

MTN Regional Meeting 2011

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What's New Since Last Year?

- Pregnancy agenda
 - MTN-008 opened and enrolling at two US sites
 - Development of the MTN-019 protocol to evaluate tenofovir gel in pregnant women in the US and Africa
 - Development of pregnancy and breastfeeding protocols for CHOICE
 - MTN-016 opened at many more sites in Africa

- Rectal microbicide agenda
 - Completion of MTN-007- results to be reported next year
 - Development of the first expanded safety study of tenofovir gel as a rectal microbicide with sites in the US, Africa, Thailand and Peru
 - MTN-017 to launch in 2012

What's New Since Last Year?

- Development of a new collaboration with IPM leading to the ASPIRE protocol

ASPIRE

A Study to Prevent Infection
with a Ring for Extended Use

- Development of the CHOICE protocol, which will provide open label access to products shown to be effective in VOICE

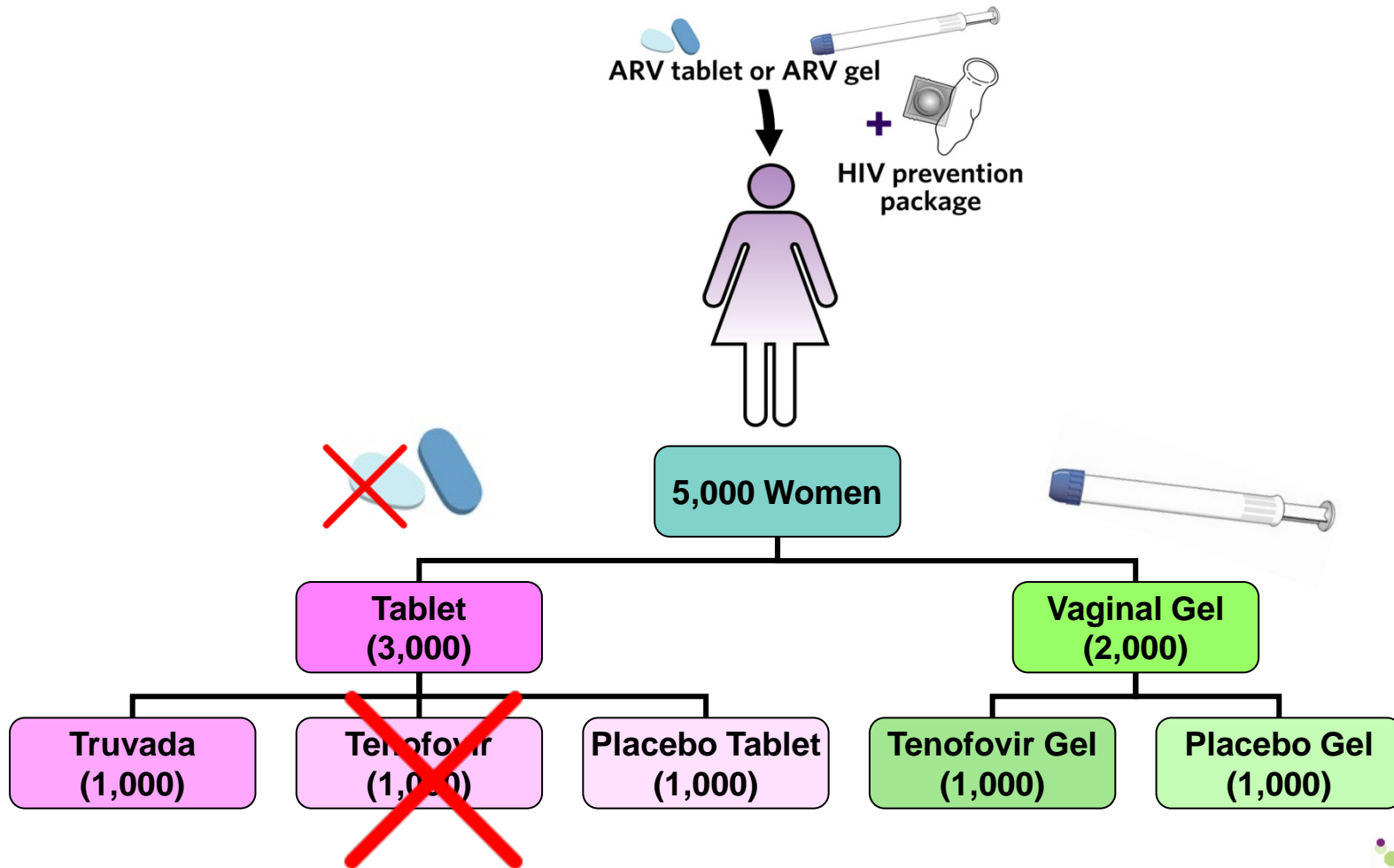
Committed to Having Options for
Interventions to Control the Epidemic

CHOICE

A Landmark Year in Prevention...

- iPrEX: 44% reduction in HIV among MSM randomly assigned to Truvada
- FemPrEP: no difference in HIV incidence comparing placebo to Truvada
- Partners PrEP:
 - 63% reduction in HIV in tenofovir oral group
 - 73% reduction in HIV in Truvada group
- TDF2 Study: 63% reduction in HIV among those randomly assigned to Truvada
- HPTN 052: 96% reduction in HIV acquisition when HIV+ partner treated with ARVs

VOICE: Loss of tenofovir oral



Now four study groups

What Happened?

- We do not know why tenofovir oral tablets were no better than placebo in VOICE
- We *do* know that we have answered a very important question
- But we cannot help but ask ourselves....
why, why, why

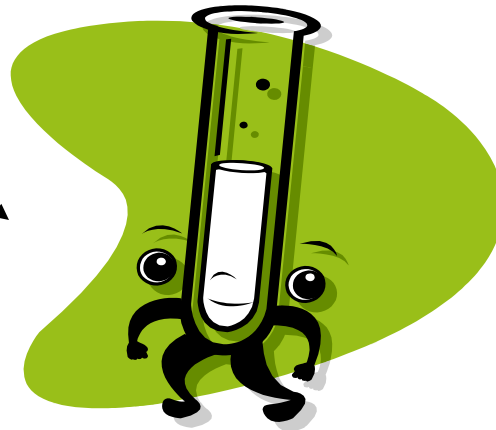
What is the Difference Between A Laboratory Experiment and a Clinical Trial?

- In a laboratory experiment great care is taken to limit the variability from test to test
 - Everything can be controlled because the experiment is done in a test tube or culture system

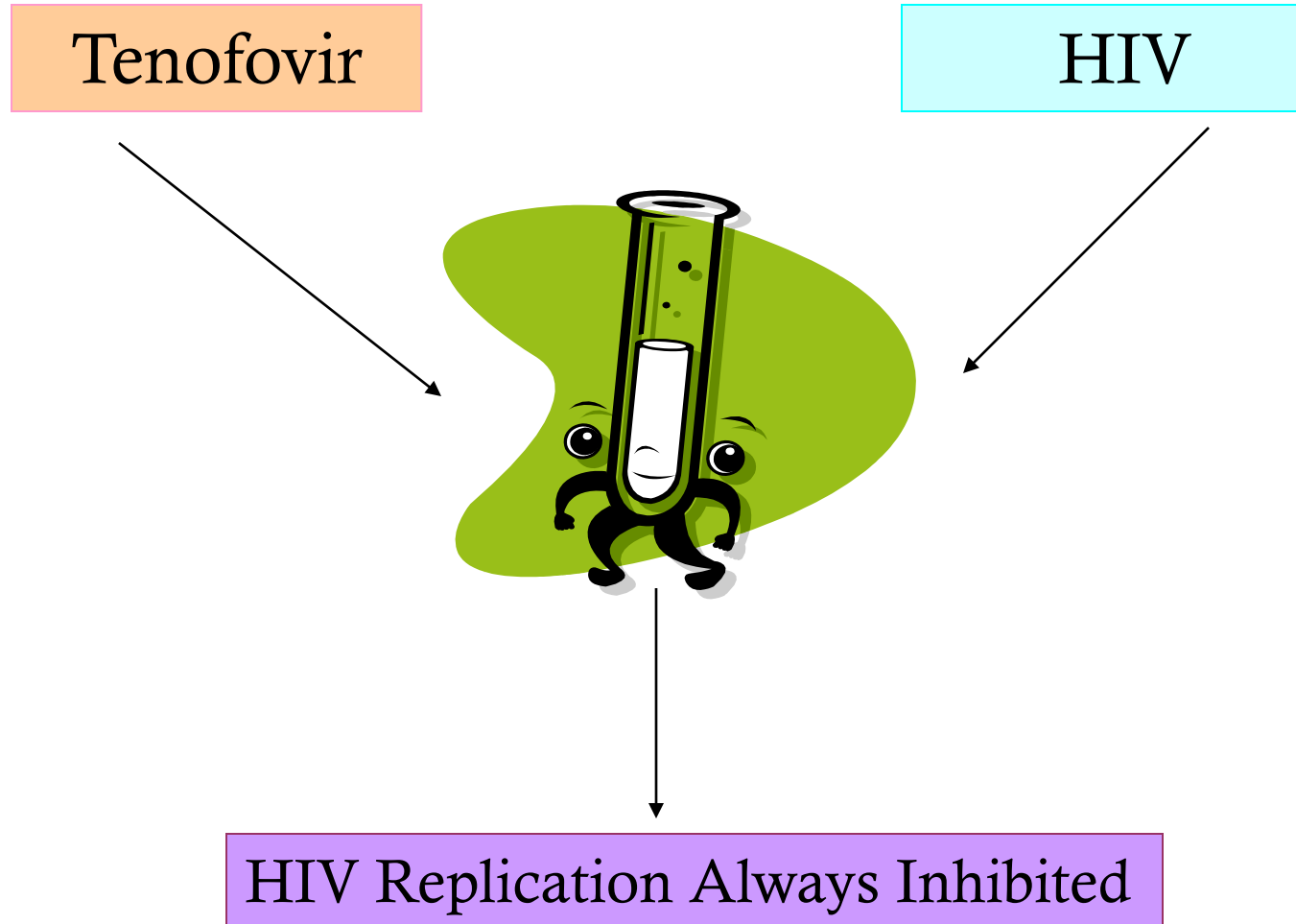
Lab Studies of Tenofovir Predictable

Tenofovir

HIV



Lab Studies of Tenofovir Predictable



What is the Difference Between A Laboratory Experiment and a Clinical Trial?

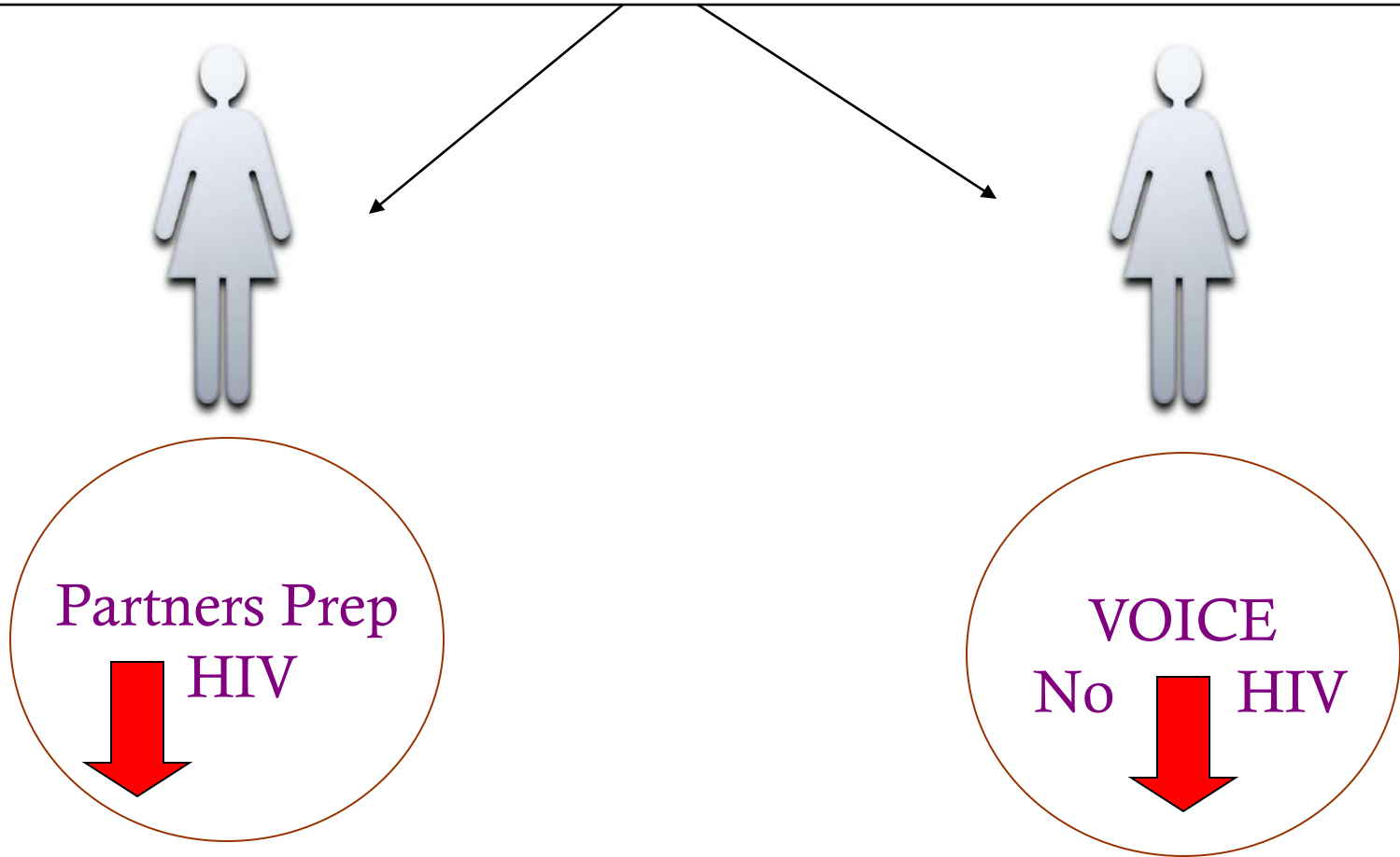
- In a clinical trial there are *many more variables*
 - Behavior (sexual practices, partner selection, adherence)
 - Differences in the populations studied
 - Different routes of exposure
- Clinical trials testing the same drug can give different results, which is one reason that regulatory agencies usually want to see results from more than one study before a product can be licensed for a specific use

TENOFOVIR



If all groups of women were the same, then every study of tenofovir tablet for HIV prevention would likely give a very similar result

TENOFOVIR



TENOFOVIR



- Community viral load
- Rates of STIs
- Frequency of sex
- Adherence to tablets
- Knowledge of partner HIV status

Partners Prep
↓
HIV

VOICE
↓
No HIV

The Road Ahead

□ There has never been a greater need to be who we are in MTN family..

- Fast
- Flexible
- Efficient



The Road Ahead

- Fast: completing VOICE, opening ASPIRE, expanding rectal microbicide studies on 3 continents
- Flexible: responding to changes recommended by the DSMB, working with our sites and communities
- Efficient: doing it with a smile, a commitment to excellence and putting our participants first

Welcome to the MTN Regional Meeting!

- And now a few words

Dr. Carl Dieffenbach, Director, Division of
AIDS, NIAID, NIH