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Global Advocacy for HIV Prevention

Research & Reality

What to expect in 2014 – and where should prevention advocates put our energy?

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Executive Director, AVAC
26 February 2014

Today's Call

- Overview of the 2014 timeline and development of AVAC's analysis
- Snapshots of some key issues
- What's on your mind?

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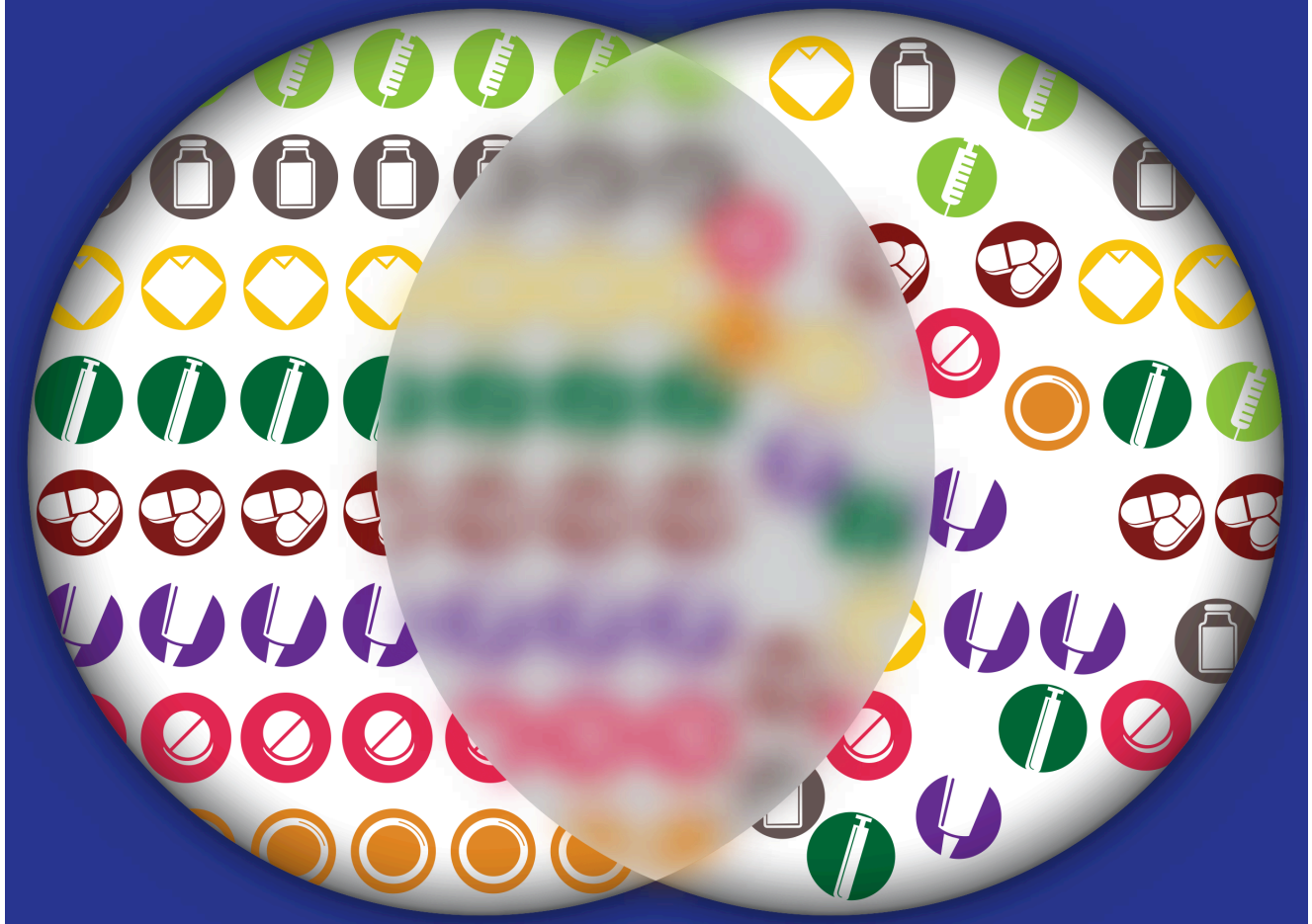

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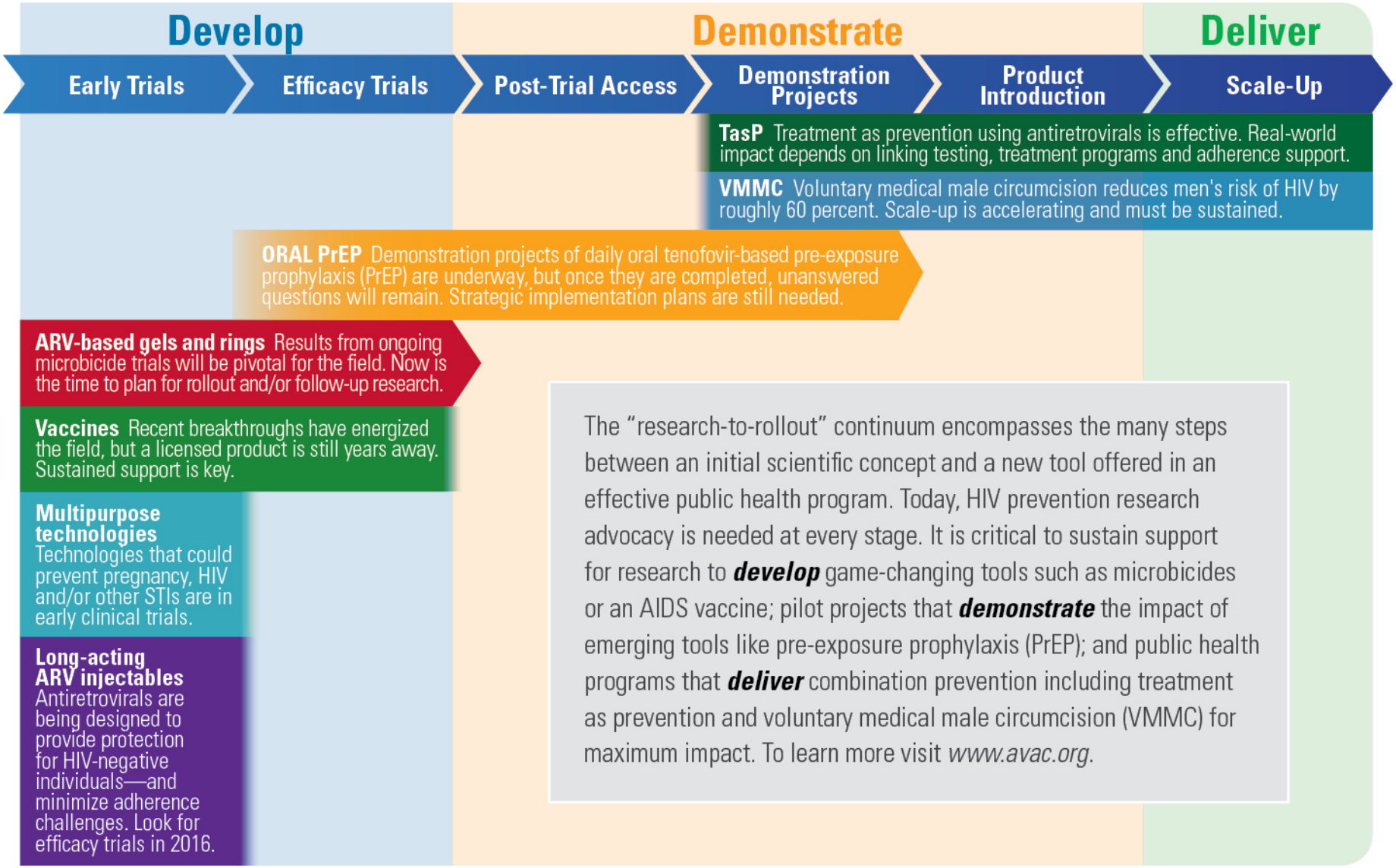
The HIV Prevention Research-to-Rollout Continuum, December 2013



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2014 Timeline: HIV Prevention Milestones and Advocacy Goals

	EVENTS	ADVOCACY GOALS
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	Debbie Birx nominated as US Global AIDS Coordinator to lead PEPFAR program	Strong leadership to ensure continued funding; responsible transition to country ownership
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	Decision on the ECHO trial evaluating contraceptives and HIV risk	Full funding for a four-arm trial is secured; protocol finalized with active civil society input
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	HIV Vaccine Awareness Day	Announcement that P5 vaccine trials are on schedule, with protein boost available for Thailand and South Africa
July-Sep	Ring Study and the ASPIRE Trial continue evaluating dapivirine ring	Responsive adjustments as needed based on adherence data; plans for product introduction are in place
	International AIDS Conference, Melbourne, Australia, July 20-25	Global commitment to fully fund a sustained effort to end the epidemic
Oct-Dec	PEPFAR releases annual progress update	Pace of US-funded ART scale-up and VMMC achieves coverage goals that maximize impact on incidence and mortality
	FACTS 001 tenofovir gel trial finishes data collection	Clear introduction plans for tenofovir gel in place
	HIVR4P inaugural conference, Cape Town, South Africa October 28-31	Increased collaboration across HIV prevention research areas
	WHO/UNAIDS announce new global VMMC total	A new deadline for reaching the target of 20 million procedures; more frequent global progress updates
	Results from evaluation studies of nonsurgical devices for VMMC	Countries make evidence-based decisions about introduction

PEPFAR Country Operational Plans

- Made every year, but every second year requires more work by PEPFAR
  - Those years are known as “COP heavy” years: 2014 is “COP heavy”
- US government document with input from national governments
  - Includes PEPFAR priorities, budgets, targets and implementing partners in the country
- Drafted by USG country team

➔ Sent to DC

➔ Changes made

➔ Approved or “red lighted”

- Uganda team in 2012 helped get the COP red lit, staff changes, huge changes toward scale up!
- Also, possibility to influence Global Fund

Influencing PEPFAR Country Operational Plans(COPS)

An Advocate's Guide

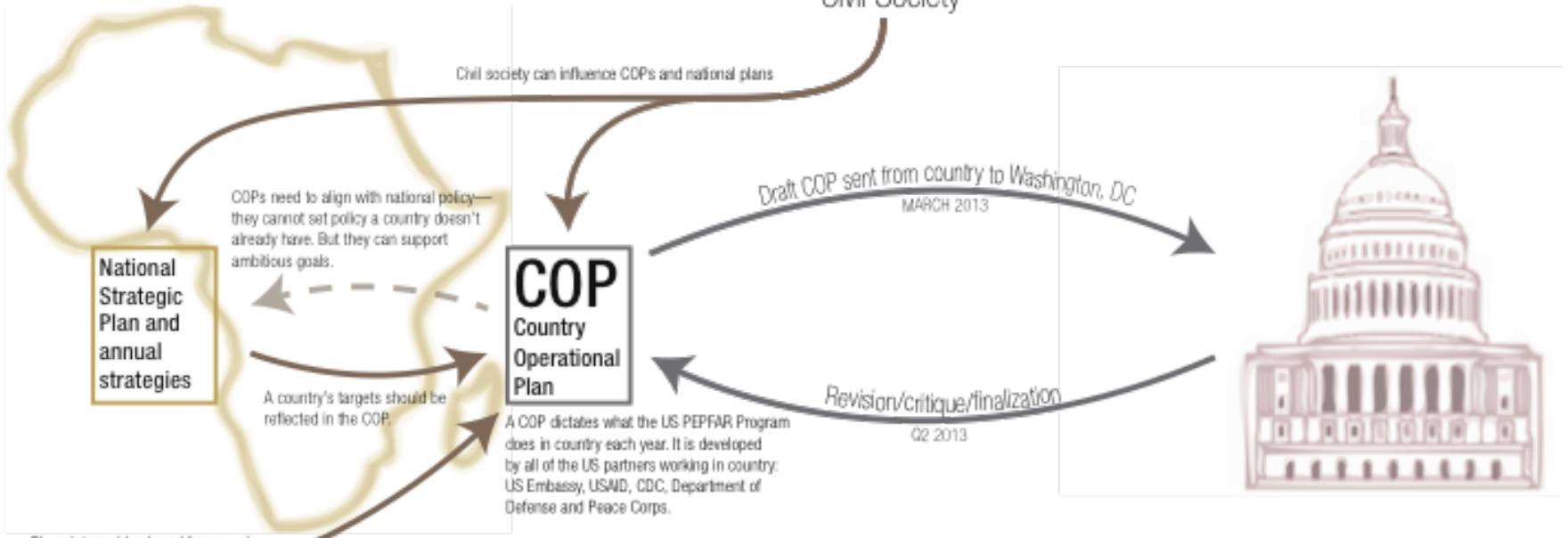
Country-Level Advocacy Points

- Ensure the COP is ambitious and consistent with the PEPFAR Blueprint
- Use PEPFAR commitments to influence national plans and policies—e.g. Blueprint statement that PEPFAR will support national programs implementing the WHO guidelines for treatment of serodiscordant couples.
- It is PEPFAR's obligation and your right that you be meaningfully involved

US-Level Advocacy Points

- Lobby to increase overall PEPFAR funding
- Ensure COP targets match Blueprint goals
- Amplify specific country concerns

Civil Society



The PEPFAR Blueprint

full report at: http://1.usa.gov/U4BNII

Priority is combination prevention: VMMC, ART, PMTCT, testing, condoms, and programs targeting key populations (p15).

Support for plans incorporating Option B+, treatment at a CD4 count of 350 and above, and treatment for the positive partner in serodiscordant couples (p 19). Financial assistance may be available to countries that need them to implement these programs.

PEPFAR is reorienting its approach in order to increase country financial commitments and ownership (p 44).

Engaging civil society in the COP process is a priority. Small grants are available for ongoing advocacy work. (p 46).

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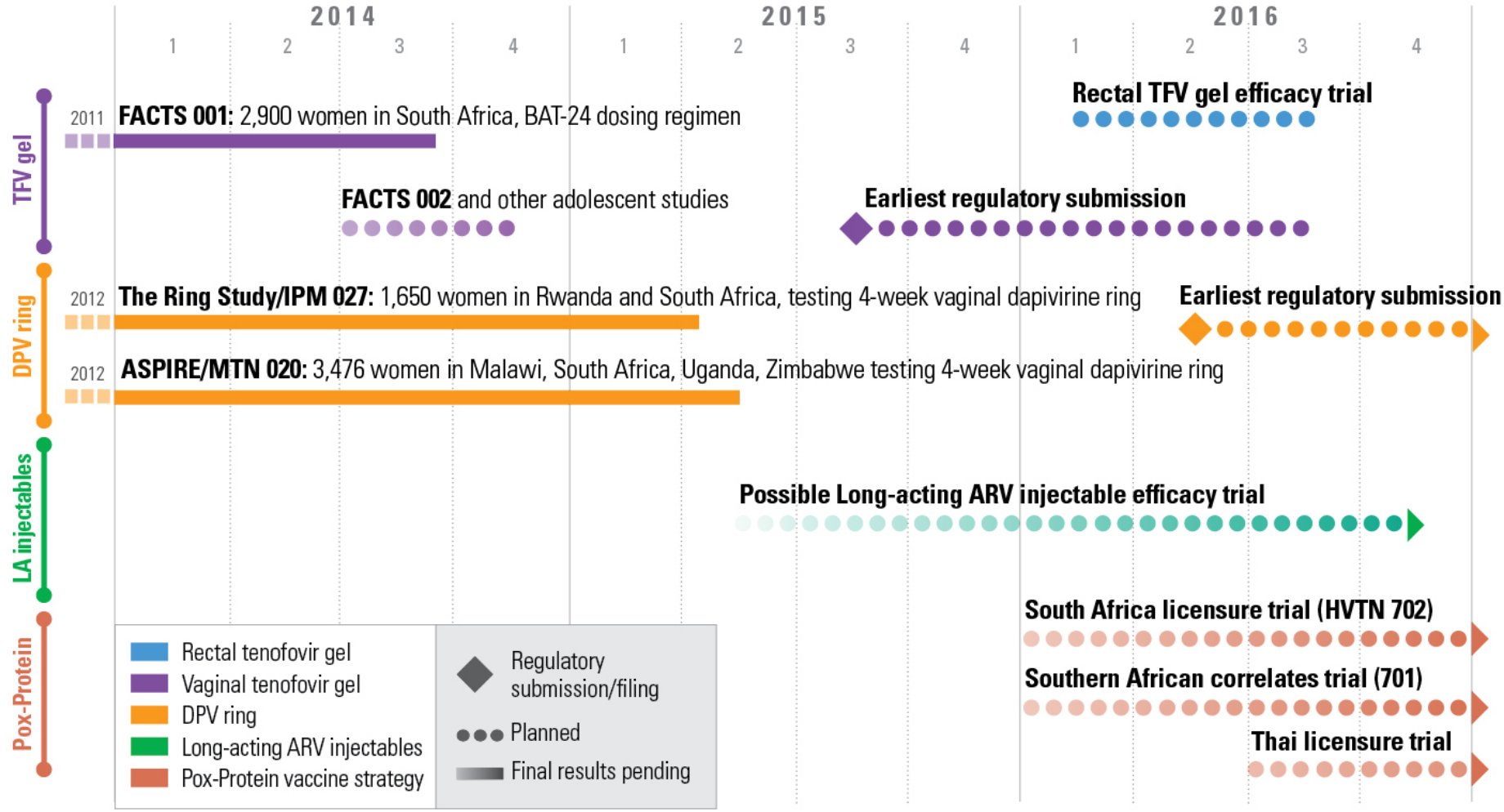
Biomedical HIV Prevention Efficacy Trials, 2014–2016*+



* Trial end dates are estimates; due to the nature of clinical trials, the actual dates may change. For full trial details, see *www.avac.org/pxrd*.

+ This table only includes efficacy evaluations of biomedical strategies in HIV-negative people. There are ongoing pilot and demonstration projects of oral PrEP, an open-label evaluation of 1% tenovfovir gel in the community where CAPRISA 008 took place, and numerous Phase I and II trials of other options.

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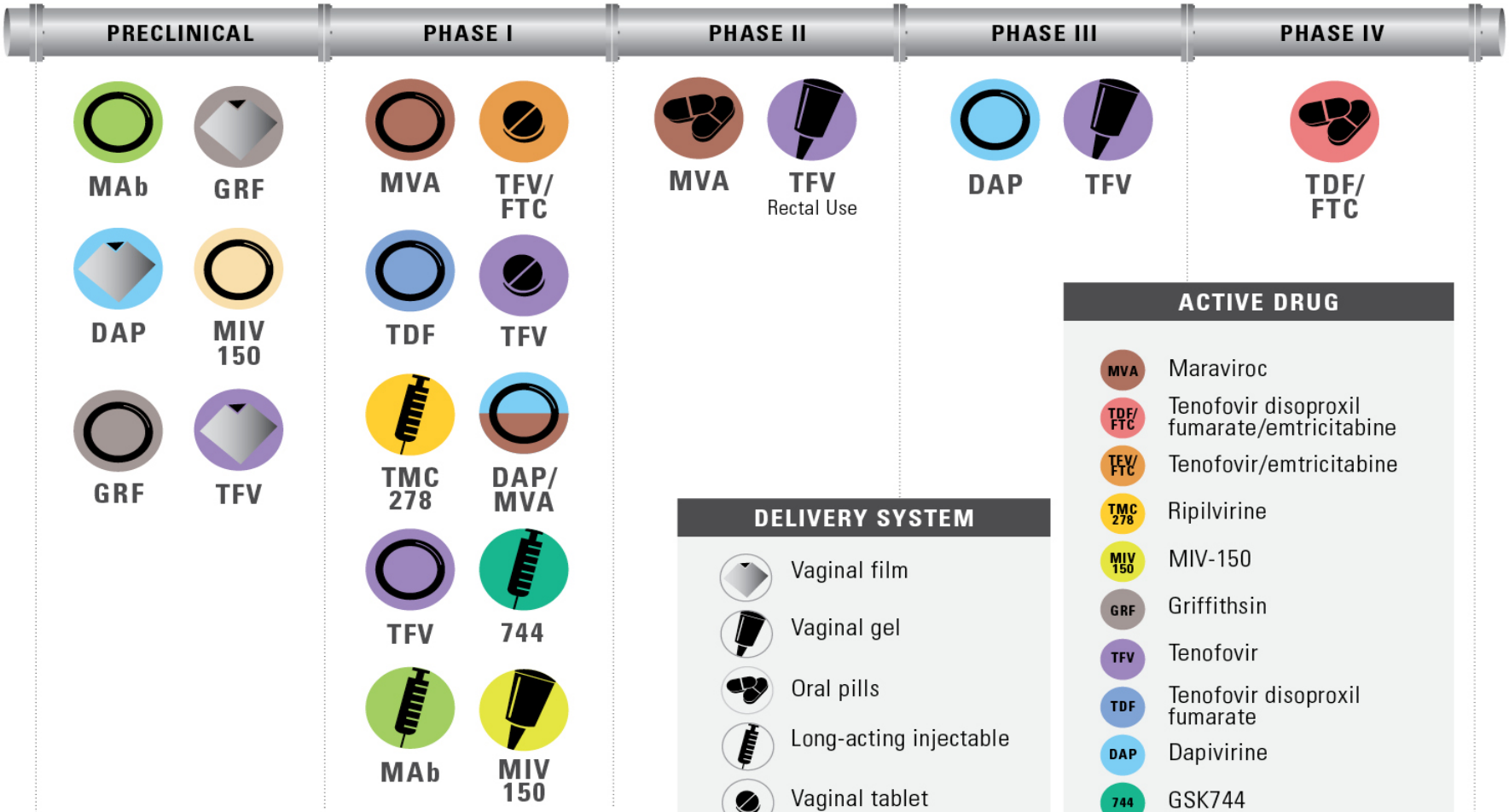
A field on the verge of change

What it will take to find new prevention options for women:

- Don't abandon vaginal gels and other user-dependent methods for women – and prepare for additional efficacy trials
- Invest in studies of why women participate in research
- Differentiate between trial participants and end users
- Measure methods to improve adherence
- Plan for success, applying lessons from oral PreP
- Prioritize informed civil society involvement

ARV-Based Prevention Pipeline (December 2013)



The pipeline of ARV-based prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable ARVs. Not pictured are a range of multipurpose technologies in development that aim to reduce women's risk of HIV and STIs, and provide effective contraception.

For up-to-date information on the ARV-based prevention pipeline, visit the HIV Prevention Research Database at *www.avac.org/pxrd*.

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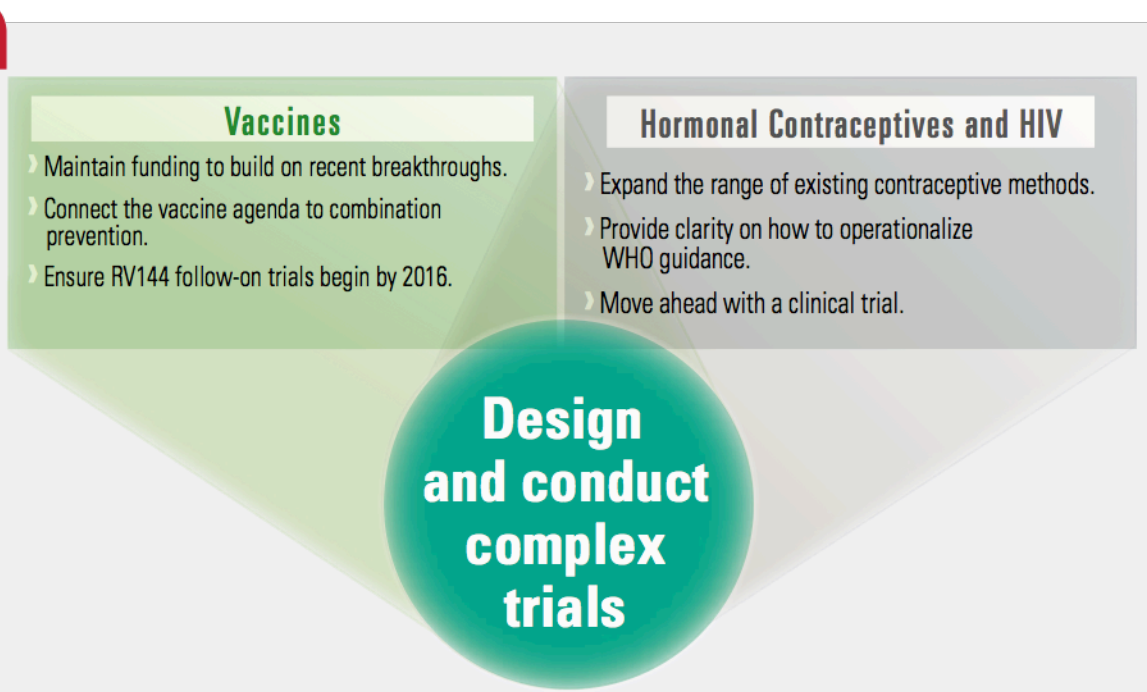
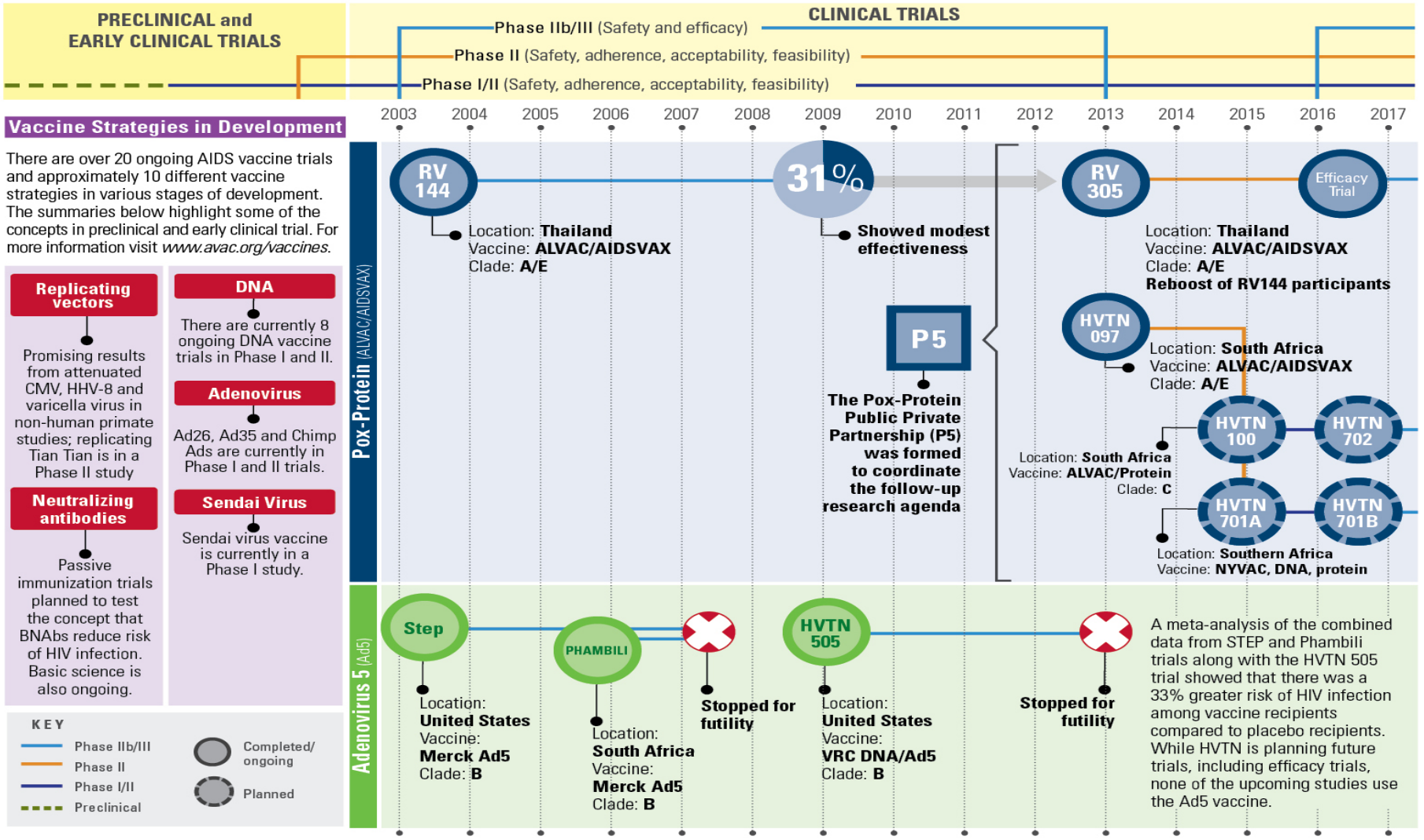
Research Reality Check 1



The AIDS vaccine field and the arena of hormonal contraception and HIV risk are both grappling with questions about how to proceed when there is uncertainty about whether a product may have caused harm. Even with—or because of— these questions, it is important to move forward with carefully designed research. This requires funding, clear messaging and smart trial designs.

AIDS Vaccine Research: An overview (December 2013)

This graphic shows the big picture of AIDS vaccine concepts and clinical trials in process and on the horizon. It is an intentionally simplified representation of a complex field. Some approaches are not listed, or described in full detail—and related arenas like therapeutic vaccines and cure research are omitted.



For up-to-date information on the vaccine pipeline, visit the HIV Prevention Research Database at *www.avac.org/pxrd*.

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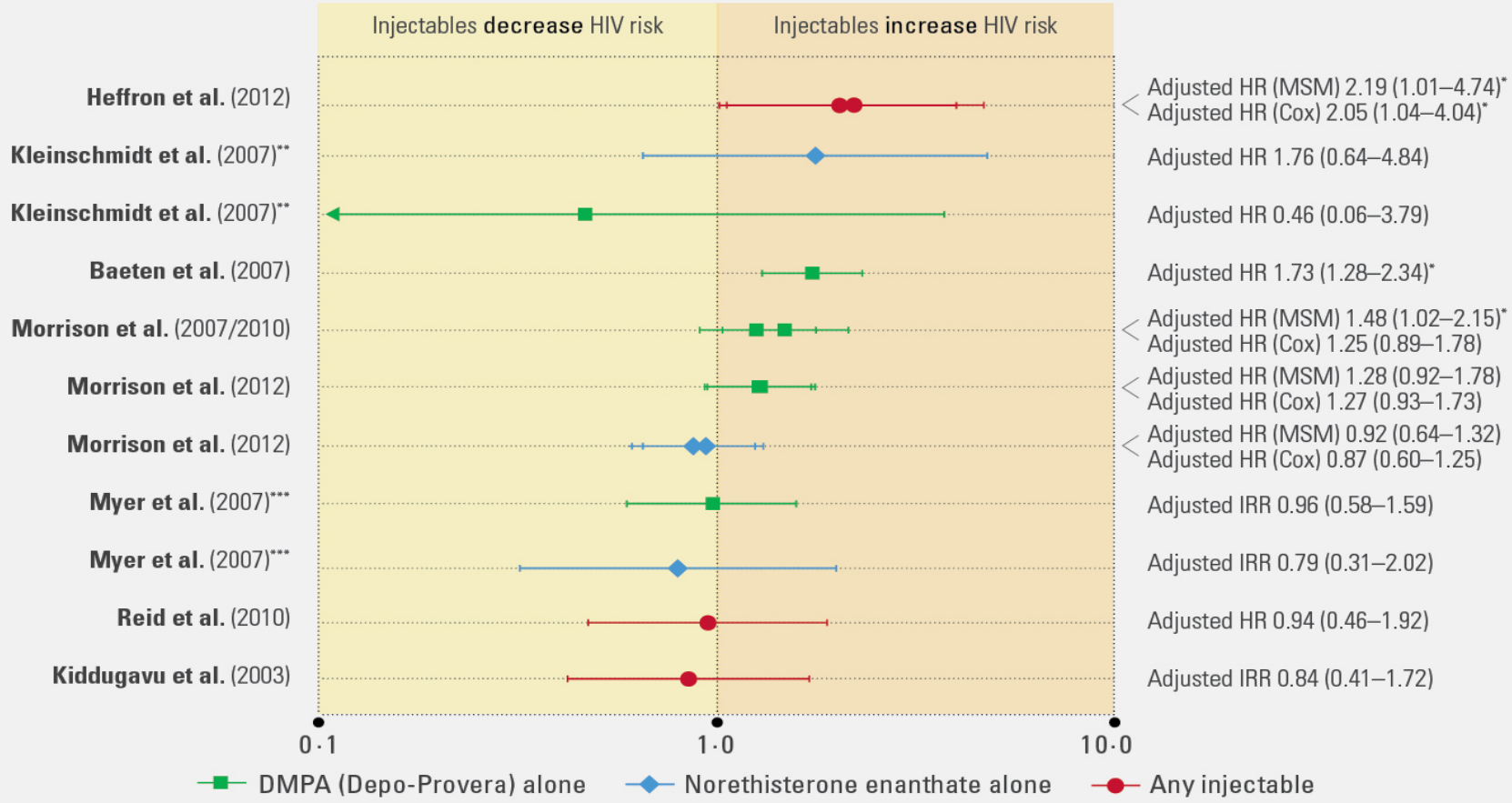
Use of Injectable Contraceptives and HIV acquisition: The data to date

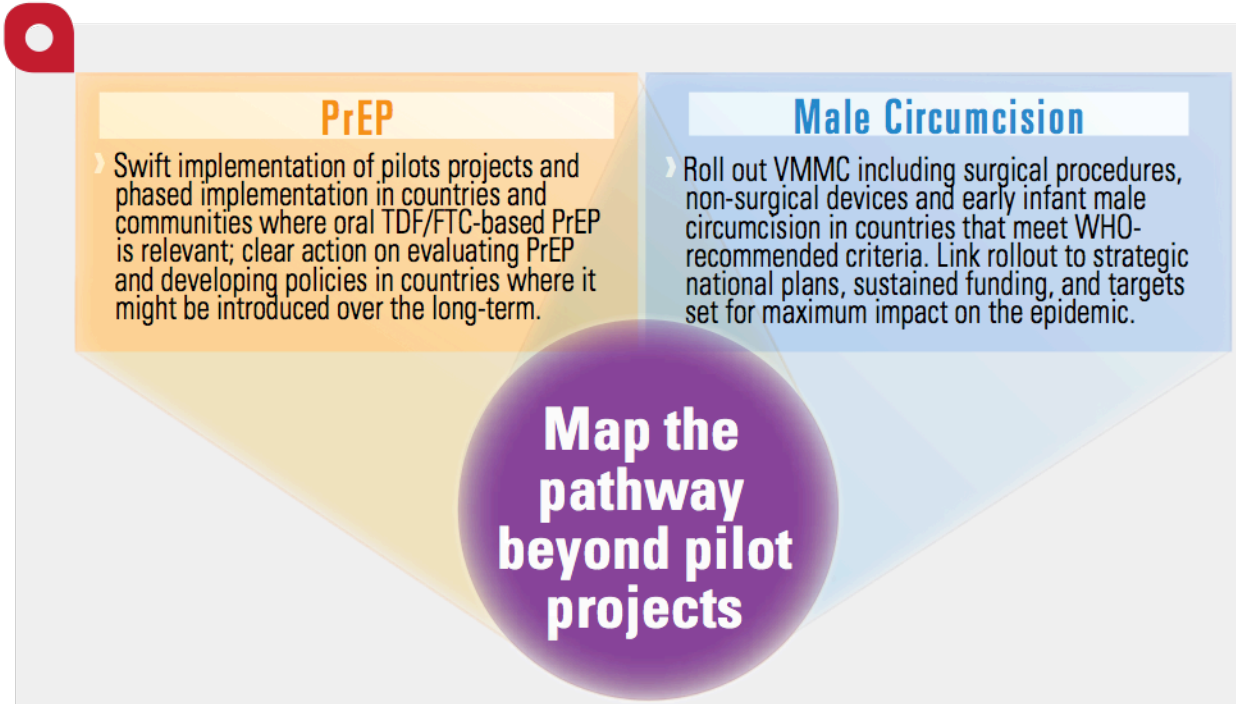
This graphic summarizes the results of studies that gathered information on the relationship between injectable hormonal contraceptives and HIV risk. Different studies have drawn different conclusions. This is the reason for current uncertainty. None of these studies was designed to specifically evaluate this interaction. Discussions about a trial that would directly address the question are underway.



Source: CB Polis and KM Curtis. "Use of hormonal contraceptives and HIV acquisition in women: a systematic review of the epidemiological evidence." The Lancet (2013) *http://dx.doi.org/10.1016/S1473-3099(13)70155-5*

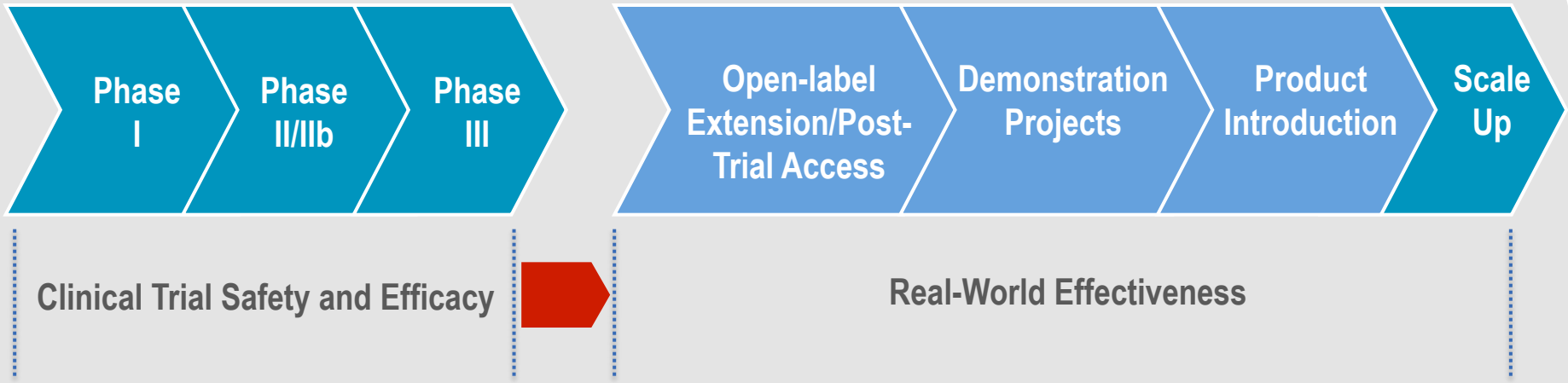
- Should there be a randomized controlled trial (known as ECHO) or not – that is a key question for hormonal contraceptives and HIV

Research Reality Check 2



Pilot projects work if they are part of a strategic plan—if some thought has been given to what will happen once results emerge. This has been done, to a large extent, with projects involving non-surgical devices for VMMC; there is less clarity and planning for demonstration projects of daily oral PrEP.

Research to Rollout: A schematic road map

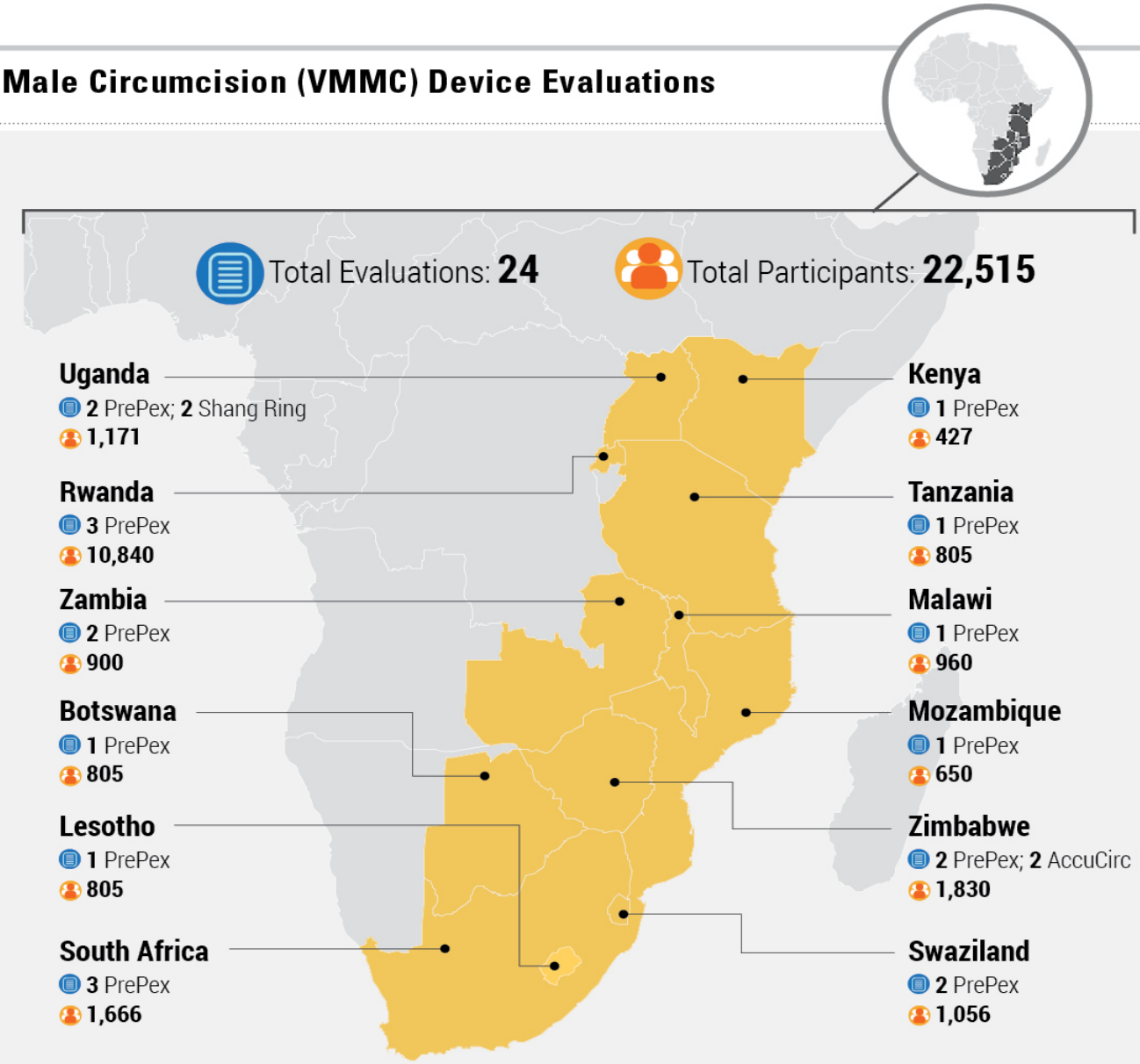


Highlighted in darker blue are the areas where biomedical HIV prevention research has the most experience to date. The "gap" between positive effectiveness data and access for trial participants and their communities is less familiar territory – as are the steps in lighter blue.

AVAC Report 2011: The End?. www.avac.org/report2011

Voluntary Medical Male Circumcision (VMMC) Device Evaluations

There is a range of evaluation studies underway to learn more about how non-surgical devices can be used for adult male circumcision. These evaluations, also called implementation pilots, address questions about safety, efficacy, etc. The World Health Organization has already determined that one device, known as PrePex, meets required standards of quality, safety and efficacy for international use. Evaluations of PrePex and other devices will provide information on how to use these strategies in the real world. Most evaluations are enrolling, ongoing or recently completed. Results can be expected within a year.



For up-to-date information on voluntary medical male circumcision visit *malecircumcision.org* and *avac.org/malecircumcision.*

Planned PrEP Demonstration Projects in Resource-Poor Settings as of December 2013

There are a range of planned or ongoing demonstration projects or open-label extension studies happening in the United States and Europe. This table includes those few projects in resource-poor settings that are not linked to one of the efficacy trials. A complete list is available at *www.avac.org/prep*.

Trial/project	Sponsor/funder	Location	Population	Status
Partners Demonstration Project	Led by a team of scientists from Kenya, Uganda and the US; funded by NIMH/NIH, USAID and BMGF	Kenya, Uganda	Serodiscordant couples	All four sites open and enrolling as of August 2013; results expected in 2016.
LVCT and SWOP	Implemented by national partners in collaboration with WHO, UNAIDS, O'Neill Institute of Georgetown University, London School of Hygiene and Tropical Medicine, Imperial College London; funded by Bill & Melinda Gates Foundation	Kenya	Young women, female sex workers and MSM	Formative research in planning phase.
Nigerian National Agency for the Control of AIDS		Nigeria	Serodiscordant couples	Formative discussions underway.
Wits Reproductive Health and HIV Institute		South Africa	Female sex workers	Expected start date of February 2014, with expected completion September 2016.
Durbar (DMSC) and Ashodaya Samithi		India	Female and transgender sex workers	Feasibility study underway.
Implementation of PrEP	Oswaldo Cruz Foundation	Brazil	MSM and transgender women	Starting January 2014.

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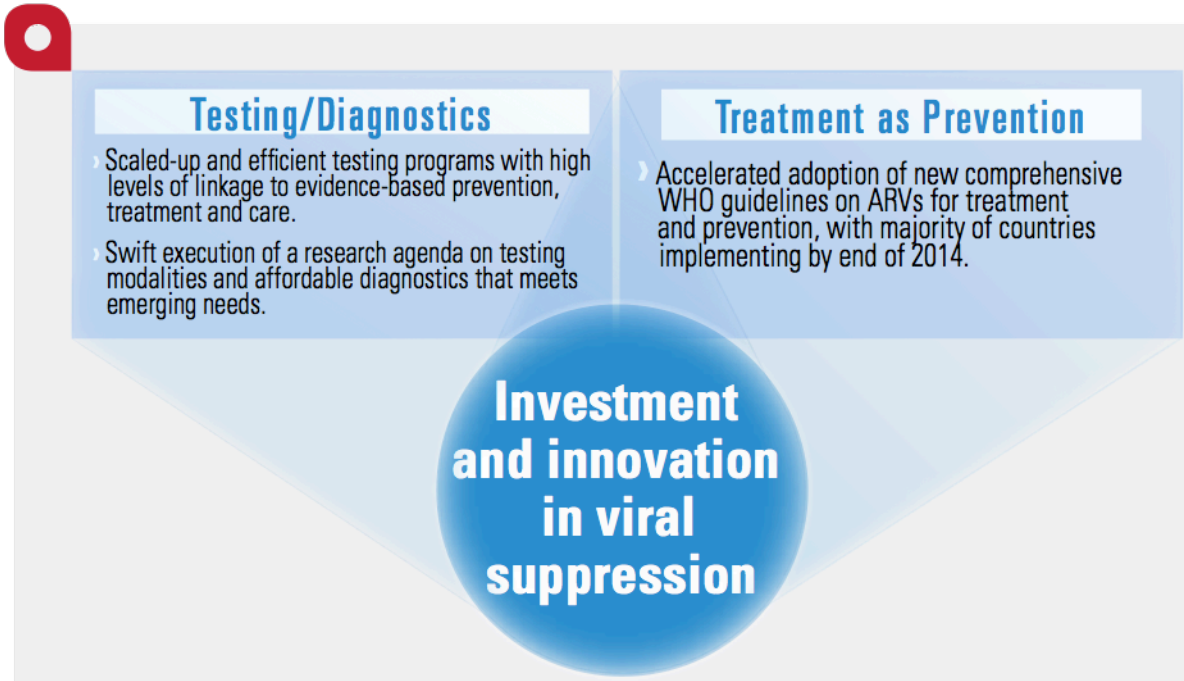
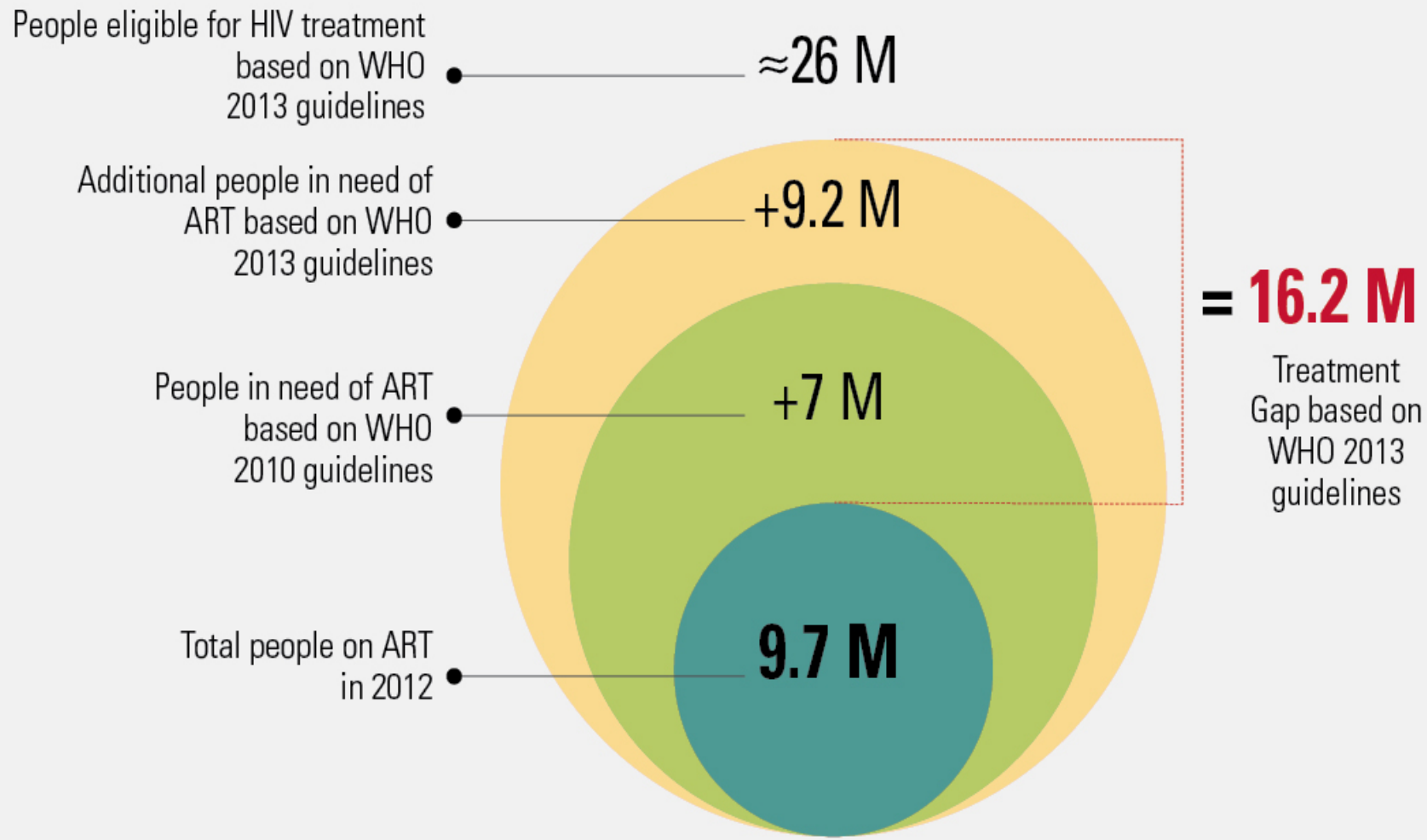
Research Reality Check 3



ART doesn't preserve health and reduce transmission risk—virologic suppression does. It's an essential distinction that prevention advocates need to help amplify. We need to pay at least as much attention to what is happening after people start ART, as we do to how many people start at all. Virologic suppression—having a viral load that is at or close to undetectable—is key.

The Global HIV Treatment Gap : Existing people on ART versus people eligible under past and current WHO guidelines



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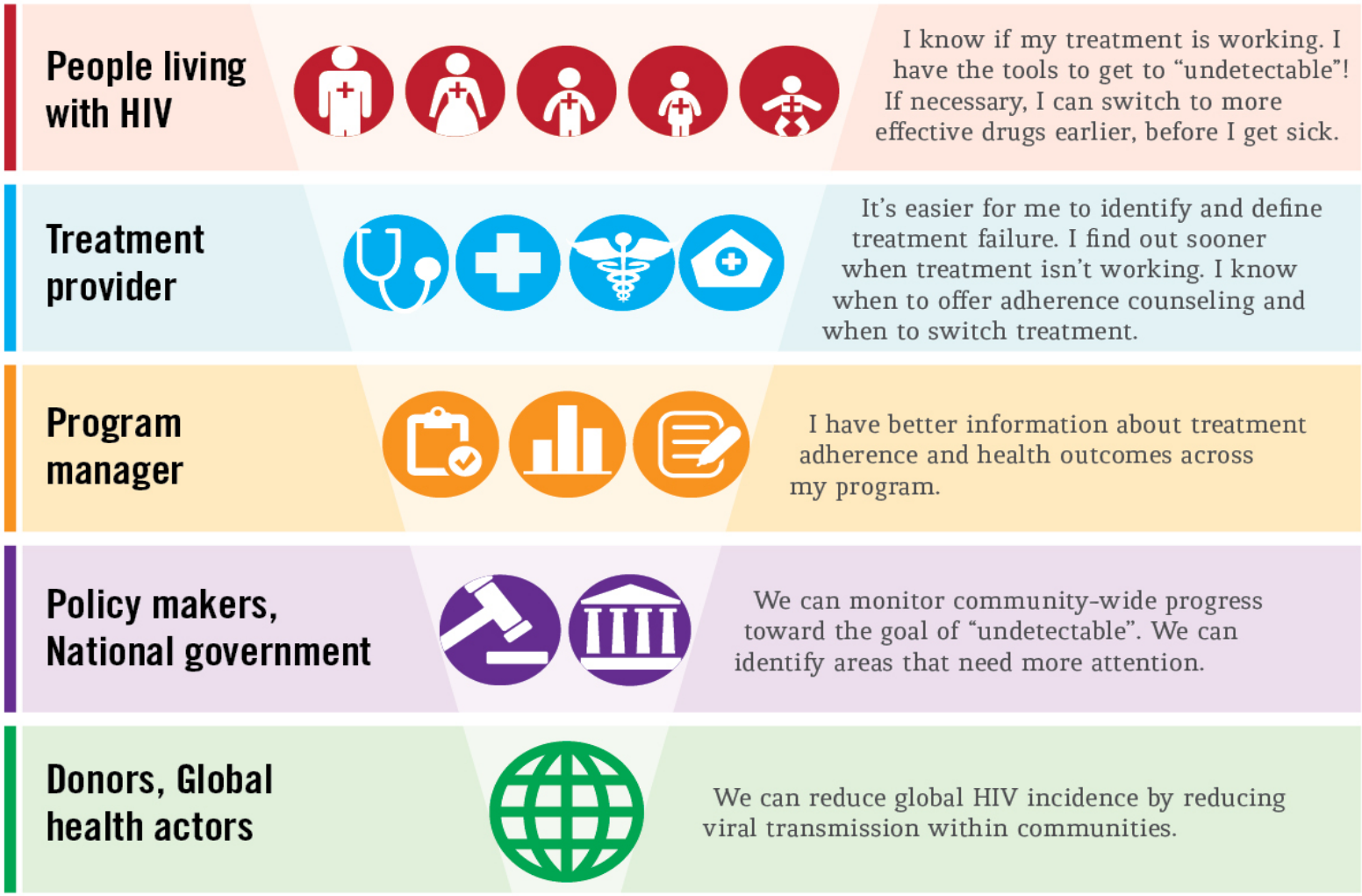
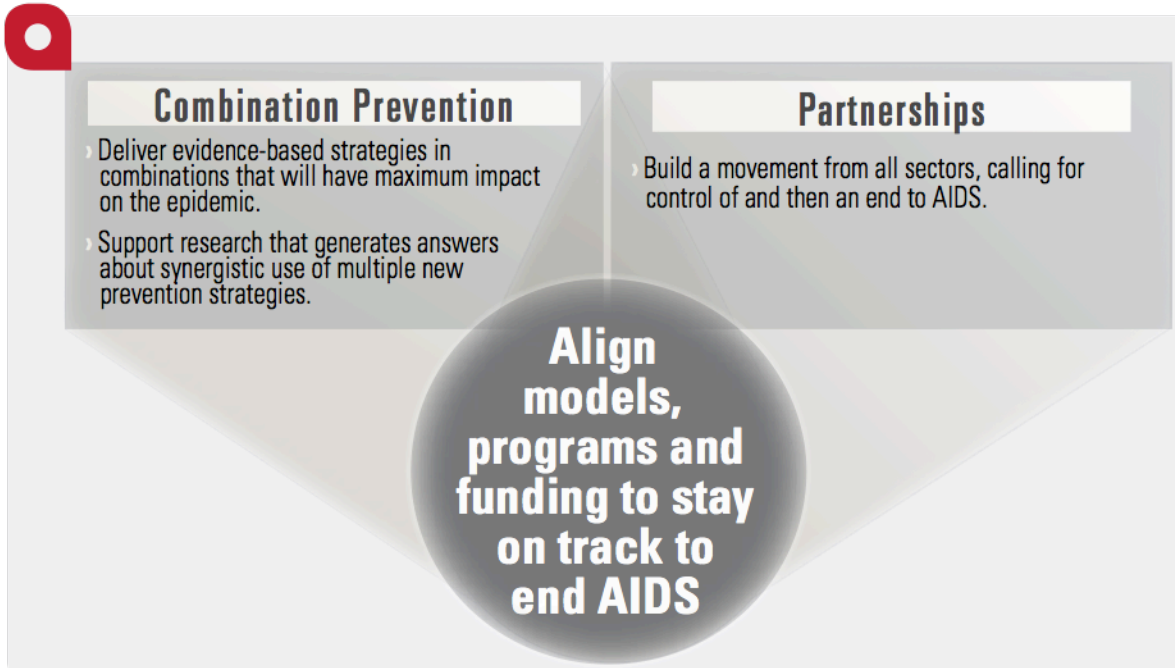
Viral Load Testing Delivers Systemic Benefits from the Individual to the Institution



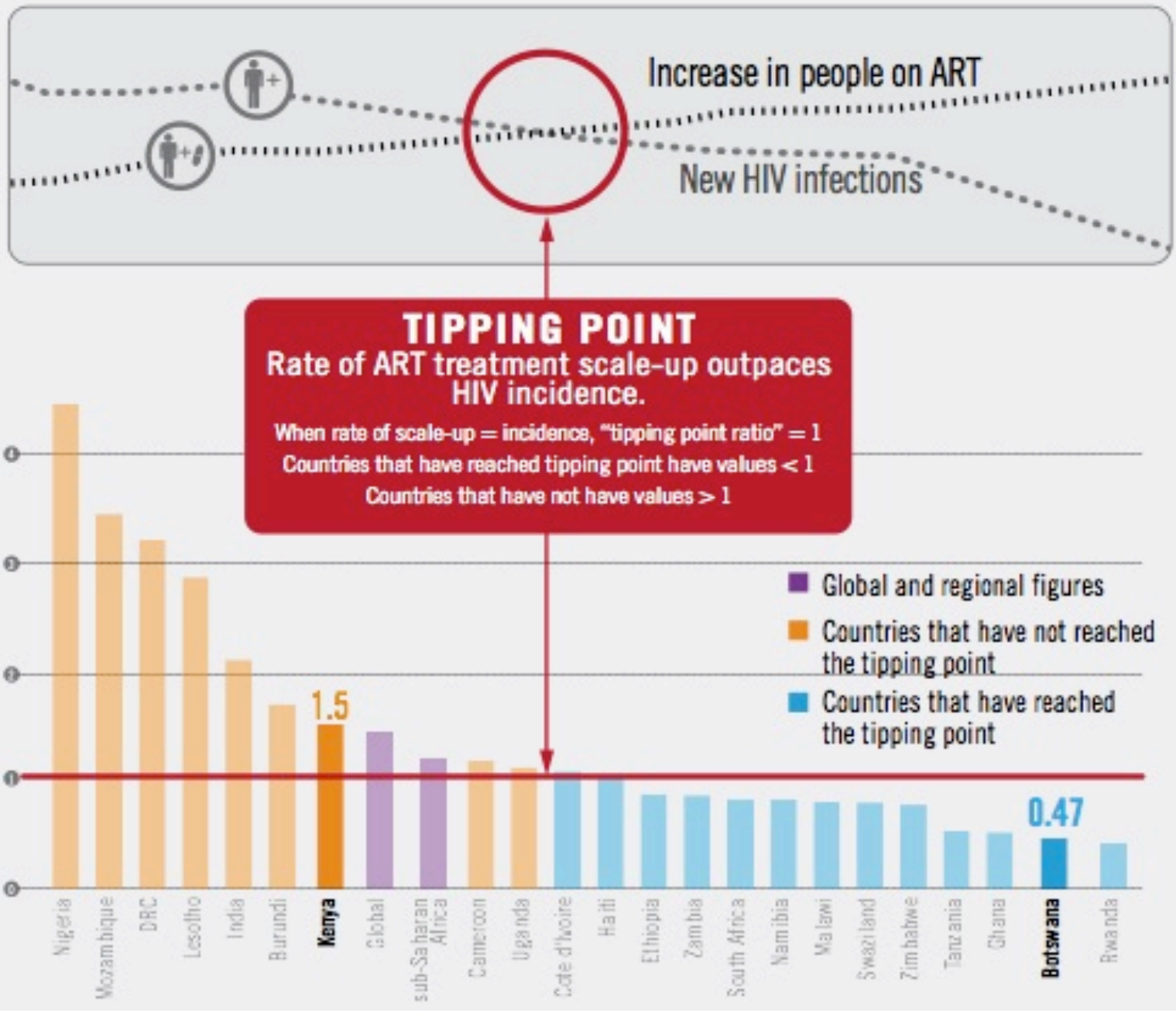
Médecins Sans Frontières/Doctors without Borders (2012). Undetectable: How Viral Load Monitoring Can Improve HIV Treatment in Developing Countries. *http://www.msfaccess.org/content/undetectable-how-viral-load-monitoring-can-improve-hiv-treatment-developing-countries* (Accessed November 7, 2013).

Research Reality Check 4



To achieve ambitious targets for high-impact prevention and treatment, models and programs need to be connected in a feedback loop. This must be supported by full funding and visionary leadership at national and international levels.

The Tipping Point: Understanding a crucial milestone in the AIDS response



The most recent bottom line(s)

- Deliver what we have for immediate impact
- Demonstrate added benefit of new options as they become available
- Develop long-term solutions to end the epidemic
- Most of all, think – and act – in terms of combination prevention, rather than silver bullets or simple solutions

What's on your mind?

- What are the issues uppermost on your mind?
- What needs action at a global level?
- What is on the "front burner" in different country contexts?

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- For more information www.avac.org
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- Sign-up for periodic updates via our Advocates' Network at www.avac.org/advocatesnetwork