

# Los Angeles County CHRP PATH: PrEP and TLC+ for HIV Prevention

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CHRP TLC+/PrEP Consortia Meeting  
September 18, 2013  
Oakland, CA



# Update on 4 TLC+ Projects and PrEP

## TLC+:

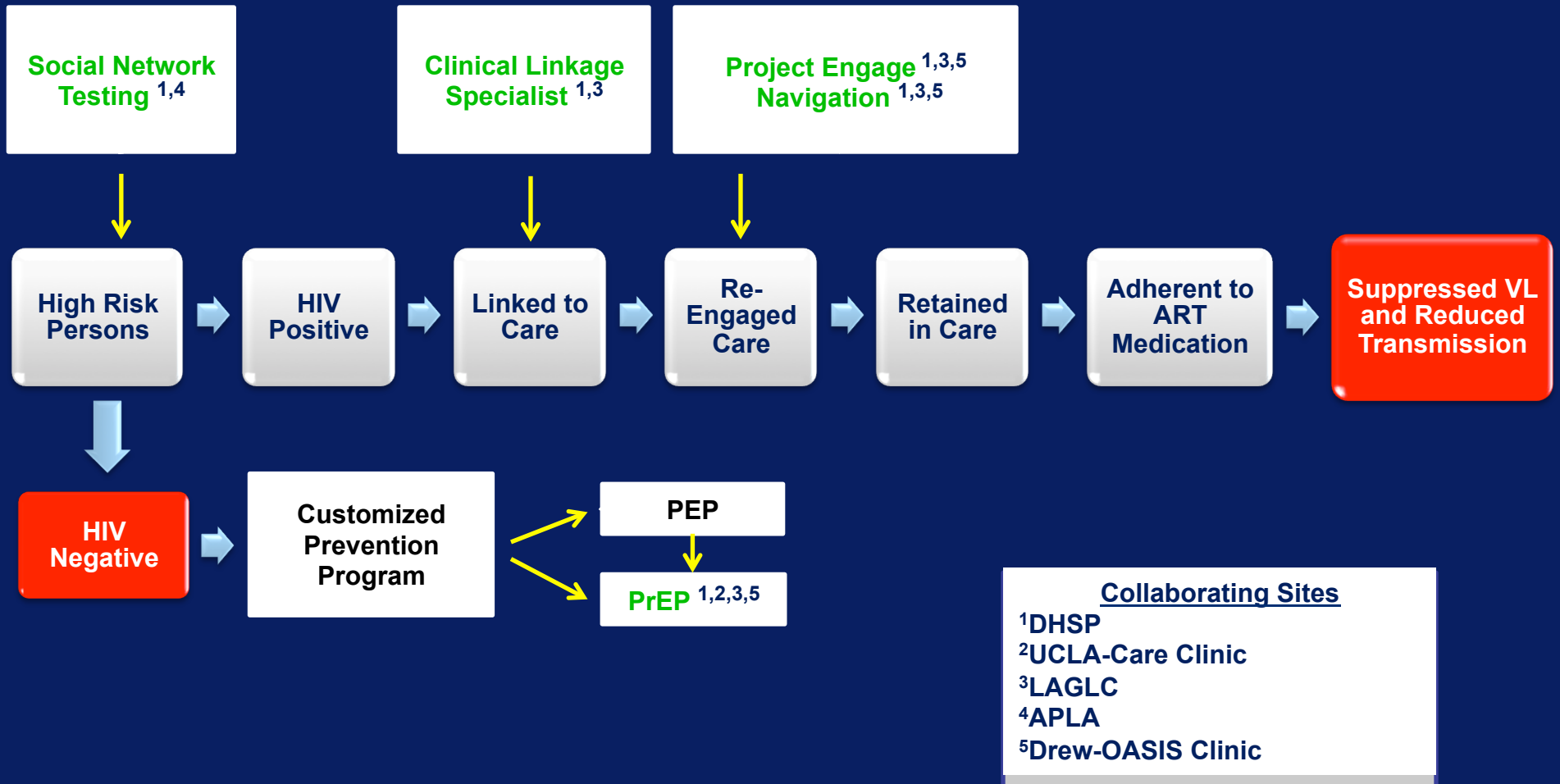
- Social Network Testing Program
- Clinical Linkage Specialist Program
- Project Engage
- Navigation Program

## PrEP:

- PrEP Demonstration Project



# LAC CHRP PATH Framework



# Social Network Testing Program



# Social Network Testing

## ■ Background:

- Goal is to identify high-risk HIV+ persons who may not be tested through conventional HIV testing programs
- RDS Sampling; \$25 for baseline survey; \$15 for HIV test
- Recruit seeds from
  1. HE/RR programs for at-risk MSM
  2. Biomedical prevention programs
  3. Commercial sex venues (CSVs)to recruit high-risk social network members (alters) for testing and reimbursement

## ■ Current status:

- Began enrollment June 2013



# Preliminary Results



# Study Screening and Recruitment

- **Screened (n=107)**
  - Seeds: 13
  - Alters: 94
- **Enrolled (n=85)**
  - Seeds: 10
  - Alters: 75
    - 4 positives (5.3% seropositivity); % new positives in process
- **Site Specific Enrollment:**
  - HE/RR Programs (APLA H&W Center): 85
  - Biomedical Prevention: 0
  - CSVs: 0



# Demographics

## ■ Alters (n=75)

- Race: 71% African American, 10% Latino, 11% White, 4% Other
- 99% MSM
- HIV Status: 5.3% HIV-positive, 95% HIV-negative
- Insurance Status: 73% insured, 27% uninsured
- Testing History: 4% never been tested for HIV
- In last 12 mos, avg # of sex partners(n=75)9.3; 77% UAI
- Self-reported STD history:
  - 12% Syphilis
  - 6% Herpes
  - 8% Chlamydia
  - 22% Gonorrhea

## ■ Seeds (n=10)

- Race: 60% African American, 20% Latino, 10% White, 10% Other
- 100% MSM
- HIV Status: 20% HIV-positive
- Insurance Status: 89% Insured, 11% Uninsured





## ■ **Preliminary Lessons Learned:**

- Sampling methodology is well-suited for target population
- To improve efficiencies, useful to verify eligibility using surveillance to screen out known positive persons
- Expand eligibility to include women and transgender persons

## ■ **Next Steps:**

- Include more detailed locator info, extensive HIV testing and risk behavior histories as part of the screening
- Add surveillance verification
- Expand recruitment to CSVs and biomedical prevention programs



# Clinical Linkage Specialist Program



# Clinical Linkage Specialist Program

- **Objectives/Methods:**

- Primary goal is to evaluate the linkage to care program at LAGLC Sexual Health Program (90% LTC)
- Secondary goal is to identify factors associated with rapid linkage to care
- Pre/post test evaluation of all newly-diagnosed HIV+ clients testing at LAGLC sites (15/month)

- **Current status:**

- Protocol being finalized; IRB submission by 9/30



- **LTC Intervention Components:**

- Focuses on a client's affective/cognitive response to a new HIV dx
- Frame care as helpful, adaptive response to dx
- Counseling and support at (or soon after) diagnosis that is resiliency-based, client-centered and results in actionable goals
- Immediate follow-up and support as needed during period between diagnosis and linkage to care
- Increasing or decreasing intensity of intervention based on monitored linkage status, until fully transitioned into care

- **Next Steps:**

- Begin enrollment (November, 2013)
- Develop a “Linkage to Care Best Practices” manual



# Project Engage



# Project Engage

## ■ Background:

- Goal is to identify out-of-care HIV+ persons and link them to HIV care
- Snowball sampling and direct recruitment; \$40 baseline survey; \$40 when alter links to care
- Target population is HIV+ persons not in regular care directly recruited or identified by seed/alter recruiters via social network referrals
- Seeds identified from:
  1. HE/RR programs at CBOs for at-risk MSM (eg crystal meth support group)
  2. HIV clinic patient populations
  3. Flyer/pocket card recruitment

## ■ Current status:

- Ongoing Enrollment



Flyer



Pocket Card



# PROJECT ENGAGE

Are you HIV+ and out of care?  
Do you know HIV+ people who  
are out of care?

Receive compensation for  
participating in Project Engage

The LA County Department of Public Health is conducting  
a project to help find HIV-positive people who are out of  
HIV care and help get them into care.

If YOU are HIV-positive and out of care, or YOU KNOW people who are  
HIV-positive and out of care and are interested in taking part in this  
project, please call or text **323-236-5363**

Those who complete a survey and help get people  
into care will be reimbursed for each person they  
help recruit.

LEARN MORE ABOUT THE PROGRAM TODAY!

PROJECT ENGAGE
323.236.5363
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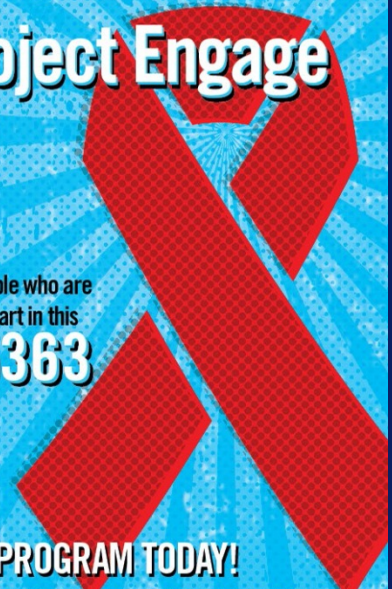
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# Preliminary Results





# Study Screening and Recruitment

- **Screened**
  - Seeds: 79
  - Alters: 71\*
- **Enrolled**
  - Seeds: 48
  - Out of Care Alters: 17
    - 6 (35%) have enrolled as recruiters
    - 13 (77%) have linked to care
- **Site Specific Enrollment:**
  - APLA: 4 seeds and 12 alters (8 linked to care)
  - OASIS Clinic: 12 seeds and 3 alters (all linked to care)
  - GLC Clinic: 30 seeds and 2 alters (both linked to care)
  - Agency-based flyers: 2 seeds 0 alters

\*Majority(52%) of alters are ineligible/not HIV infected per HIV surveillance



# Demographics

## ■ Out-of-Care Alters (n=17)

- Race: 47% African American, 18% Latino, 12% White, 23% Other
- HIV Status: 100% HIV-positive
- 68% MSM; 35% heterosexual
- Insurance Status: 24% Insured, 76% Uninsured
- Reported Sex Work: 35%
- Incarceration History: 88% lifetime, 76% past 12 months
- Recent/Current Homelessness: 71%
- Illicit Substance Use:
  - IDU: 53% lifetime, 29% past 3 months
  - Non-IDU: 71% lifetime, 47% past 3 months

## ■ Seeds (n=48)

- Race: 40% African American, 25% Latino, 25% White, 10% Other
- HIV Status: 79% HIV-positive
- 88% MSM; 12% heterosexual
- Insurance Status: 90% Insured, 10% Uninsured
- Reported Sex Work: 4%
- Recent/Current Homelessness: 15%
- Incarceration History: 52% lifetime, 2% past 12 mos



# Out-of-Care Alters (n=17)

## ■ Testing and Care History

- Time since infection: Avg=9.7 years(range: 3 mos-25yrs)
- Time between infection and 1<sup>st</sup> HIV doctor visit: Avg=15.9 months (range: 1d-4yrs)
- Number of clinics attended: Avg=1.6 (range: 1-3)
- ART use: Ever taken=58%, Currently taking=12%

## ■ Readiness to Engage in Care Scale\*

- 7 “contemplative” about starting care
- 10 “ready for action” about starting care

## ■ Sexual Behaviors (last 6 mos)

- # of sexual partners (n=15): Avg=8.3 (range: 1-40)
- 47% UAI



# Characteristics of Out-of-Care Alters

## ■ Clinical Characteristics

### ■ Linkage and Care

- Avg time out of care (n=17): 7.1 mos (range: 0-26)
- Avg time to link to care (n=13): 11.8 days (range: 0-97)
- Avg staff time dedicated to link to care (n=17): 347.4 min/5.8 hours (range: 140-780 min)

### ■ Viral Load

- Last reported vl before enrollment (n=16): Avg=57,825 copies/ml (range: 48-370,660)

## ■ Acceptability Survey

- Out-of-care alters who linked to care (n=13) stated:
  - Project Engage helped get them into care
  - They were satisfied with the help they received
  - They would recommend PE to friends who were out of care
- 7/12 (58%) stated that without this project they would not have entered care themselves



# Barriers to Care for Out-of-Care Alters

- **Unmet needs (social & medical services)\***
  - Number of unmet needs: Avg=8.6 (range: 1-14)
  - Most reported not being able to obtain:
    - Regular HIV care (n=16)
    - Medical Case Management (n=14)
    - Dental care (n=14)
  - Reasons for barriers varied:
    - Not knowing where to obtain services
    - Disrespect from staff/facility
    - Paperwork not completed

\* Cunningham et al 2000, Medical Care



# Case Study #1

Case 1 is a 44-yr-old homeless African American MSM who tested HIV positive in 2006. He has been out of care for 26 months. He is a crystal meth user and prostitutes for survival and sleeps in parks and alleys. He reported 5 sex partners in the last 6 mos and was the insertive partner for UAI with all 5 partners. He has been incarcerated several times due to his drug use and prostitution. His physical appearance suggested he was feeling the effects of both his medical and social situation (several lesions on his face and arms, frail body and missing teeth).

After enrolling him into Project Engage, he was linked into care in one day(4 hrs PE staff time). He was very excited and happy that someone took such an interest in his situation. After his first treatment appointment, he went back to the park where he hangs out and told his friends about his positive experience. One week later his physical appearance had improved dramatically and he stated that he is on the medication and feeling much better.



## Case Study #2

Case 2 is a 29-yr-old homeless African American MSM from a mixed racial background who tested positive anonymously in June, 2013 but had never linked to care. His mother gave him and his two sisters up for adoption when he was a child. He became homeless at the age of 18 after his adopted parents passed away and moved from Ohio to California. He is currently homeless and lives on the streets in Los Angeles.

He is a crystal meth user but does not currently engage in prostitution. He has spent time in jail for stealing, drug possession and prostitution. He reported 5 sex partners in the last 6 months and was the insertive partner for UAI for all 5 and also receptive partner with 1 of the 5 partners. He was very well-spoken and was appreciative that a program was in place like Project Engage to help people with HIV link into care. After enrolling into Project Engage, he was linked into care within two days by Project Engage staff (6 hours PE staff time). He is currently working with the HIV clinic staff to secure housing and other needed social services.



## ■ **Preliminary Lessons Learned:**

- Agency-based recruitment more effective than clinic-based recruitment
- A few productive seeds is critical to success
- Labor intensive for PE staff to get OOC alters to HIV care
- Capacity needed to help OOC alters obtain photo ID to enroll in medical care/ADAP
- LTC intervention needed for some

## ■ **Next Steps:**

- Scale up staff (currently 1 field staff)
- Explore effectiveness of direct field recruitment techniques at parks/street corners, enhanced recruitment at more CBOs, at-risk youth agency, mobile testing vans, skid row clinic
- Add LTC intervention (ARTAS) in next phase
- Recruit effective SNT seeds as PE seeds





# Economic Analysis



# Estimation of Project Engage Costs

- **Administrative data used to estimate cost of planning and implementing intervention:**
  - **Staff time**
  - **Services**
  - **Supplies and equipment**
  - **Incentives provided**
- **Seeds and alters asked about their transportation costs**
- **Healthcare cost savings due to intervention estimated from reductions in disease transmission**



# Estimation of Short- and Long-Term Benefits

- **Estimation of short-term treatment effects:**
  - PE recruited alters vs. matched control sample
  - Estimate differences in viral load
- **Estimation of long-term benefits:**
  - Mathematical model of HIV transmission among MSM in Los Angeles County over 10 years
  - Estimated short-term treatment effects and literature review used to populate model's parameters



# Economic Analysis of Other TLC+ Components

- **Similar approach to Project Engage will be used for other components**
  - **Intervention costs from administrative data**
  - **Participant costs collected in surveys**
  - **Short-term impact estimated from available data**
  - **Cost savings and long-term health benefits simulated using mathematical model**



# Navigation Program



# Navigation Program

## ■ Background:

- Goal is to re-engage lost HIV clinic patients in HIV care using enhanced locator techniques and modified strengths-based cm intervention (ARTAS)
- Sample will be OOC GLC/OASIS HIV patients identified using surveillance data
- Eligibility includes HIV+ patients who have not had a primary care visit in the past 6 mos and last vl >200 copies/ml; or no HIV primary care visits in 12 mos; or newly-dx'd and never in care

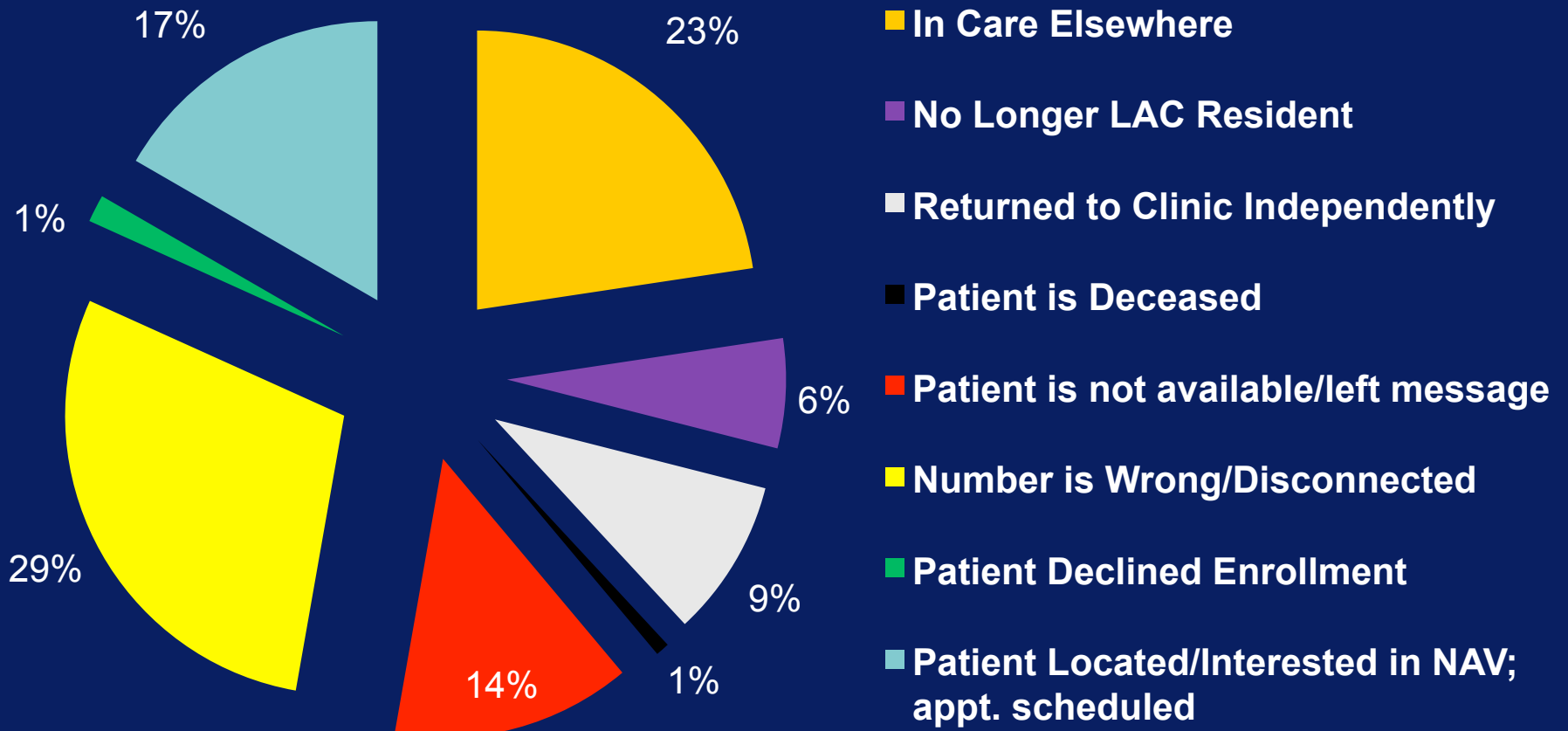
## ■ Current status:

- IRB approved, recruiting staff. Anticipated start Nov, 2013
- DHSP is currently conducting a less-evaluated version of NAV w comm'ty partners



# Preliminary Pilot Data

- Disposition of 252/600 Lost Clinic Patients



Data Source: NAV Checklists as of 07/17/2013



# Lessons Learned and Next Steps

- **Lessons Learned**

- Pilot-tested recruitment techniques will strengthen PATH-NAV implementation
- Surveillance database for identifying OOC patients better than clinic records; home visits not productive; HIV surveillance, clinic and Lexis/Nexis contact info most useful
- Structural roadblocks
  - LACDPH legal concerns with sharing surveillance information
  - Clinic administrative requirements

- **Next Steps**

- Take lessons learned and incorporate into PATH-NAV; implementation





# **PATH – PrEP**

**A Pilot Demonstration Project to Operationalize  
Pre-exposure Prophylaxis as part of Combination HIV  
Prevention among MSM and Transgender Women in  
Los Angeles County**

**Raphael J. Landovitz, MD MSc**

# Presentation Overview

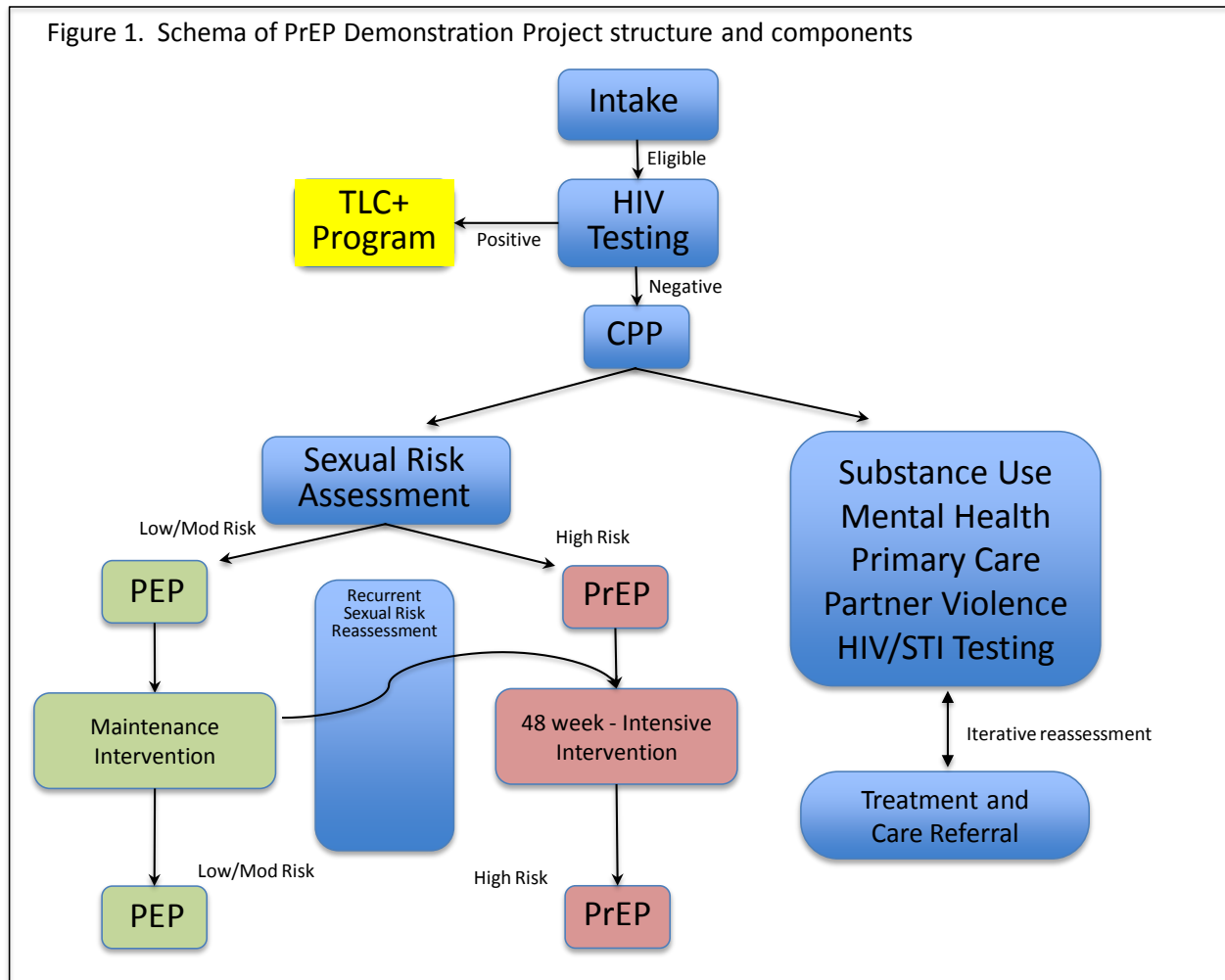
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- Clinical Site Monitoring
- Community Advisory Board and Scientific Advisory Board
- Screening & Enrollment
- Plans and Future Directions

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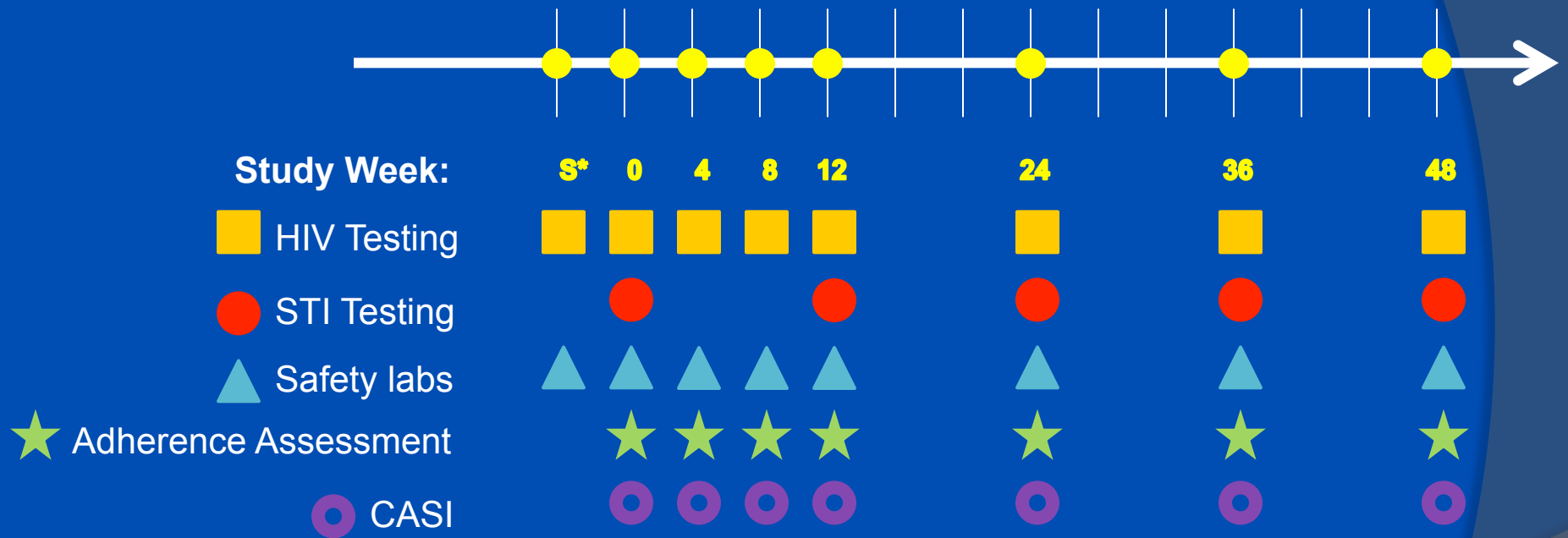
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# Study Overview

Figure 1. Schema of PrEP Demonstration Project structure and components



# Study Schema



\*Screening visit occurs 1-2 weeks prior to baseline visit  
Note: CASI = Computer Assisted Self Interview

# IRB Protocol Update

- Study opened at LAGLC under Protocol V3.0
  - Protocol V4.0 approved by UCLA IRB on September 12, 2013
  - Protocol V2.0 approved by Charles Drew University
  - Protocol V3.0 and V4.0 simultaneously submitted to CDU IRB on September 13, 2013

## IRB Protocol Update

# Major Changes from V 3.0 to V 4.0

- Currently Collected in V 3.0:
  - Self-reported adherence & Pill Counts
  - Real time plasma TFV and FTC levels
  - Intraerythrocytic TFV-DP levels (batched DBS)
- Missing: Patterns of adherence
- Use of MEMS Caps added to V 4.0
  - To be used on a random sample of 100 participants



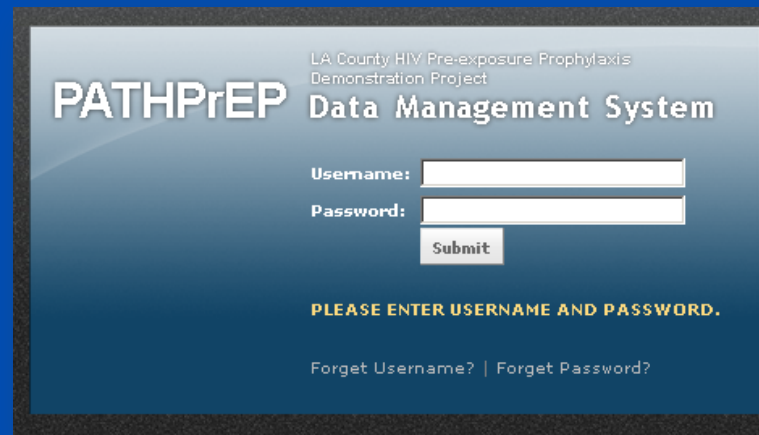
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# eCRF & Data Management System

- The Semel Institute Biostatistics Core (SISat) created an advanced eCRF and data management system unique to the PATH-PrEP study
- Computer Assisted Self-Interviewing (CASI) component built-in
  - Emails are generated by the CASI system to notify research team when thresholds for alcohol/drug use, domestic violence and depression are met and referrals are needed
- Additional features and modifications are made on a regular basis



LA County HIV Pre-exposure Prophylaxis Demonstration Project

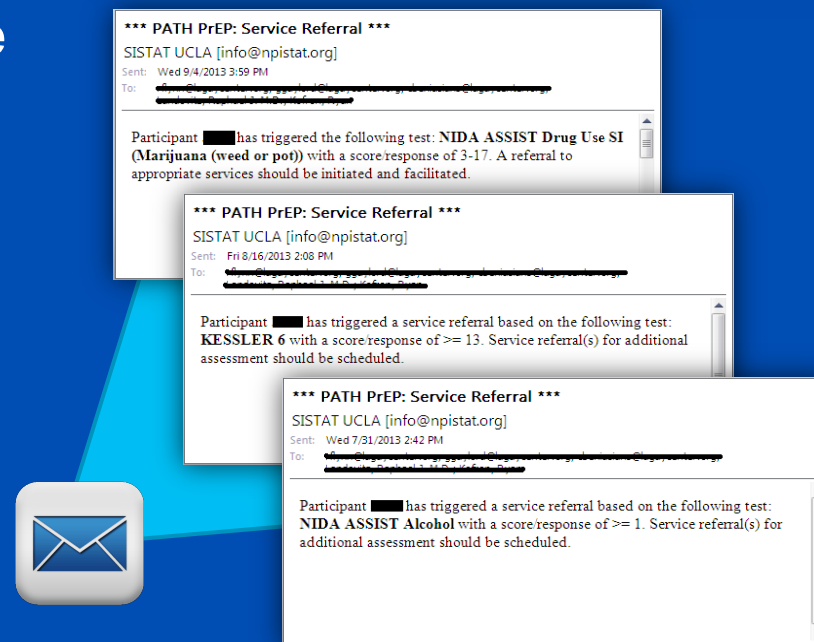
## PATHPrEP Data Management System

Username:

Password:

PLEASE ENTER USERNAME AND PASSWORD.

[Forget Username?](#) | [Forget Password?](#)



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# Site Update: LAGLC

- First screening occurred 5/17/2013
- First participant enrolled 5/28/2013
- Approximately 5 participants have enrolled in the study each month
- LAGLC's current monthly goal is to enroll between 10 and 15 participants each month
- Scale up is in progress with a goal of 20-25 per month

LAGLC	
<b>Site Medical Director</b> Dr. Robert Bolan	<b>Site Executive Research Director</b> Risa Flynn
<b>Site Project Director</b> Glenn Gaylord <i>Corinne Beniasians</i>	
<b>Site Provider</b> Corinne Beniasians <i>Everado Mejia</i>	<b>Site Care Navigator</b> Henry Meraz <i>Glenn Gaylord</i>
<b>Designated Lab Tech</b> Marysol Gonzalez <i>Corinne Beniasians</i> <i>Ruben Rivera</i> <i>Raymundo Mercado</i>	<b>Site Pharmacist</b> Kevin Marx
<b>Key</b>	
Study Role	
Staff Member	
<i>Backup/Alternate</i>	

# Site Update: OASIS Clinic

- Hiring in progress, staff to be in place by the end of September, 2013
- During start-up activities staff will engage with Community Education/ Outreach efforts to prepare South LA Communities for biomedical HIV prevention options
- Administrative and operational hurdles currently being navigated



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# Composite Adherence Counseling

- The goals of the PATH-PrEP Adherence Intervention is to:
  - Help participants be as adherent to PrEP as possible
  - Encourage changes to sexual health that will decrease HIV risk
  - Provide a forum to discuss missed PrEP doses and sexual risk
- The Adherence Intervention is staged into 3 components:
  1. Education & Integrated Next Step Counseling (iNSC)
  2. Targeted iNSC
  3. PrEP Steps

Education

Occurs at first dispensation of drug and as needed

iNSC

15 min. Session at each scheduled visit Post HIV Test

\*Drug not detected (1)

Targeted iNSC

1 20-30 min. Session on phone or in person conducted when results are available

\*Drug not detected (2)

PrEP Steps

4 Weekly 50 min. sessions + 2 Monthly 50 min. sessions

\* Determined by real-time (14-day turnaround) plasma TFV and FTC levels of <10ng/mL

# Deploying Adherence Strategies with Fidelity

## LAGLC

- Received 2-day in-person training
- Received 2 “booster” trainings via Skype
- In-person “booster” training scheduled for Nov. 20<sup>th</sup>
- Ongoing fidelity monitoring of audio recorded sessions

## OASIS

- First 2-day in-person training scheduled for Nov. 21<sup>st</sup> and 22<sup>nd</sup>
- Booster training to follow
- Audio recorded sessions to be monitored

██████ FEEDBACK ██████ BL iNSC

**Style/Spirit:**

- Style is a mix of guiding and some directing, but in a very supportive way. I think that worked out fine here. She seems to be someone who is used to deferring to authority and values her demure style of communicating. I have a feeling that she plays different “selves” depending on who she is interacting with. Given that, mixing up some expert role with collaborator role may work well over time as she gains more comfort in that collaborator/autonomous role. Just hunches from a very limited exposure.

**Specifics + opportunities/- miss**

- + Nice invite to look at notes if desired
- + Good transition from exploring co
- How often having sex- not sure what she is talking to others about protection. Not so directing.
- + Nice summary of what she is doing
- + Good use of “could you ever see... commit to change but lets you dream a little
- + Stuck with exploration until it “clicked
- + Great use of third-personning and
- + Several process comments- nice!

**Fidelity to steps:**

**INTRODUCE**  
Still framed as a “this is going to happen”- if used intentionally. But if that is not the goal

**REVIEW**  
Consider asking not only what you are doing now, but also what you are thinking of doing or considering doing- just to see where it goes. She is doing quite a bit. Not necessarily things that will protect her now, but certainly telling of being invested in exploring prevention.

**EXPLORE**  
Sounds like she is focused on communicating with partners and placing a higher value on herself. You ask “where do you want to go” “What would you want to change”. Good way to draw her in- let her direct. She says she wants to be more comfortable with what she wants and needs. She wants to express herself- “I care about myself as a person”.

**TAILOR/IDENTIFY**  
You worked hard on this one! What is great is that you did not move to strategies until you heard what she really wanted and needed.

**STRATEGIZE**  
Nice- you say “what would need to change” and not “what can you do”. Allows for more exploration. Good 3<sup>rd</sup>-personning and suggesting possible strategies without “prescribing” them. You also give her the chance to practice that.

**AGREE/SELECT**  
She is willing to bring up testing. You turn her attention to the message it sends. Excellent focus—helps her think about the realities of doing this. I am not entirely sure this will fit for her. May need to be more discrete- can you do that with one person? Who? Someone in mind? And role play it out. My hunch is that she may come back wanting to say she did this but not necessarily having done it. Again- just concerned it is too diffuse. In any case, the engagement is really good, so you are in good shape to continue to work with her.

**TRANSITION:**  
Good transition.

**PREP:**  
Good summary of PrEP efficacy. May want to add that PrEP will not prevent STIs which in truth are far more prevalent than HIV. She is going to link up her PrEP with other meds. She uses a pill box and dose time. You direct towards a reminder- alarm. She seems open to it. Might want to work in what to do if you miss the “dose time”- ok to take when you remember.

**CLOSE:**  
Good recap.

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# Clinical Site Monitoring

- ◎ Study Monitor: Laurie Shaker-Irwin, Ph.D, UCLA CTSI
- ◎ Initial LAGLC site monitoring visit: 8/29/2013
  - Review of first 10 participants' charts/data
  - No major deficiencies/aberrancies found
  - Process-improvements implemented
  - Next scheduled monitoring visit: October, 2013
- ◎ Dr. Shaker-Irwin will also monitor the OASIS site after site initiation

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# Community Engagement

## ⦿ PrEP Working Group

- Community group composed of engagement/ education staff from all 5 LA County PrEP projects - with other interested parties
- Planning an aggressive PrEP community education effort
- Coordinating outreach efforts to avoid duplication
- Community Education pamphlets and PowerPoint presentation currently in development for planned pan-LAC educational blitz for Winter 2013/Spring 2014

# Clinical Trials of Pre-Exposure Prophylaxis (PrEP) in Los Angeles

**A** Children's Hospital LA (Project PrEPare)  
 5000 Sunset Blvd. 4<sup>th</sup> Floor #407  
 Los Angeles, CA 90027  
 Contact: Robert Renteria  
 Phone: 323-361-7520  
 Email: [rrenteria@chla.usc.edu](mailto:rrenteria@chla.usc.edu)  
 Target:  
 a) MSM/TG, 15-17 yrs **OPEN**  
 b) MSM/TG, 18-22 yrs **ENROLLMENT COMPLETED**

**E** Harbor-UCLA Medical Center (CCTG 595)  
 1000 W Carson St  
 Torrance, CA 90502  
 Contact: Angela Grbic  
 Phone: 310-222-3848  
 Email: [agrbc@labiomed.org](mailto:agrbc@labiomed.org)  
 Target: MSM/TG, 18+ yrs  
 Enrollment Status: **OPEN**

**B** LA Gay & Lesbian Center (PATH-PrEP)  
 1625 N Schrader Blvd  
 Los Angeles, CA 90028  
 Contact: Glenn Gaylord  
 Phone: 323-993-7423  
 Email: [path@laglc.org](mailto:path@laglc.org)  
 Target: MSM/TG, 18+ yrs  
 Enrollment Status: **OPEN**

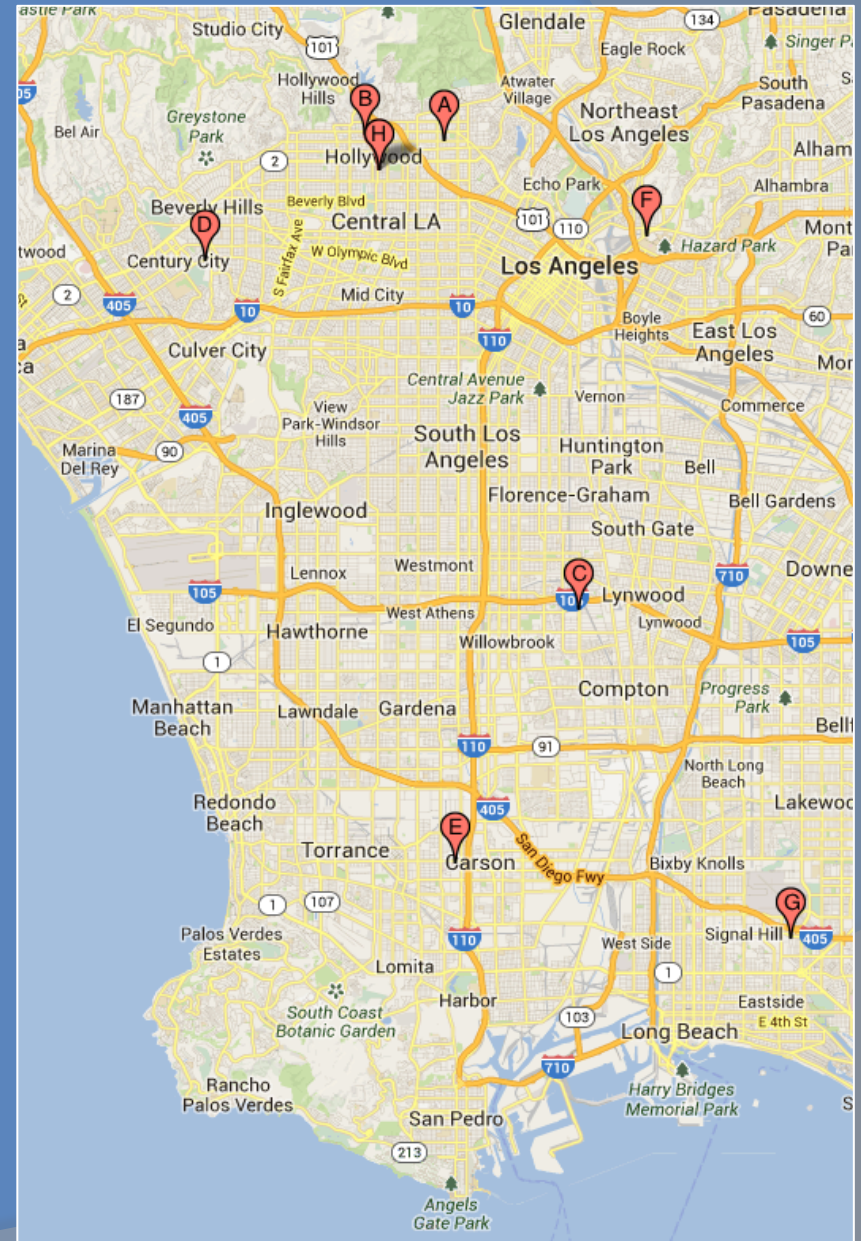
**F** USC Rand Schrader Clinic (CCTG 595)  
 1300 N Mission Rd  
 Los Angeles, CA 90033  
 Contact: Connie Funk, RN  
 Phone: 323-343-8282  
 Email: [funk@usc.edu](mailto:funk@usc.edu)  
 Target: MSM/TG, 18+ yrs  
 Enrollment Status: **OPEN**

**C** OASIS Clinic (PATH-PrEP)  
 1807 E 120th St  
 Los Angeles, CA 90059  
 Contact: TBD  
 Target: MSM/TG, 18+ yrs  
 Enrollment Status: **NOV 2013**

**G** Long Beach Health Services (CCTG 595)  
 2525 Grand Ave  
 Long Beach, CA 90815  
 Contact: Michael Crump  
 Phone: 562-570-4125  
 Email: [michael.crump@longbeach.gov](mailto:michael.crump@longbeach.gov)  
 Target: MSM/TG, 18+ yrs  
 Enrollment Status: **OPEN**

**D** UCLA CARE Center (NEXT-PrEP)  
 1399 S Roxbury Drive, Suite 100  
 Los Angeles, CA 90035  
 Contact: Kieta Mutepefa or Alex Ponce  
 Phone: 310-557-9062  
 Email: [careoutreach@mednet.ucla.edu](mailto:careoutreach@mednet.ucla.edu)  
 Target:  
 a) MSM/TG, 18+ yrs **SEPT/OCT 2013**  
 b) women, 18+ yrs **SEPT/OCT 2013**

**H** UCLA Vine Street Clinic (HPTN 073)  
 910 N Vine Street  
 Los Angeles, CA 90038  
 Contact: Gregory Victorienne or Rotrease Regan  
 Phone: 866-449-UCLA (8252)  
 Email: [uclavsc@mednet.ucla.edu](mailto:uclavsc@mednet.ucla.edu)  
 Target: Black MSM, 18+ yrs  
 Enrollment Status: **OPEN**



**NOV 2013** Anticipated date of open enrollment  
**OPEN** Currently enrolling  
**ENROLLMENT COMPLETED** Enrollment completed  
 Note: Eligibility for participation varies by study.

Last updated on 08/13/13

# CAB Meetings

- The CAB has met 3 times and continues to meet on a quarterly basis.
- Topics from past meetings include:
  - Feelings about community engagement around PrEP with heterosexual women
  - Reviewing VOICE data from CROI and its implications for biomedical prevention in Los Angeles
  - Reviewing the recent the Bangkok Tenofovir study of PrEP for HIV prevention with injection drug users
  - TLC+ components of the study
- Next Meeting: September 25, 2013
  - Designing community education and engagement events around PrEP
  - Collaborations with the PrEP in Los Angeles work group

# Scientific Advisory Board

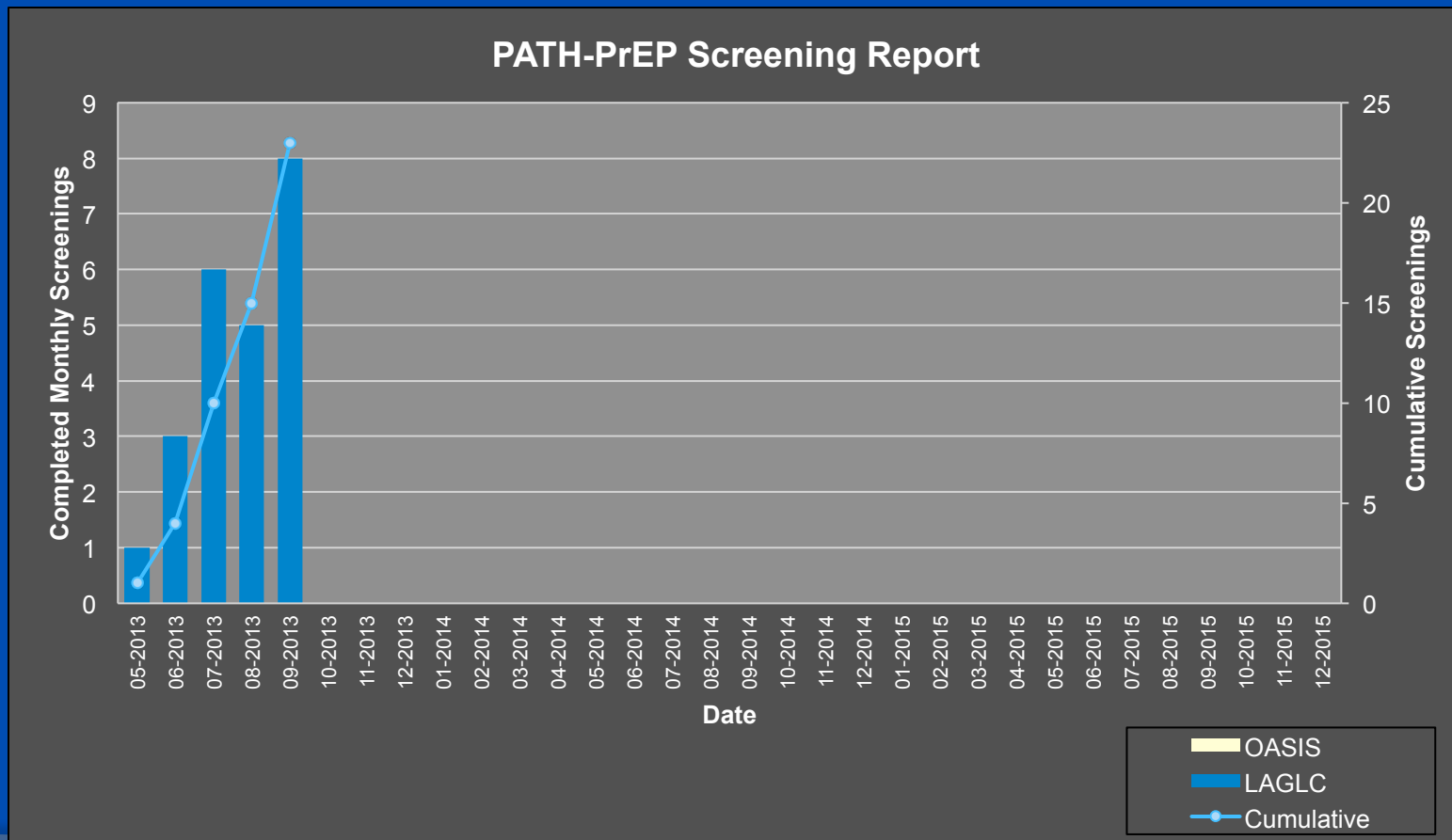
- ⦿ The SAB has met twice and continues to meet every 6 months
- ⦿ SAB members:
  - Dr. Mitchell Katz, LAC DPH
  - Dr. Judith Currier, UCLA CARE Center, ACTG Vice-chair
  - Dr. Tom Coates, UCLA Program in Global Health, HPTN executive committee
  - Dr. Jennifer Sayles, Care LA
  - Dr. Jonathan Fielding, LAC DPH
- ⦿ Continues to offer a high level of guidance and a number of helpful suggestions
- ⦿ Continues to be excited by progress of the studies
- ⦿ Next call: Tuesday, Feb 4, 2014

# Presentation Overview

- Study Overview
- eCRF & Data Management System
- Site Updates
- Composite Adherence Counseling
- Clinical Site Monitoring
- Community Advisory Board and Scientific Advisory Board
- **Screening & Enrollment**
- Plans and Future Directions

# Screening and Enrollment

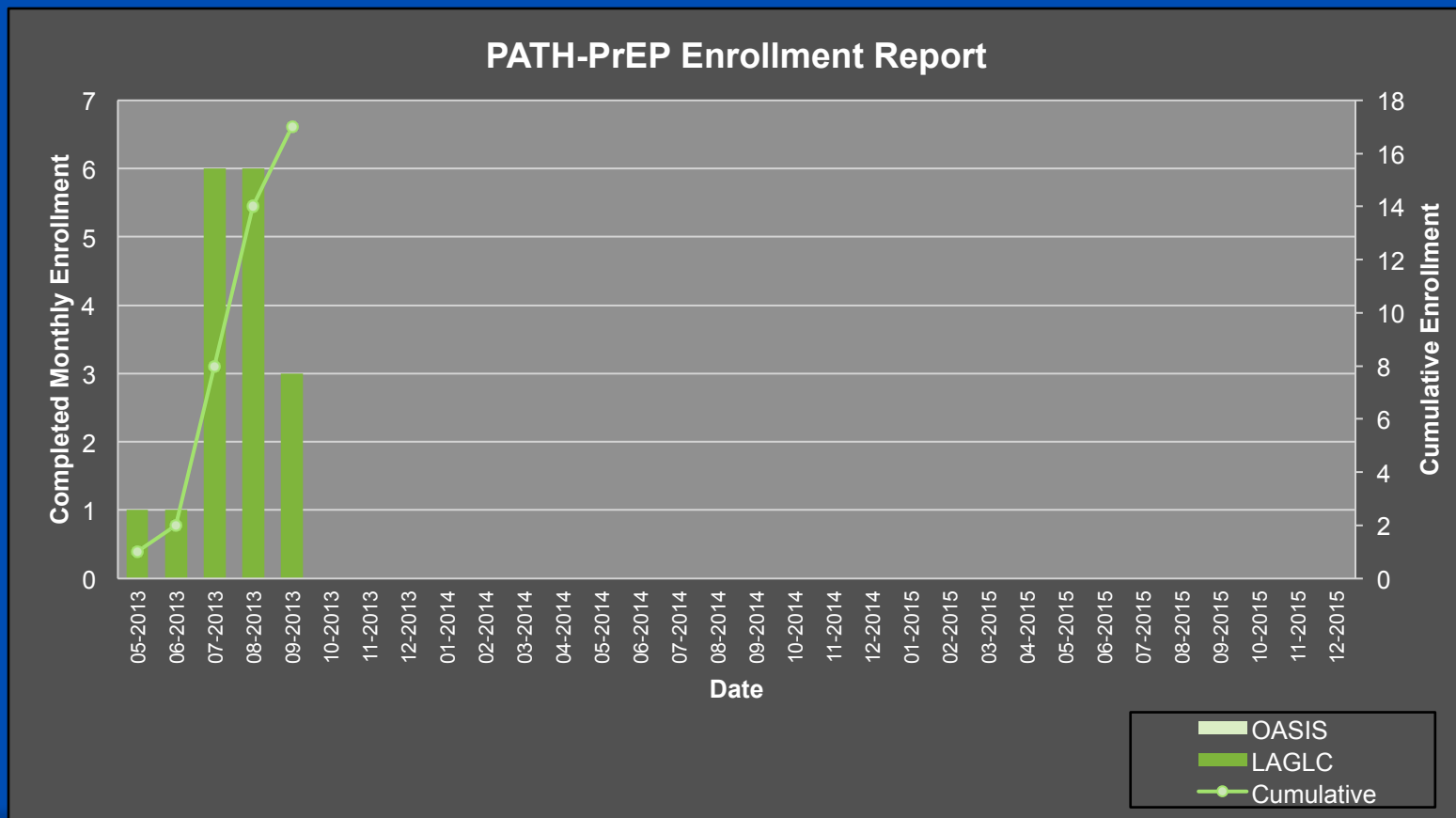
- LAGLC has been actively screening and enrolling participants in the study since May 17, 2013





# Screening and Enrollment

- Screening and enrollment started off slow, but is now on track with a goal of screening approximately 5 potential participants each week.



# Screening and Enrollment

## Basic Demographics & Cohort Assignments

Table 1: PATH-PrEP: Demographic Characteristics of Enrolled Participants - Cumulative

	TOTAL			LAGLC			OASIS		
	N	Median	Range	N	Median	Range	N	Median	Range
<b>Age</b>	17	33	25 - 50	17	33	25 - 50	0	0	0 - 0
	N	%		N	%		N	%	
<b>Race/Ethnicity</b>									
Non-Hispanic White	8	47.1%		8	47.1%		0	0.0%	
Non-Hispanic Black	3	17.6%		3	17.6%		0	0.0%	
Hispanic/Latino	3	17.6%		3	17.6%		0	0.0%	
Asian, Other, Mixed Race	3	17.6%		3	17.6%		0	0.0%	
<b>Cohort</b>									
LM	0	0.0%		0	0.0%		0	0.0%	
H	17	100.0%		17	100.0%		0	0.0%	
LM to H	0	0.0%		0	0.0%		0	0.0%	
Seroconverted	0	0.0%		0	0.0%		0	0.0%	
Withdrawn	0	0.0%		0	0.0%		0	0.0%	

As of: Friday, September 13, 2013

# Screening and Enrollment

## Missed Sessions

**Table 2: PATH-PrEP: Missed Sessions by Time Point - Cumulative**

Number of Enrolled Participants = 17

Number of Participants with a Missing Visit = 1

Timepoint	TOTAL			LAGLC			OASIS		
	Attended	Missed	%	Attended	Missed	%	Attended	Missed	%
4-Week	11	1	8.3%	11	1	8.3%	0	0	0.0%
8-Week	5	1	16.7%	5	1	16.7%	0	0	0.0%
12-Week	1	1	50.0%	1	1	50.0%	0	0	0.0%
24-Week	0	0	0.0%	0	0	0.0%	0	0	0.0%
36-Week	0	0	0.0%	0	0	0.0%	0	0	0.0%
48-Week	0	0	0.0%	0	0	0.0%	0	0	0.0%

As of: Friday, September 13, 2013

**Table 3: PATH-PrEP: Reasons for Missed Visit**

Number of Enrolled Participants = 17

Number of Participants with a Missing Visit = 1

Reason	TOTAL		LAGLC		OASIS	
	N	%	N	%	N	%
Unable to Contact	0	0.0%	0	0.0%	0	0.0%
Unable to Schedule	0	0.0%	0	0.0%	0	0.0%
Visit Refusal	0	0.0%	0	0.0%	0	0.0%
Incarcerated	0	0.0%	0	0.0%	0	0.0%
Admitted to Hospital	0	0.0%	0	0.0%	0	0.0%
Withdrawn	0	0.0%	0	0.0%	0	0.0%
Deceased	0	0.0%	0	0.0%	0	0.0%
Moved out of area	3	100.0%	3	100.0%	0	0.0%
Other	0	0.0%	0	0.0%	0	0.0%

As of: Friday, September 13, 2013

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## Plans and Future Directions

- ⦿ Initiate OASIS Clinic and enroll first participant by the end of November 2013
- ⦿ Ramp up enrollment to 20-25 per month by December 2013
  - ⦿ Enrollment complete by April 2015
- ⦿ Focus on retention and adherence intervention
- ⦿ Educational and outreach activities to make diverse populations aware of biomedical HIV prevention opportunities in LAC
- ⦿ Begin discussions with LAC DHSP re: ongoing service delivery options once pilot is complete

# Thank You!

## Comments/Questions

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