oral PrEP- Implementation Timeline

From Proof-of-Concept to Prevention Phenomenon in Five Years



Has the global action on daily oral PrEP been as fast as possible? No. But there has been tremendous activity over the past five years. This timeline can be used to anticipate and speed action on the next generation of ARV-based prevention options.

AVAC Report 2014/15: Prevention on the Line
www.avac.org/report2014-15/graphics

From Trial World to Real World

Post-trial access

- Provided to trial participants and, sometimes, their communities, after trial & before product is available for widespread use

Open label extensions

- Available in follow-on protocol in which participants from previous RCT know they are receiving active intervention
- Product use in people who are aware of potential benefit

Open label/ Implementation studies

- Protocols similar to above but enrolling new participants

Demonstration projects

- "Road test" use of new option in real-world settings – not in trial site
- Can address both infrastructure needs to deliver intervention and ways individuals integrate it into daily activities and decision making.
- Can help answer core questions about for whom and how

Product introduction

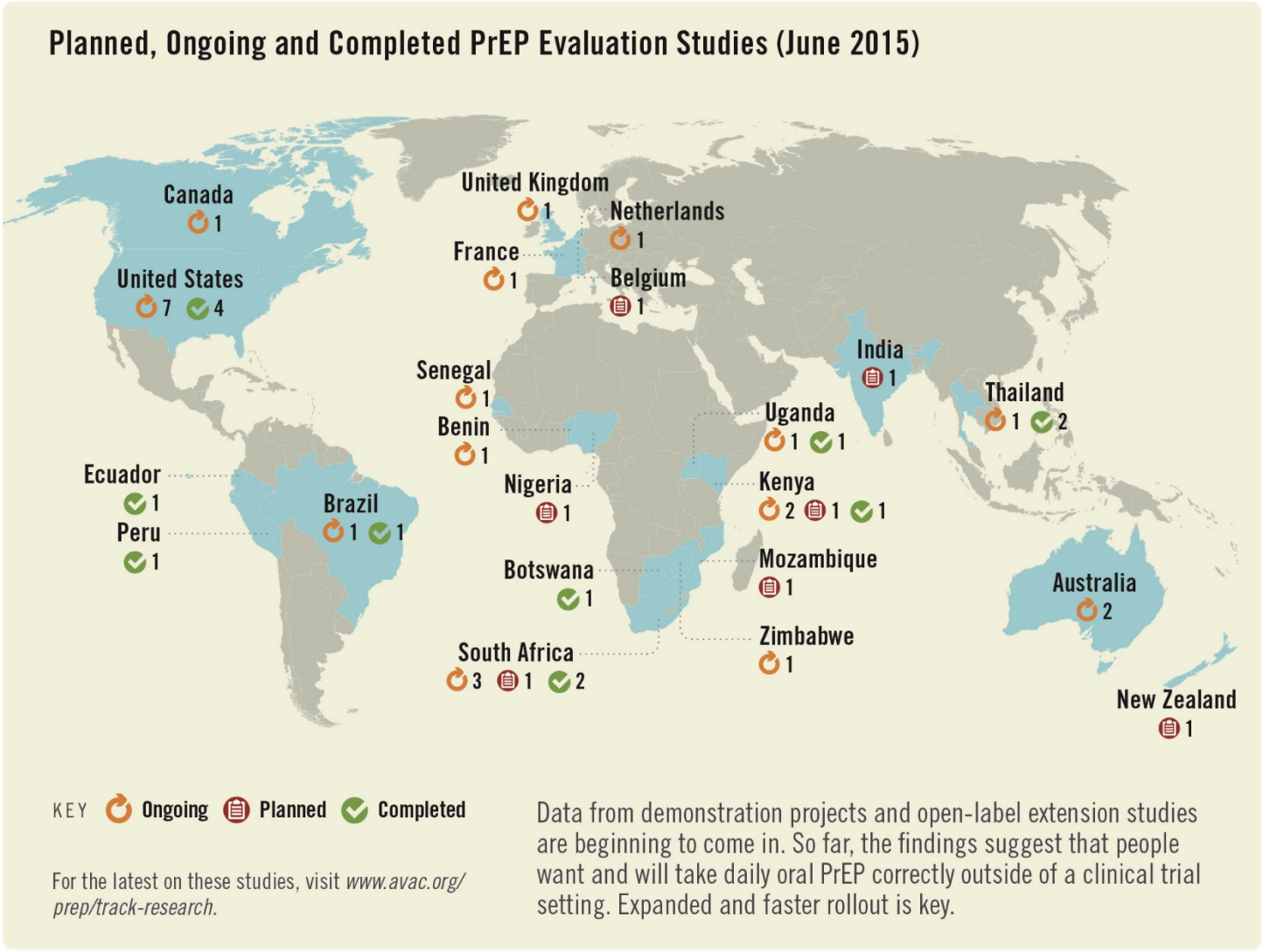
- Complex process of formally making new options widely available. Can include meeting regulatory requirements, WHO prequal, various country-specific requirement, logistical challenges

Scale-up

- Ramping up access to new options for all who need them – mobilization of resources for procurement, distribution, delivery, worker training and costs associated with rollout; quick ID and resolution of bottlenecks

Courtesy – Mitchell Warren, AVAC, 2015

PrEP Demonstration Studies (AVAC Map, 2015)



Applications of Demonstration Project Data

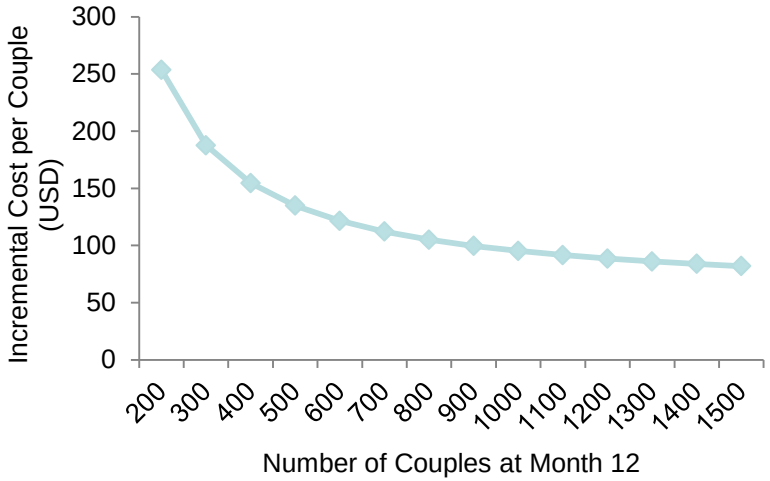
- Developing and testing adequacy of intervention
- Assessing whether the intervention is realistic and workable
- Identifying near-real-world implementation issues
- Assessing the feasibility of scaling up
- Collecting preliminary data on cost and cost-effectiveness
- Determining resource needs (finance, staff, systems)
- Assessing initial steps toward program integration
- Trying out innovations and novel delivery approaches
- Convincing stakeholders that the intervention is feasible

The Cost of Adding PrEP to ART Services

Program Change	Number of Couples	Total cost per couple including PrEP	Incremental cost of PrEP addition per Couple
Baseline	769	$1,058	$408
With public-sector staff salaries	769	$1,005	$370
With reduced medication cost	769	$720	$254
With fewer laboratory tests†	769	$497	$101
With task-shifting	1111	$453	$92

Estimated additional cost of integrating one year of PrEP into current programs at public health prices = $92

The incremental cost declines as more couples are serviced by the public health system



Ying et al. (Partners' Demo), JIAS 2015

IDEA TO IMPACT designed to support better planning for introduction and scale

The "GUIDE":

IDEA TO IMPACT

- Framework Overview
- Priority Activities
- Case studies

Practitioner's Workbook

- Project Management tool
- Track progress and increase coordination

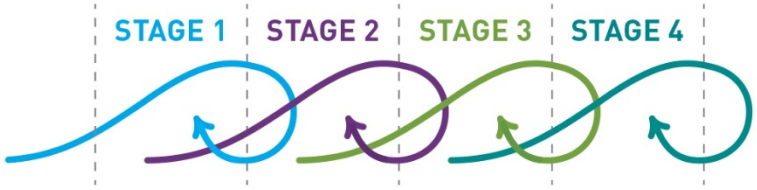
Toolkit

- Dynamic set of examples and templates for many of the priority activities

www.usaid.gov/cii

All activities are iterative throughout

STAGE 1	STAGE 2	STAGE 3	STAGE 4
Identify Needs and Design	**Begin Research & Development**	**Plan for Introduction**	**Introduce & Scale**
Define problem and design requirements	Evaluate market feasibility and potential for scale	Develop and execute an operational launch plan	Monitor execution and optimize



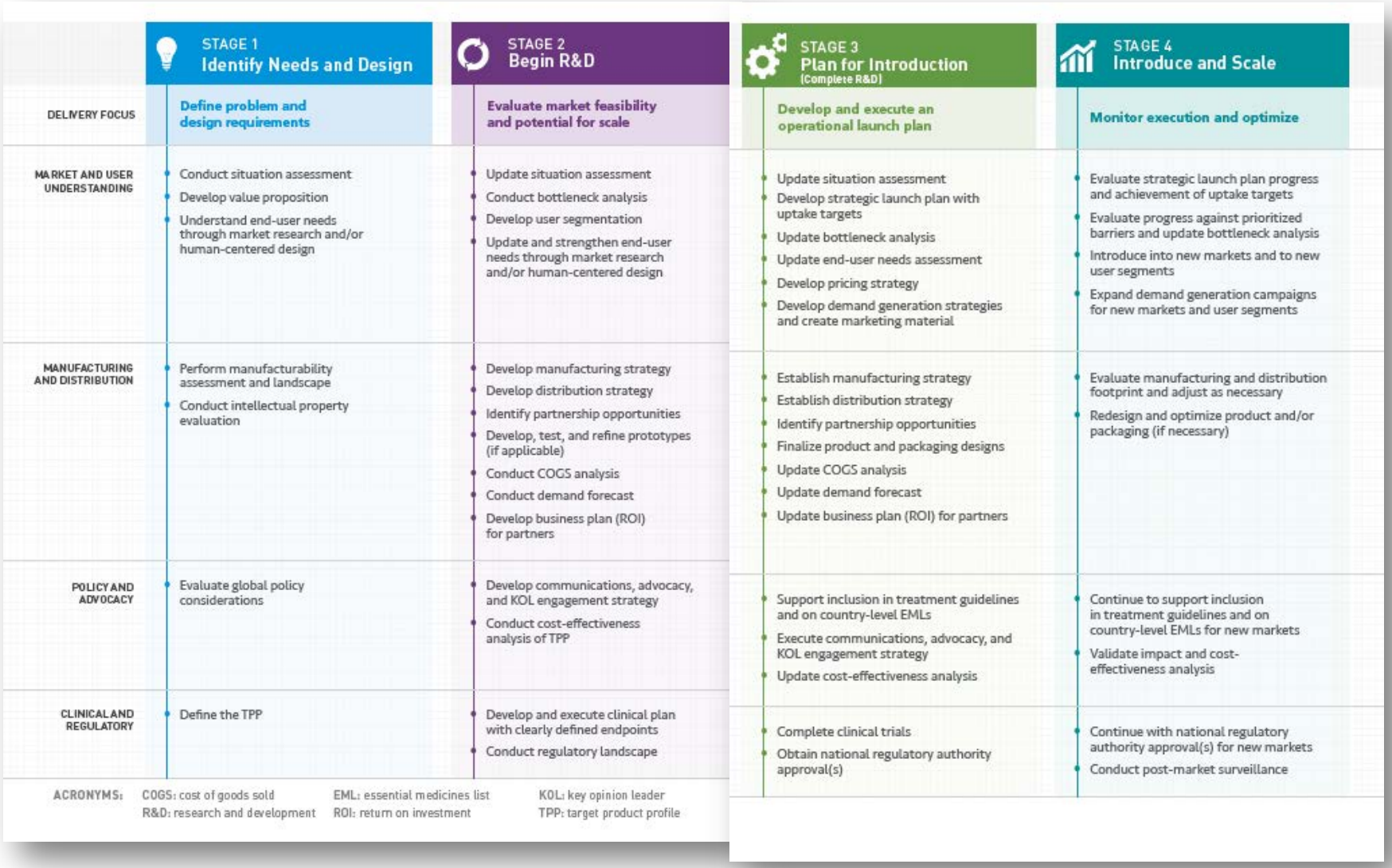
Market and user understanding

Manufacturing and distribution

Policy and advocacy

Clinical and regulatory

Activity-level details across four stages



	STAGE 1 Identify Needs and Design	STAGE 2 Begin R&D	STAGE 3 Plan for Introduction (Complete R&D)	STAGE 4 Introduce and Scale
DELIVERY FOCUS	Define problem and design requirements	Evaluate market feasibility and potential for scale	Develop and execute an operational launch plan	Monitor execution and optimize
MARKET AND USER UNDERSTANDING	• Conduct situation assessment • Develop value proposition • Understand end-user needs through market research and/or human-centered design	• Update situation assessment • Conduct bottleneck analysis • Develop user segmentation • Update and strengthen end-user needs through market research and/or human-centered design	• Update situation assessment • Develop strategic launch plan with uptake targets • Update bottleneck analysis • Update end-user needs assessment • Develop pricing strategy • Develop demand generation strategies and create marketing material	• Evaluate strategic launch plan progress and achievement of uptake targets • Evaluate progress against prioritized barriers and update bottleneck analysis • Introduce into new markets and to new user segments • Expand demand generation campaigns for new markets and user segments
MANUFACTURING AND DISTRIBUTION	• Perform manufacturability assessment and landscape • Conduct intellectual property evaluation	• Develop manufacturing strategy • Develop distribution strategy • Identify partnership opportunities • Develop, test, and refine prototypes (if applicable) • Conduct COGS analysis • Conduct demand forecast • Develop business plan (ROI) for partners	• Establish manufacturing strategy • Establish distribution strategy • Identify partnership opportunities • Finalize product and packaging designs • Update COGS analysis • Update demand forecast • Update business plan (ROI) for partners	• Evaluate manufacturing and distribution footprint and adjust as necessary • Redesign and optimize product and/or packaging (if necessary)
POLICY AND ADVOCACY	• Evaluate global policy considerations	• Develop communications, advocacy, and KOL engagement strategy • Conduct cost-effectiveness analysis of TPP	• Support inclusion in treatment guidelines and on country-level EMLs • Execute communications, advocacy, and KOL engagement strategy • Update cost-effectiveness analysis	• Continue to support inclusion in treatment guidelines and on country-level EMLs for new markets • Validate impact and cost-effectiveness analysis
CLINICAL AND REGULATORY	• Define the TPP	• Develop and execute clinical plan with clearly defined endpoints • Conduct regulatory landscape	• Complete clinical trials • Obtain national regulatory authority approval(s)	• Continue with national regulatory authority approval(s) for new markets • Conduct post-market surveillance

ACRONYMS: COGS: cost of goods sold; EML: essential medicines list; KOL: key opinion leader; R&D: research and development; ROI: return on investment; TPP: target product profile

Bottleneck analysis: tool developed to assess country-specific product uptake challenges…

	PRODUCT PROFILE / MANUFACTURING	PROCUREMENT	DISTRIBUTION	DELIVERY / ADOPTION

Demand	• Efficacy and effectiveness
	• Ease of use
	  - Side effects
	  - Reactions with other treatment
	• Ease of administration
	  - Toxicity risks
	• Cost-effectiveness
		• Public/donor purchaser's awareness, acceptance, willingness to pay
		• Inclusion in, and specificity of, WHO guidelines
		• Inclusion in and clarity of national EML and guidelines (and subnational, as applicable)
		• Recency of guidelines update
		• Effectiveness of inventory tracking, quantification and procurement
			• Geographic access
			  - Public channel
			  - Private channel
			  - Nonprofit and faith-based organization channel
				• End users' awareness, acceptance, willingness to pay and adherence
				• Awareness and acceptance of influencers:
				  - Family
				  - Opinion leaders, cultural norms
				• Referral system and practices, including attrition
				• Use and clarity of community-based case management
				• Consistency between de facto practice and national guidelines

Supply	• Ease and quality of production
	• Availability of inputs
	• Storage and cold chain requirements
	• Required accessory products (e.g., sterile water, syringes, etc.)
	• Required training of providers
	• Production cost (COGS)
	• Manufacturing margins/profit
	• Manufacturing capacity
	• Availability of suppliers
	  - Current and potential
	  - Opportunity for local production
		• Demand characteristics
		  - Fragmentation
		  - Consistency vs Fluctuation
		  - Clarity/Certainty
		• Registration process for new suppliers
		• Intellectual property landscape
		• Quality of available products
		• Adequate procurement of accessory products (e.g., syringes)
		• Purchaser reliability (e.g., payment timeliness)
		• Contracting terms (e.g., timelines for delivery)
		• Management of product donations
			• Profit opportunity for supply chain actors, such as:
			  - Distributor
			  - Retailer
			• Availability (vs stockouts)
			  - Public channels
			  - Private channels
			  - Variation by facility level
			  - Availability of required accessories
			  - Supply chain performance: infrastructure, planning, data management, etc.
				• Permitted level of facility to stock
				• Permitted level of health care provider to administer
				• Health care providers' (and professional associations') awareness, acceptance and confidence to administer, including possible wastage concerns
				• Proportion of providers with adequate training (by cadre as applicable)

Healthy Markets For Global Health: A Market Shaping Primer

1 The Primer presents a flexible, five-step framework…

2 …to identify 5 major market shortcomings…

- Affordability
- Availability
- Assured Quality
- Appropriate Design
- Awareness

3 …and match potential interventions to the market inefficiencies they address.

- Reduce Transaction Costs
- Increase Market Information
- Balance Supplier & Buyer Risks

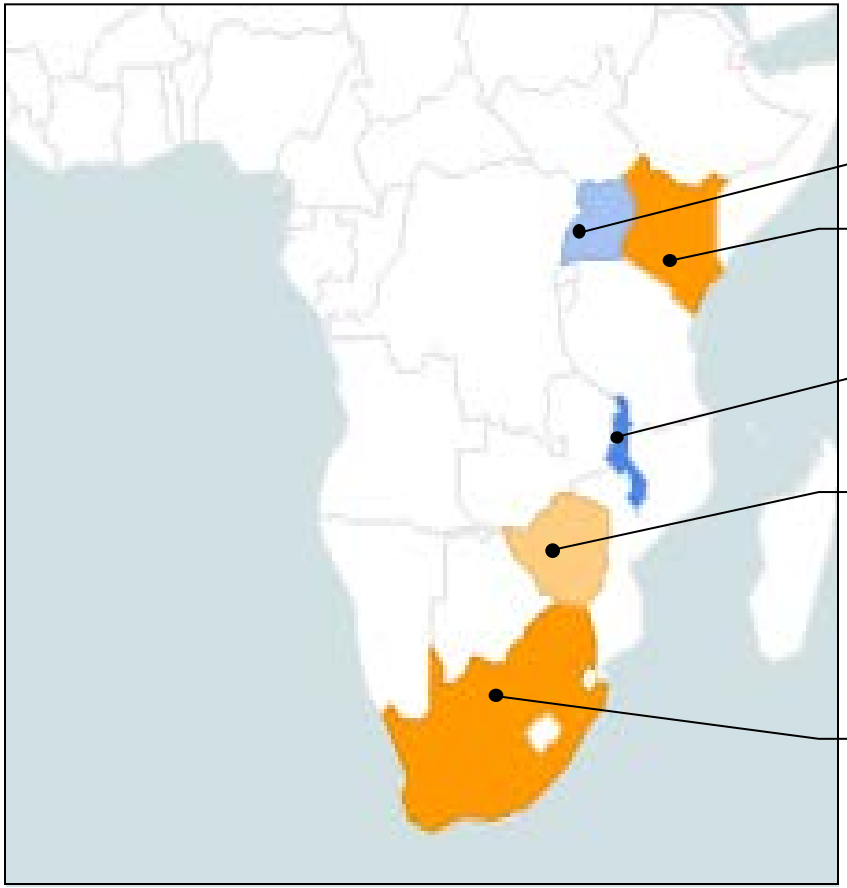
A Pragmatic, Flexible Approach To Shaping Healthcare Markets

- Created in partnership with technical experts across health sectors, disciplines and organizations including CHAI, DFID, BMGF, RHSC, GAVI, UNICEF and others
- Draws on examples from HIV, malaria, family planning, immunization and other health sectors
- Incorporates input and best practices from practitioners at USAID

New USAID Awards to Support Product Introduction

- **OPTIONS (FHI360) -** Develop a streamlined, adaptable product delivery platform for current and future microbicide and ARV-based HIV prevention.
- **POWER (U Washington) -** Develop and evaluate effective, scalable strategies for microbicides and PrEP delivery for African women in high HIV incidence settings.
- **EMOTION (CONRAD) -** Define a user-centered strategy, validated by socio-behavioral research, to design a comprehensive introduction package and campaign.
- **CHARISAMA (RTI) –** Develop and test approaches to address harmful gender norms with microbicide and PrEP introduction to efficiently address potential challenges to use.
- **GEMS (U Pittsburgh) -** Inform policies and define programmatic considerations related to use of microbicides and risk of ARV resistance.

Location of USAID Microbicides and PrEP Introduction Activities



Kenya: GEMS, CHARISMA, EMOTION, POWER, OPTIONS

Uganda: CHARISMA, GEMS

Malawi: CHARISMA

Zimbabwe: GEMS, CHARISMA, EMOTION, OPTIONS

South Africa: GEMS, CHARISMA, EMOTION, POWER, OPTIONS

The keys to sustainable scale up

- 4 A's (appropriate, affordable, acceptable, accessible)
- Targeting relevant communities and populations
- Linkage to complementary programs (e.g., PrEP & ART)
- Optimal integration into broader health programs
- Effective use of clinical trial and pilot data (initially) and *real-time data (ongoing basis)* to inform program strategies
- Engagement and education of providers and beneficiaries
- Ongoing communication and knowledge management
- Product improvement and/or modification, if necessary
- "Deep reach" to the target populations
- Cost-effectiveness once initial roll out is successful

The Key Takeaway Points

- Product need, anticipated impact and product life cycle can be pre-determined
- Roll out and integration of new prevention products are challenging and require concerted strategies
- Demonstration projects provide critical evidence on effectiveness and promising delivery approaches
- Knowledge management is key
- Strengthen capacity while concurrently achieving results
- Some interventions may have limited program life span
- Implementation science is a critical component to ensure scale-up, institutionalization and sustainability
- Delivery science is not yet perfect science

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How about equity and human rights?

Lake Victoria Kasenyi Landing Site, Uganda, October 3, 2015
Photo Courtesy – Margaret McCluskey, USAID

Acknowledgement

- USAID
  - Amy Lin, Neal Brandes, Matt Barnhart, Lee Claypool, Margaret McCluskey, Andrew Goumas
- University of Washington
  - Jared Baeten, Connie Celum
- AVAC
  - Mitchell Warren