AVAC

Global Advocacy for HIV Prevention

What Defines "Good" in GPP?

Mitchell Warren
Executive Director, AVAC
MTN Regional Meeting
29 October 2013

Why GPP? Why Now?

- Because HIV prevention trials are getting increasingly complex –
  - By design
  - Because of recent results
  - Because of the geographies and contexts in which trials – and participants' lives – take place
  - Because people are watching
  - And because people remember

PrEP 2004


GILEAD
CLOSED
TO
DEATH


GILEAD
Viread
Emtriva
(emtricitabine)
SEX WORKERS:
INFECTED
BY GILEAD
TENOFOVIR
MAKES
ME SICK
GILEAD
PREFERS US
HIV+

Ring the bells that still can ring;
Forget your perfect offering.
There is a crack in everything;
That's how the light gets in.

Leonard Cohen

PrEP 2012

U.S. Food and Drug Administration

Protecting and Promoting *Your* Health

For Immediate Release: July 16, 2012

FDA approves first drug for reducing the risk of sexually acquired HIV infection

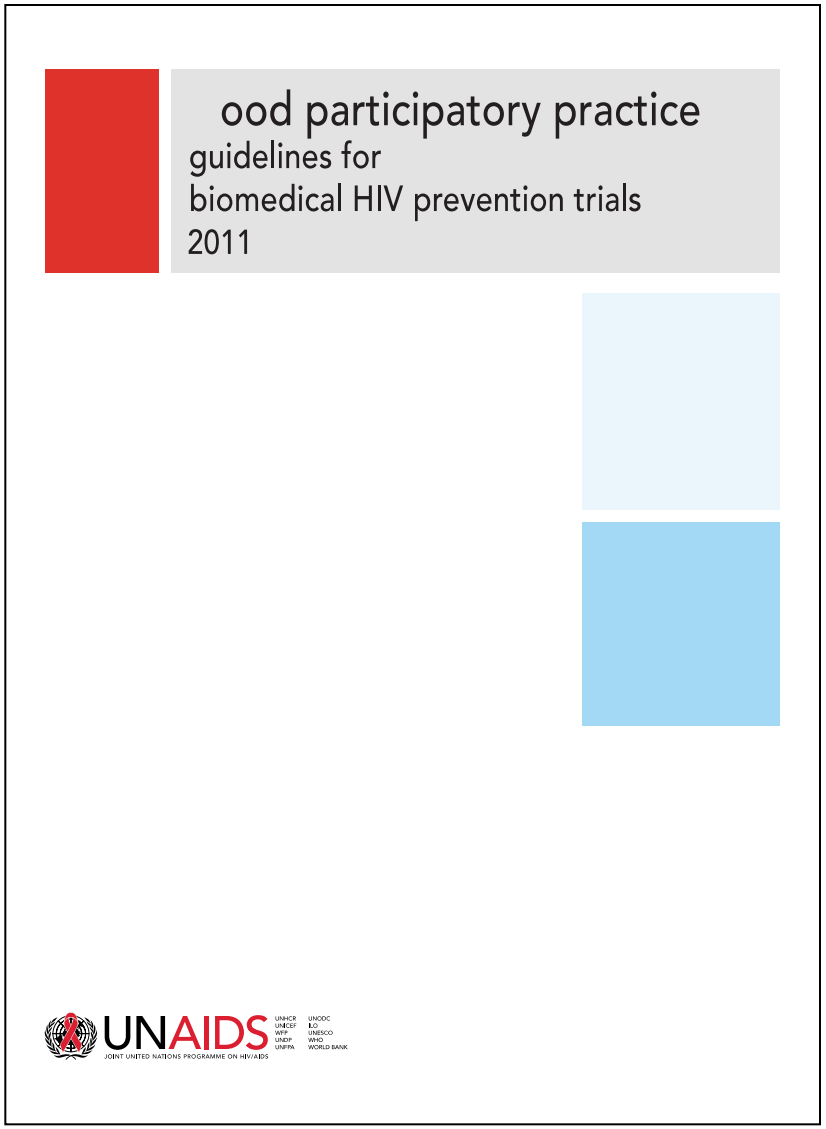
Evidence-based approach enhances existing prevention strategies

Why GPP

- In response to trial controversies
- Help prevent misunderstanding and miscommunication among research stakeholders
- Premise: what happens with one product, in one trial, in one region affects all biomedical HIV prevention stakeholders – trial participants, research teams, funders, sponsors, community stakeholders, and product developers

What is GPP

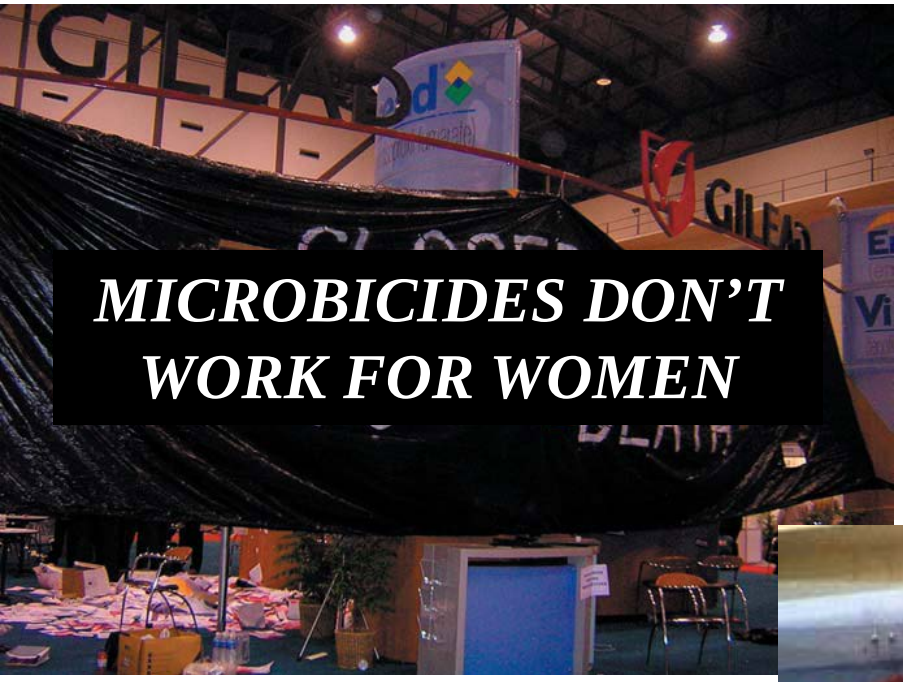
- GPP guidelines were developed to facilitate building of effective partnerships among all research stakeholders – just as other aspects of trial conduct are informed by guidelines



What is Good?

- Research that truly reflects the surrounding community
- Research that is supported by stakeholders
- CABs that identify their role as watchdog
- Feedback – negative, positive or neutral – that is addressed by research teams
- Not the best recruitment numbers
- Most often, the absence of an outcome – “an invisible outcome”

Not PrEP 2013



RESEARCH IS WASTING VALUABLE RESOURCES!

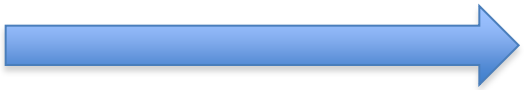
SCIENTISTS TESTING USELESS PRODUCTS ON VULNERABLE WOMEN!

What is Participatory?

GCP ≠ GPP

Research Investigator

GCP

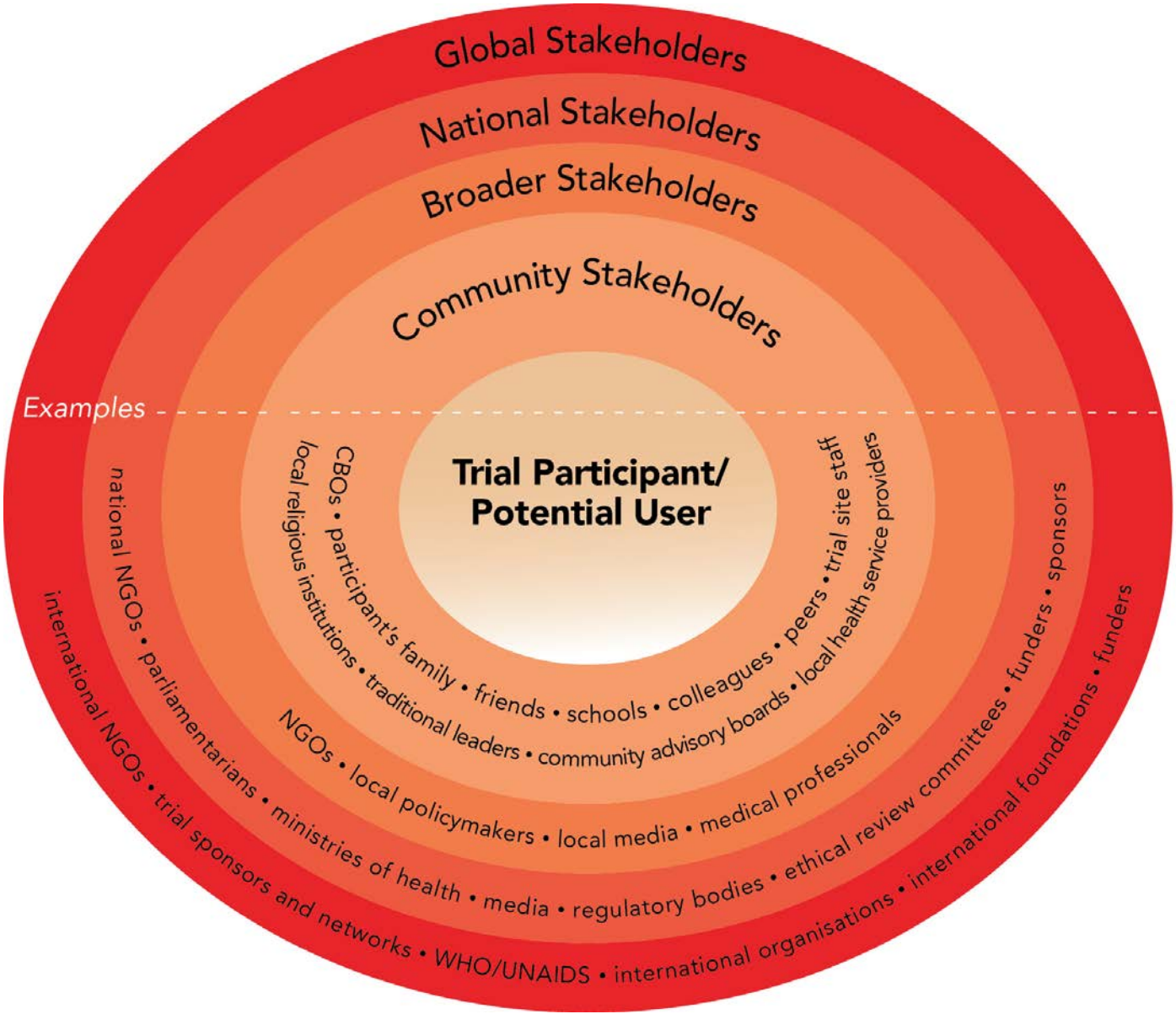


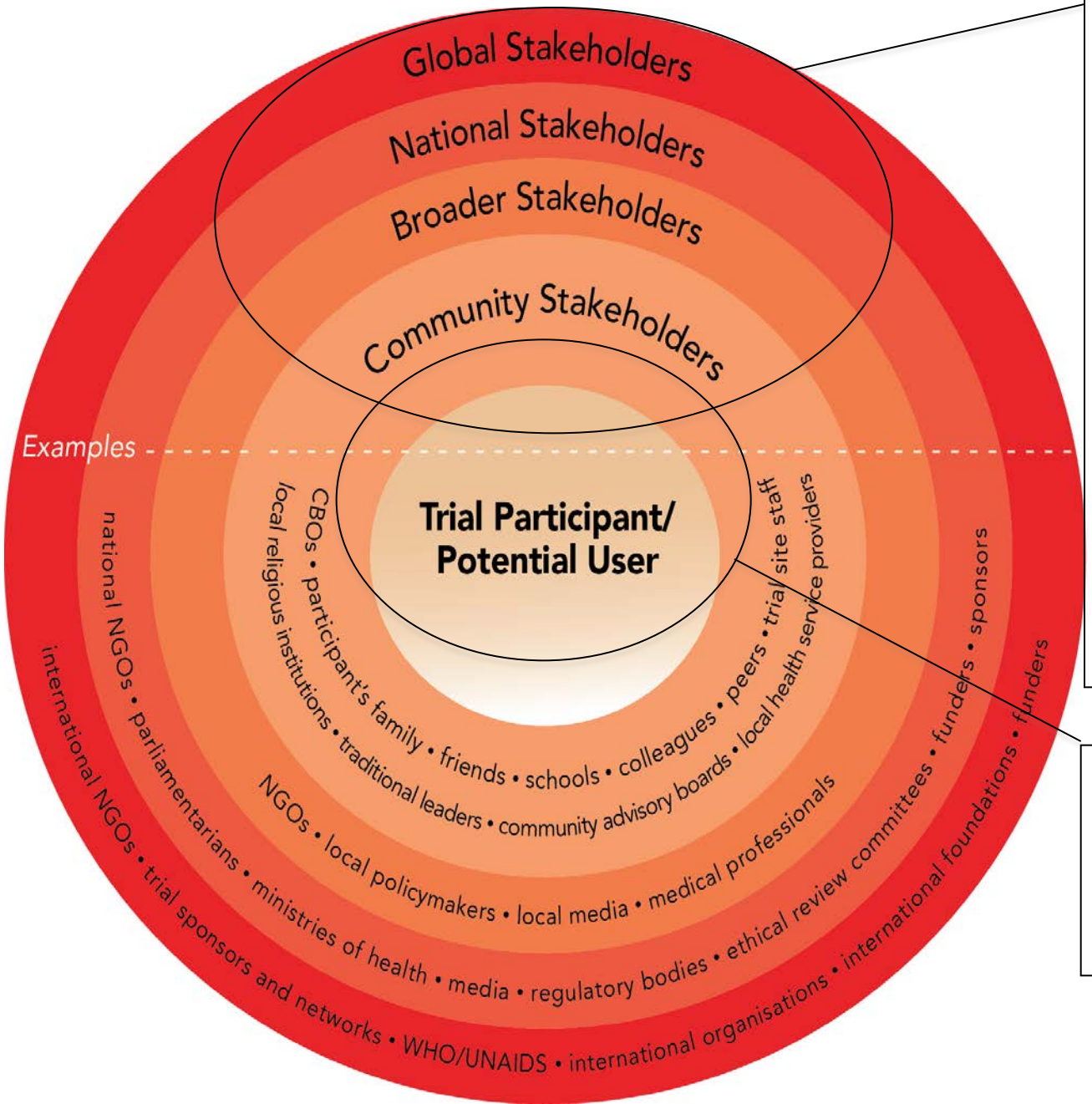
Trial participants

Research teams (and trial sponsors and funders)

GPP

What is Participatory?



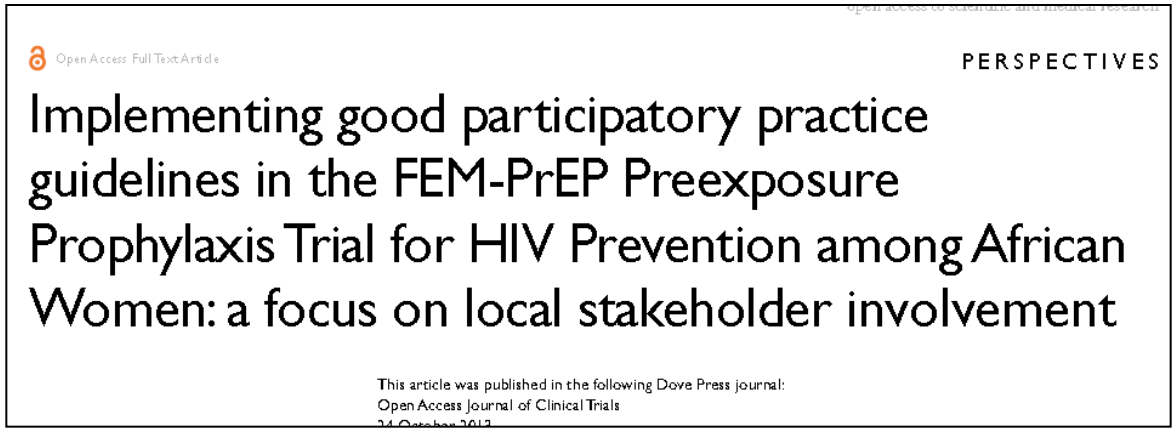


- Build transparent, meaningful, collaborative, & mutually beneficial relationships among stakeholders with ultimate goal of shaping research collectively.

- Answer the research question!

What is Practice?

- Ongoing; not just about one trial
- Before, during, after, and *in between* trials
- Most straightforward and common at trial site level, for trials
- Global tools and Community of Practice – building out guidelines with real world practice
- Case studies
- Better tracking of cause and effect



Open Access Full Text Article

PERSPECTIVES

Implementing good participatory practice guidelines in the FEM-PrEP Preexposure Prophylaxis Trial for HIV Prevention among African Women: a focus on local stakeholder involvement

This article was published in the following Dove Press journal:
Open Access Journal of Clinical Trials

What GPP is NOT

- Not recruitment
- Not retention
- Not a CAB
- Not a tick-box, a magic formula, or a guarantee
- Not participant-trial site interactions – Good Participant Practice?
- Not about a single trial
- Not a “nice to have” or “cherry on top”

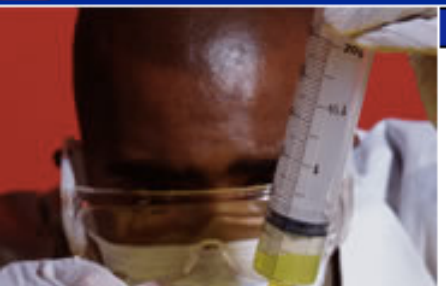
It IS core to the research and development process

Good Participant Practice?

SAAVI
South African AIDS Vaccine Initiative

080 8222 463
080 VACCINE
HIV Vaccine Info-line

RESOURCES
USEFUL LINKS
CONTACT US



HOME | PARTNERS | PRESS RELEASES | FAQs | GETTING INVOLVED

Participant's Bill of Rights

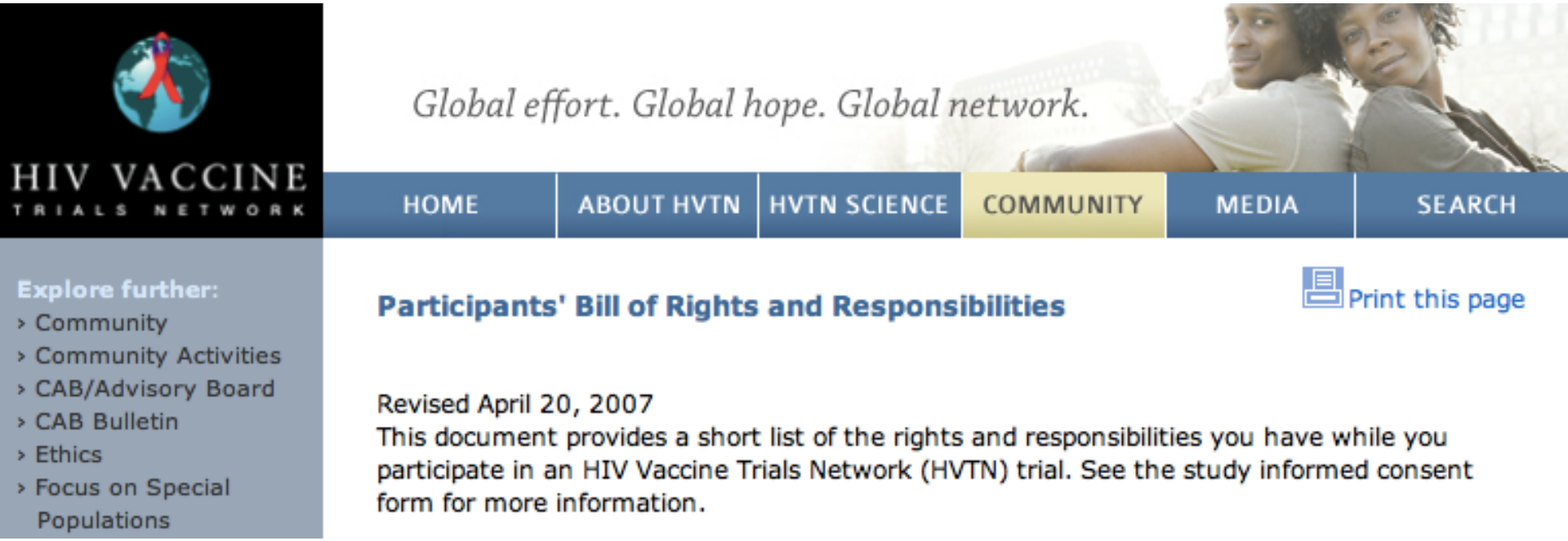
SOUTH AFRICAN PREVENTIVE HIV/AIDS VACCINE TRIAL PARTICIPANT CHARTER OF RIGHTS

Final draft – 11 March 2004

http://www.saavi.org.za/billofrights.htm

f. comply with trial study requirements to the best of one's ability and provide complete and accurate information.
g. inform trial site staff as soon as possible if one is unable to continue or decides to discontinue one's study participation.

Good Participant Practice?



http://www.hvtn.org/community/rights.html

- **Give the study staff complete and accurate study-related information.** Tell the study staff about any changes in your contact information or health information.
- **Follow the instructions of the study staff to the best of your ability.** Work together with the study staff to maintain your health and safety during the trial.

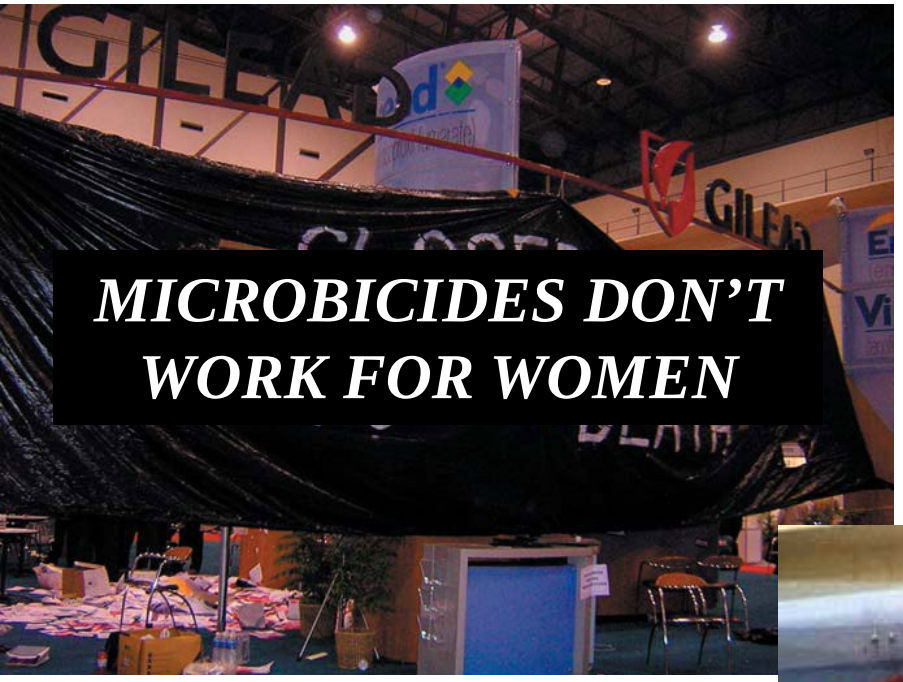
Top 5 Questions for 2013 & Beyond

1. Why didn't our extensive outreach, engagement and good participatory practices "work"?
2. Why didn't the participants use the product?
3. Why didn't they accurately self-report?
4. Why didn't they understand that adherence matters in answering the question?
5. Now what?

1. Why didn’t GPP “work”?

- It actually did – in ways:
  - We answered the research question
  - Communities and (most) stakeholders remained supportive

Not PrEP 2013



RESEARCH IS WASTING VALUABLE RESOURCES!

SCIENTISTS TESTING USELESS PRODUCTS ON VULNERABLE WOMEN!

1. Why didn’t GPP “work”?

- But
  - We need consensus about what we all mean by “what works” and “what is good”
  - Building participatory relationships does not guarantee participant actions

2. Why didn’t participants use product?

3. Why didn’t they accurately self-report?

4. Why didn’t they understand adherence?

5. Now what?

- Improve adherence
  - By improving adherence in trials
  - By “improving” existing products through marketing after trials
  - By innovating – developing other types of products and designing new efficacy and effectiveness trials

5. Now what?

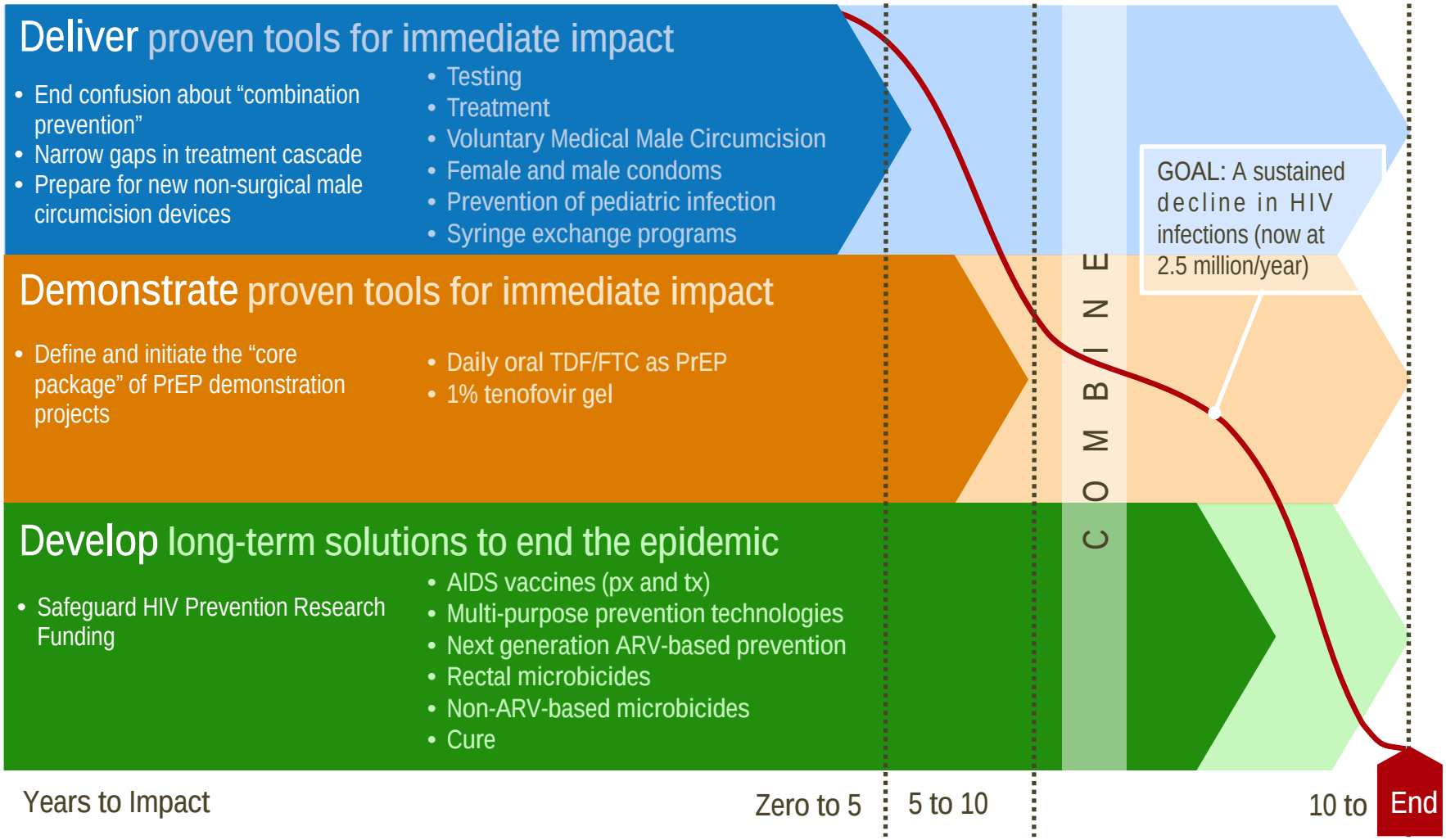
- Better understand behaviours – sexual, product use, trial participation and personal reporting…and the “pre-behaviours” (e.g. risk perception)
- Better understand the social and cultural contexts in which participants live that will influence their behaviours – generally and in trials.

5. Now what?

- Build even better relationships – for the long-term
- Do not confuse Participatory Practice with Participant Practice, but ensure that “we” do them both well

- Prevention research is hard – and unpredictable (Duh!)
- – and it is essential

Three-Part Agenda for Ending AIDS



AVAC Report 2012: Achieving the End – One year and counting. www.avac.org/report2012.