

# Chemoprophylaxis Studies

## Person Years on Study Drug

<i><b>Risk</b></i>	<i><b>FTC/TDF</b></i>	<i><b>TDF</b></i>	<i><b>Total</b></i>
Heterosexual	1,800	476	2,276
IDU		1,200	1,200
MSM	2,100	650	2,750
<i><b>TOTAL</b></i>	<i><b>3,900</b></i>	<i><b>2,326</b></i>	<i><b>6,226</b></i>

**Women 1,496 (24%)**

**Children 0**

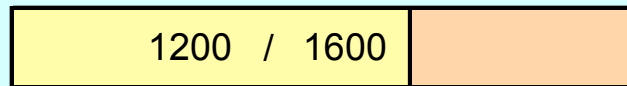
# Timeline of Current PrEP Trials

year	2004				2005				2006				2007				2008				2009			
quarter	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4

**Ghana**  
400 high risk women

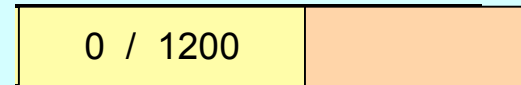
**US**  
400 MSM

**Thailand**  
1600 IDUs



**Botswana**  
1200 heterosexual men + women

**Andean**  
1400 MSM



*From Al Liu*



Enrollment period



Follow up period



Results presented

# Iniciativa PrEx **Power for Efficacy**

<b>Yearly Incidence of Infection (Placebo Group)</b>	<b>Risk Reduction in FTC/TDF Group</b>	<b>Study Power</b>
<b>5%</b>	<b>50%</b>	<b>0.79</b>
	<b>60%</b>	<b>0.93</b>
	<b>75%</b>	<b>1.00</b>
<b>4%</b>	<b>50%</b>	<b>0.68</b>
	<b>60%</b>	<b>0.86</b>
	<b>75%</b>	<b>0.98</b>
<b>3%</b>	<b>50%</b>	<b>0.59</b>
	<b>60%</b>	<b>0.78</b>
	<b>75%</b>	<b>0.95</b>

**Questions  
Not Being  
Addressed  
in  
The Current  
Generation  
of Research**

- Moderate Efficacy (<60%)
- Safety
  - Limited Data in HBV Infection
  - With Acyclovir
  - In Pregnancy
  - In Adolescents
  - Long Term Safety
- Dosing Route
  - Topical vs Oral vs Depo
- Optimal Dosing
  - Event Driven?
  - Weekend Dosing (Friday, Monday)
- Optimal Drug?
  - TDF vs FTC/TDF
  - 3TC, FTC, and Entry Inhibitors

# Challenges Over-Burdening Research



# Choke-Points

- No Correlates of Prophylactic Activity
  - No Validated Animal Model
  - No 3TC Data In Non-Human Primates
  - Minimum Protective Concentration Not Known
- No Policy For Compensating Adverse Events
  - Recommended by CIOMS, UNAIDS
  - DHHS Emphasizes Informed Consent
    - Applicable for Insured Populations
  - Ambiguity Extends to Seroconverter Care
- No Standards For Community Practices
  - Differing And Changing Expectations
- Not Enough HIV-Negative Study Sites
  - With Proven Capacity To Recruit On Time
  - And, Retain High Incidence Populations