
WIHS Report

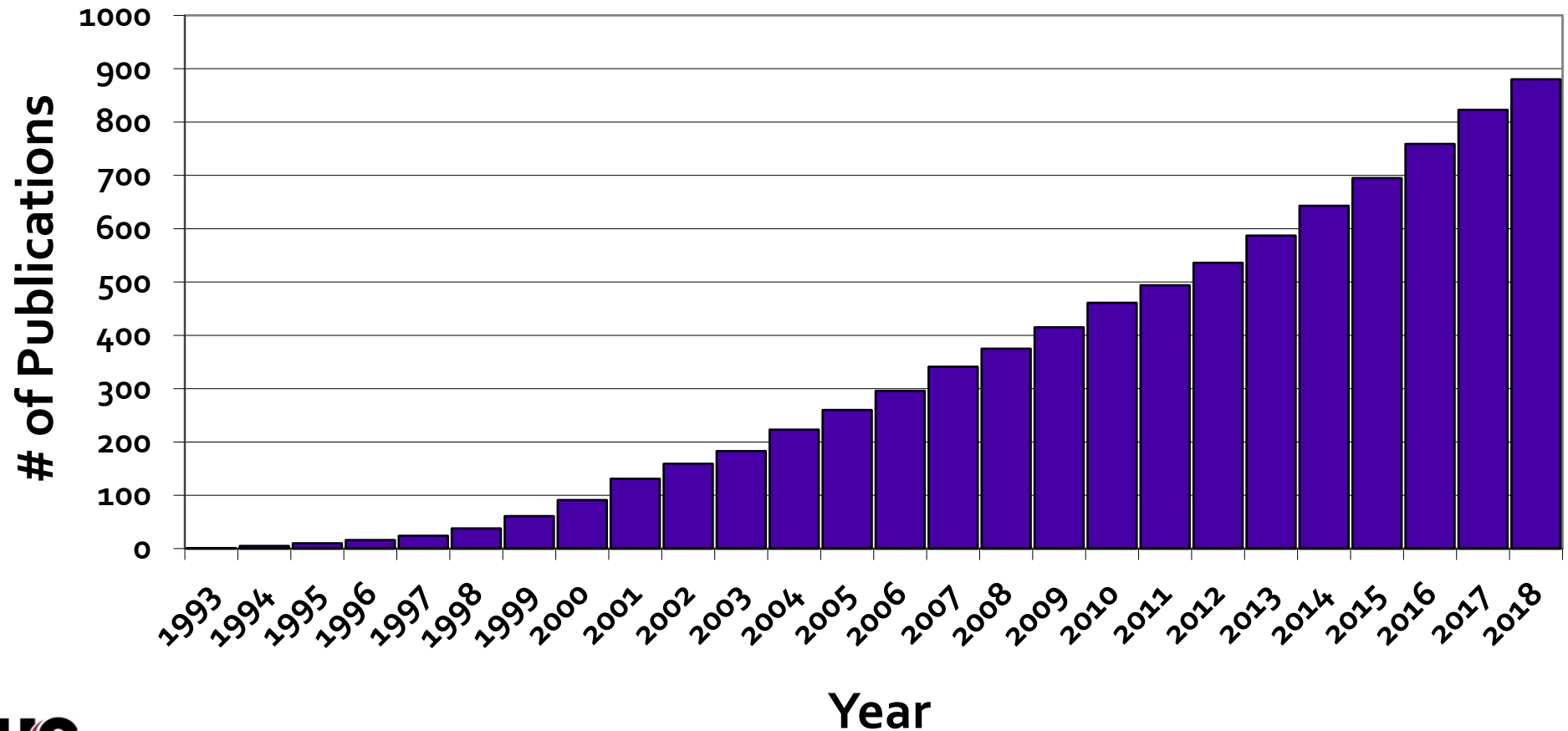
WOMEN'S INTERAGENCY HIV STUDY
Semiannual Executive Committee Meeting
October 29-31, 2018
Rockville, Maryland

Prepared by:
WIHS Data Management and Analysis Center (WDMAC)
email: JHSPH.wdmac@jhu.edu
web: www.wihshealth.org

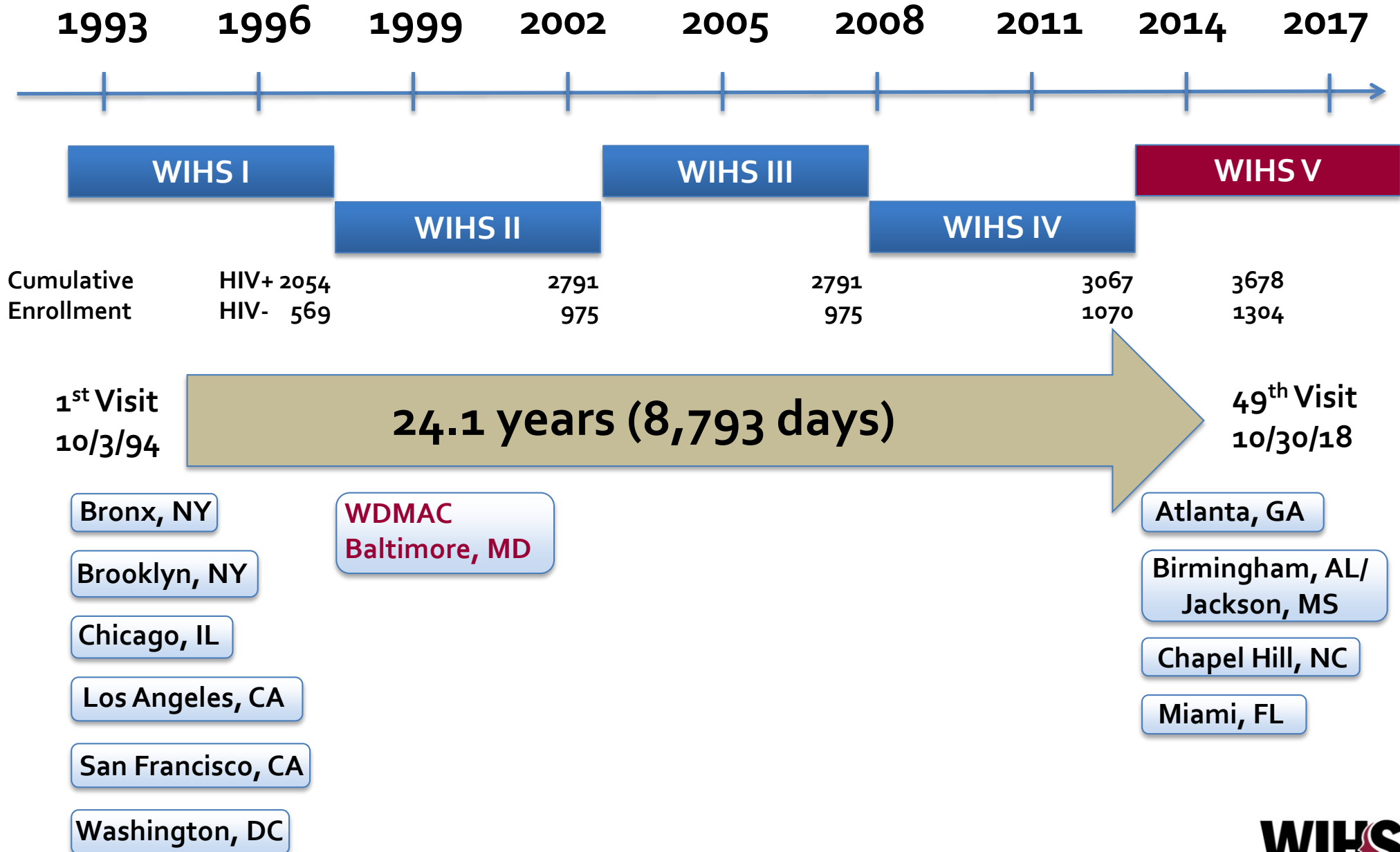
WIHS Publications 1993-2018

880!

* Number of publications as of October 2018. Includes published and in press for 2018.

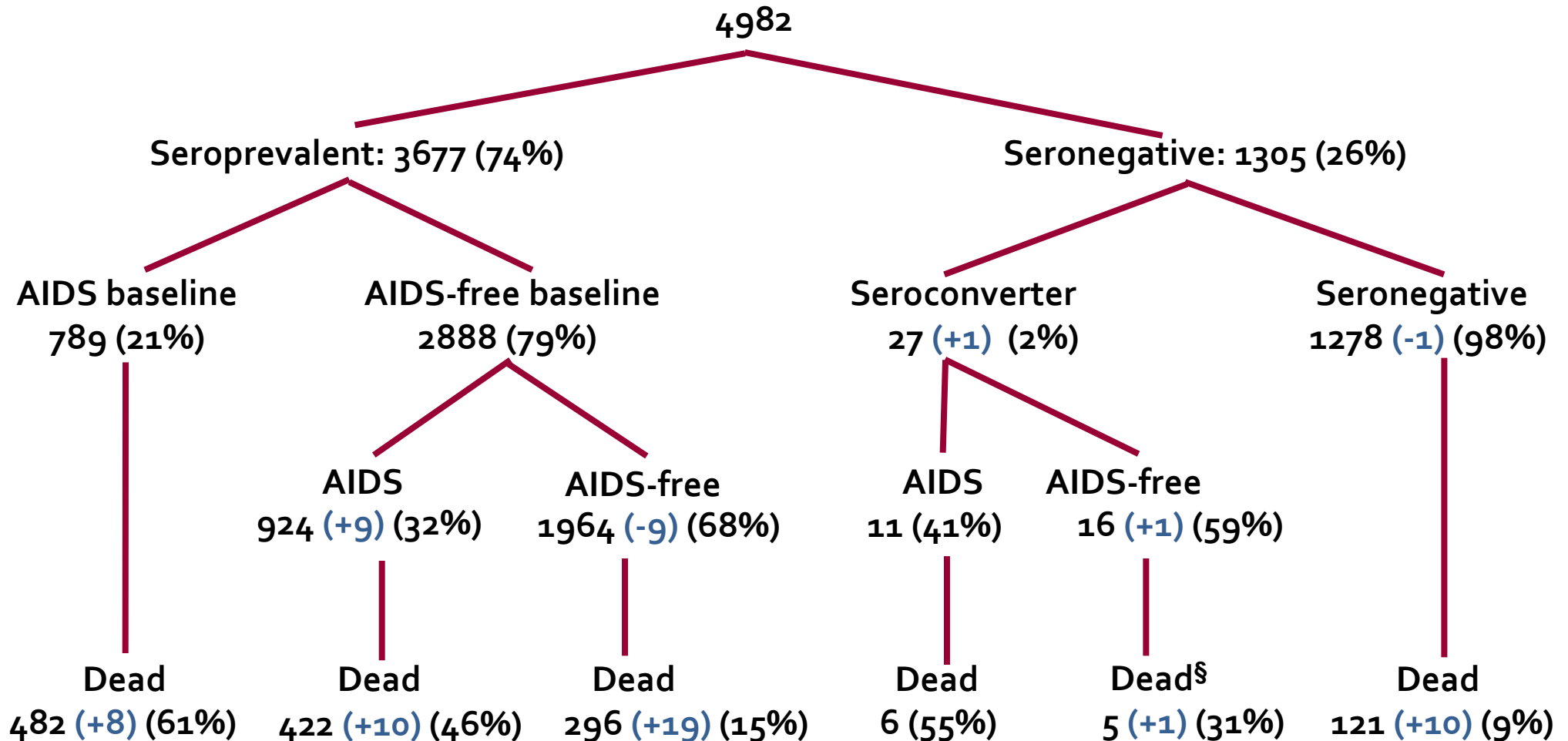


WIHS Timeline



Cohort Status

WIHS Cohort*



* HIV & AIDS status as of the end of visit 47 (3/31/18). Deaths via NDI (through 12/31/14 for site 4 & 12/31/16 for all other sites) and through 3/31/18 via other reports

§ Three seroconverters found at death

WIHS Cohort by Enrollment Wave

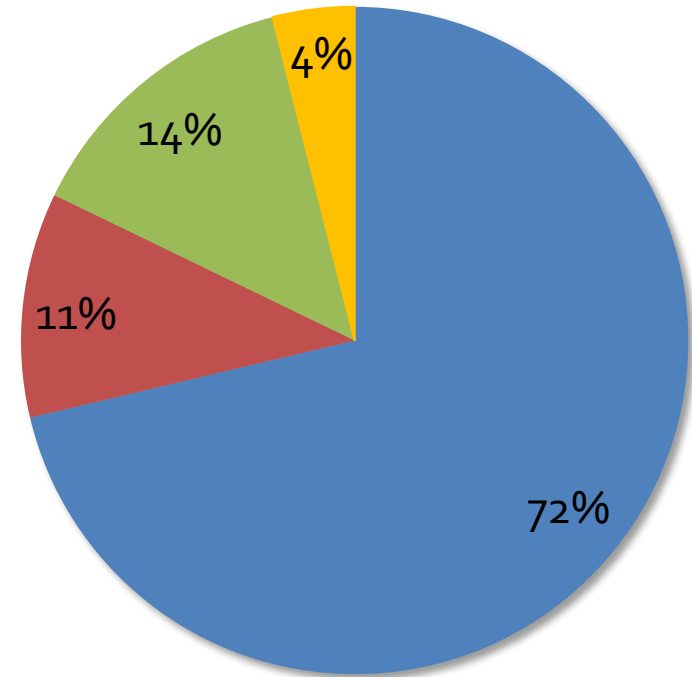
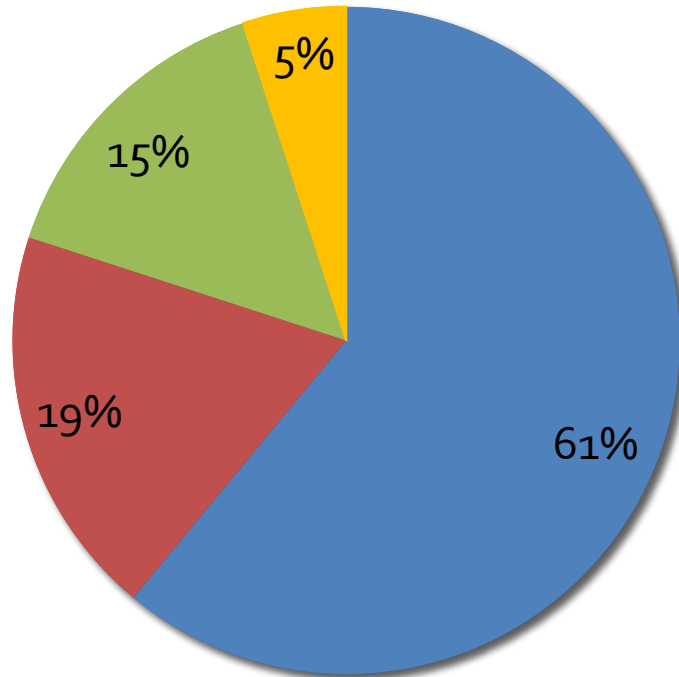
	WIHS I 1994-95 N=2623 (53%)	WIHS II 2001-02 N=1143 (23%)	WIHS IV 2011-12 N=371 (7%)	WIHS V 2013-15 N=845 (17%)
HIV Serostatus at Baseline				
Seronegative	569 (22)	406 (36)	95 (26)	234 (28)
Seropositive				
<i>Therapy-naïve</i>	2054 (78)	255 (22)	78 (21)	92 (11)
<i>Therapy-exp'd</i>	--	482 (42)	198 (53)	519 (61)
Current Cohort ^a (N=2259)	678 (30%)	550 (24%)	272 (12%)	759 (34%)

^a Current cohort = All participants seen at Visit 46 or 47

Race/Ethnicity among HIV+ Women: U.S. & WIHS

*Diagnoses of HIV Infection, U.S.**

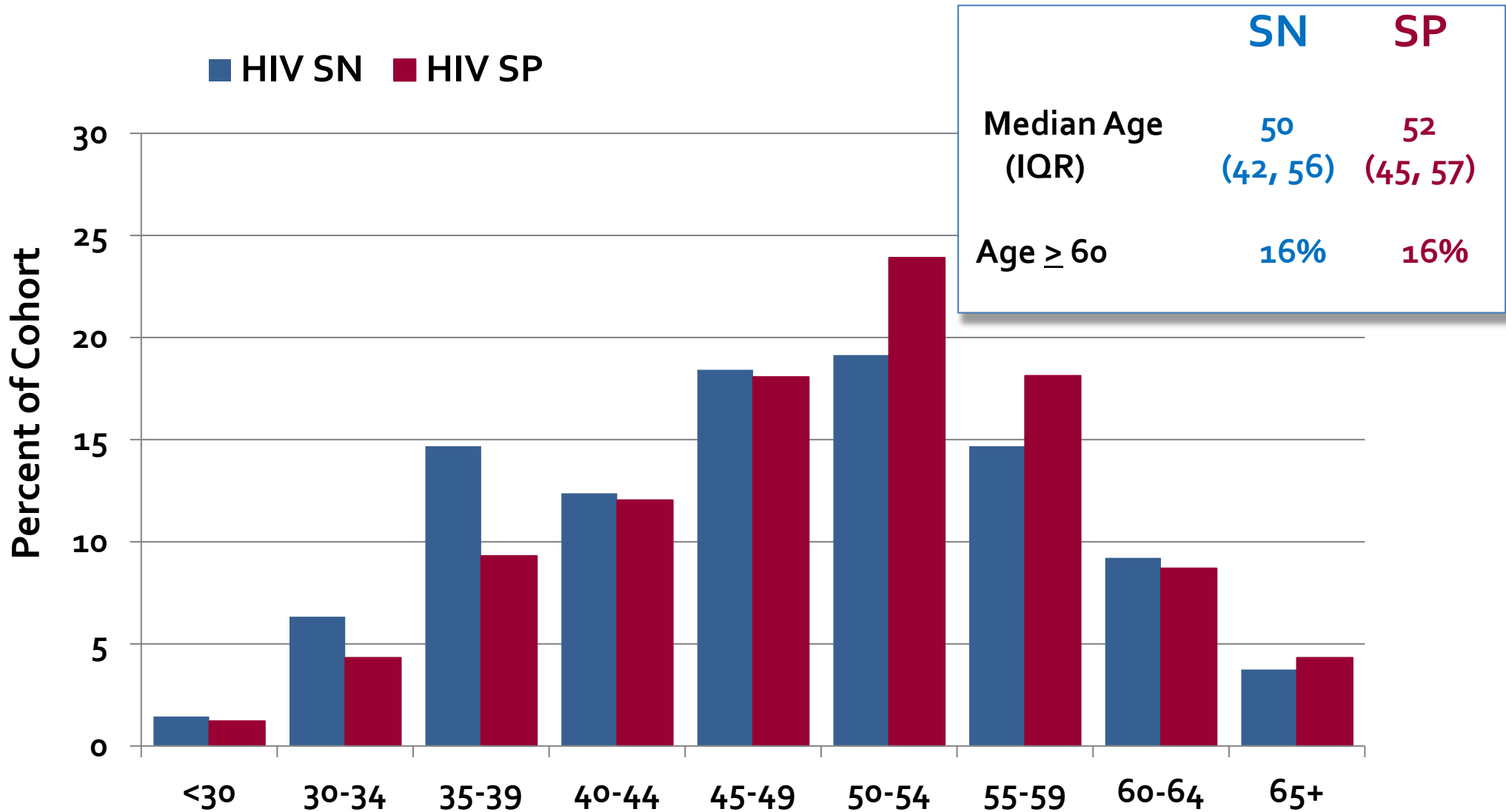
WIHS Active HIV+ Participants



■ Black/African American ■ Hispanic/Latina
■ White ■ Multiple Races / Other

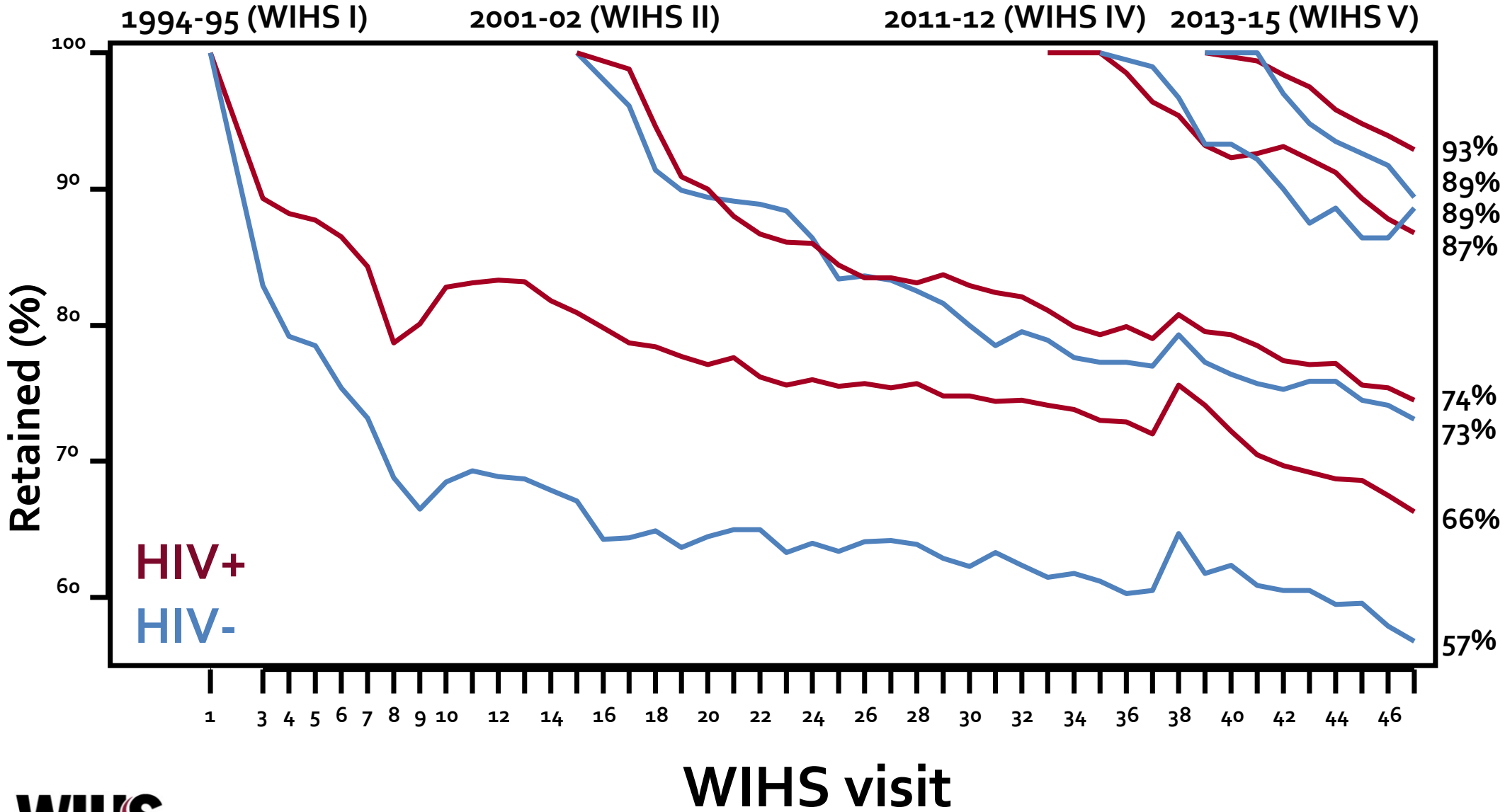
* Data from the *Centers for Disease Control and Prevention*; includes diagnoses of HIV infection among adult and adolescent females (n=7,402), by race/ethnicity in 2015.

Age Distribution of Active* Participants



* Active = All participants seen at Visit 46 or 47

Retention Rates among WIHS Recruits



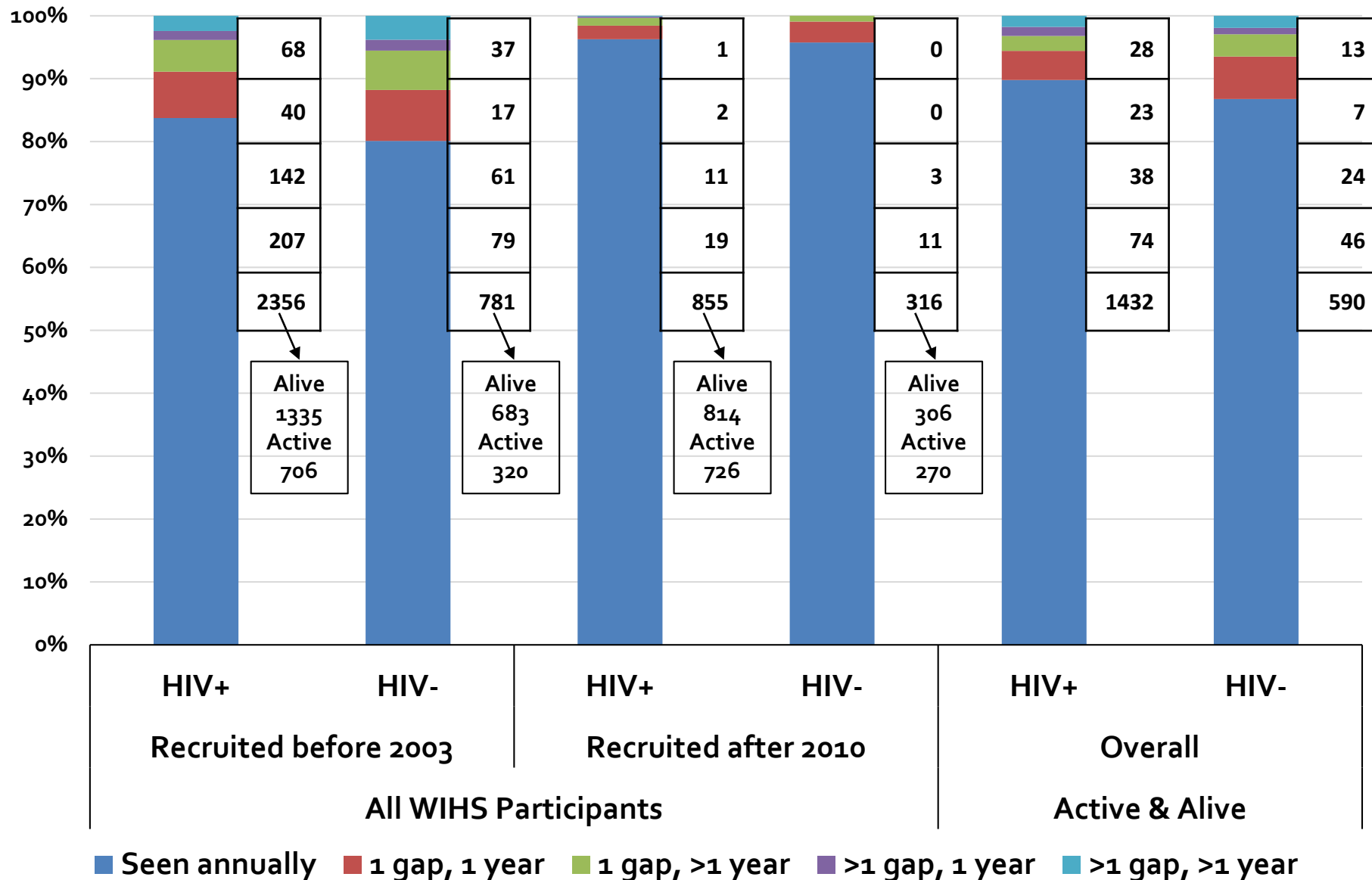
WIHS Database (as of 3/31/18)

Total number of PARTICIPANTS enrolled	3,701	HIV+
	1,281	HIV-
Total number of PERSON-YEARS	36,765	HIV+
	13,743	HIV-
Median (Mean) FOLLOW-UP TIME in years	13.35 (12.53)	WIHS I
	14.14 (11.51)	WIHS II
	5.90 (5.10)	WIHS IV
	3.25 (3.13)	WIHS V
Total number of PERSON-VISITS	69,536	HIV+
	25,813	HIV-
Total number of CD ₄ MEASUREMENTS	65,070	HIV+
	10,556	HIV-
Total number of VIRAL LOAD MEASUREMENTS	64,827	
Total number of REPOSITORY ALIQUOTS*	2,888,521	

* Available as of 10/04/2018

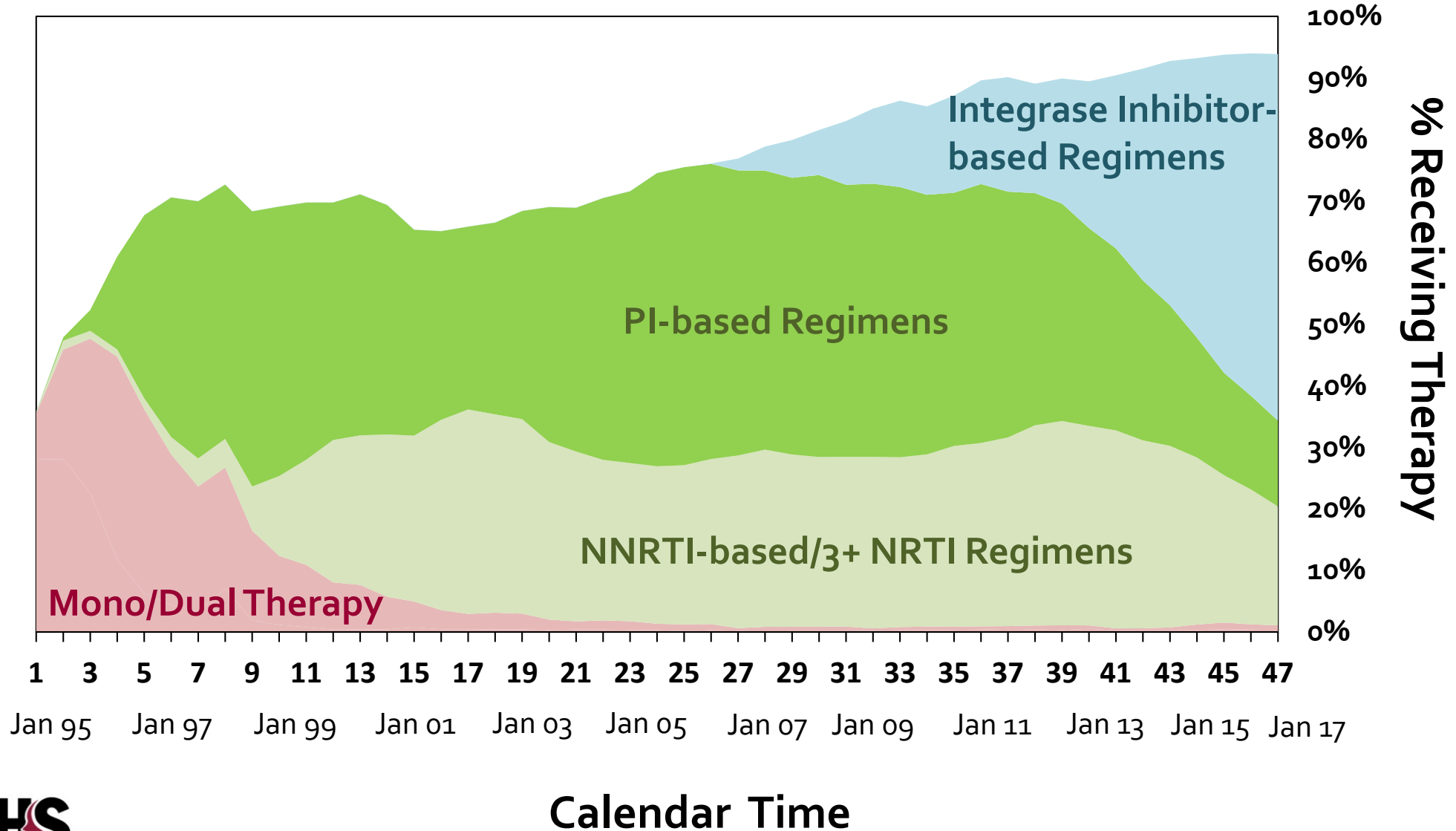


Gaps in Follow-up

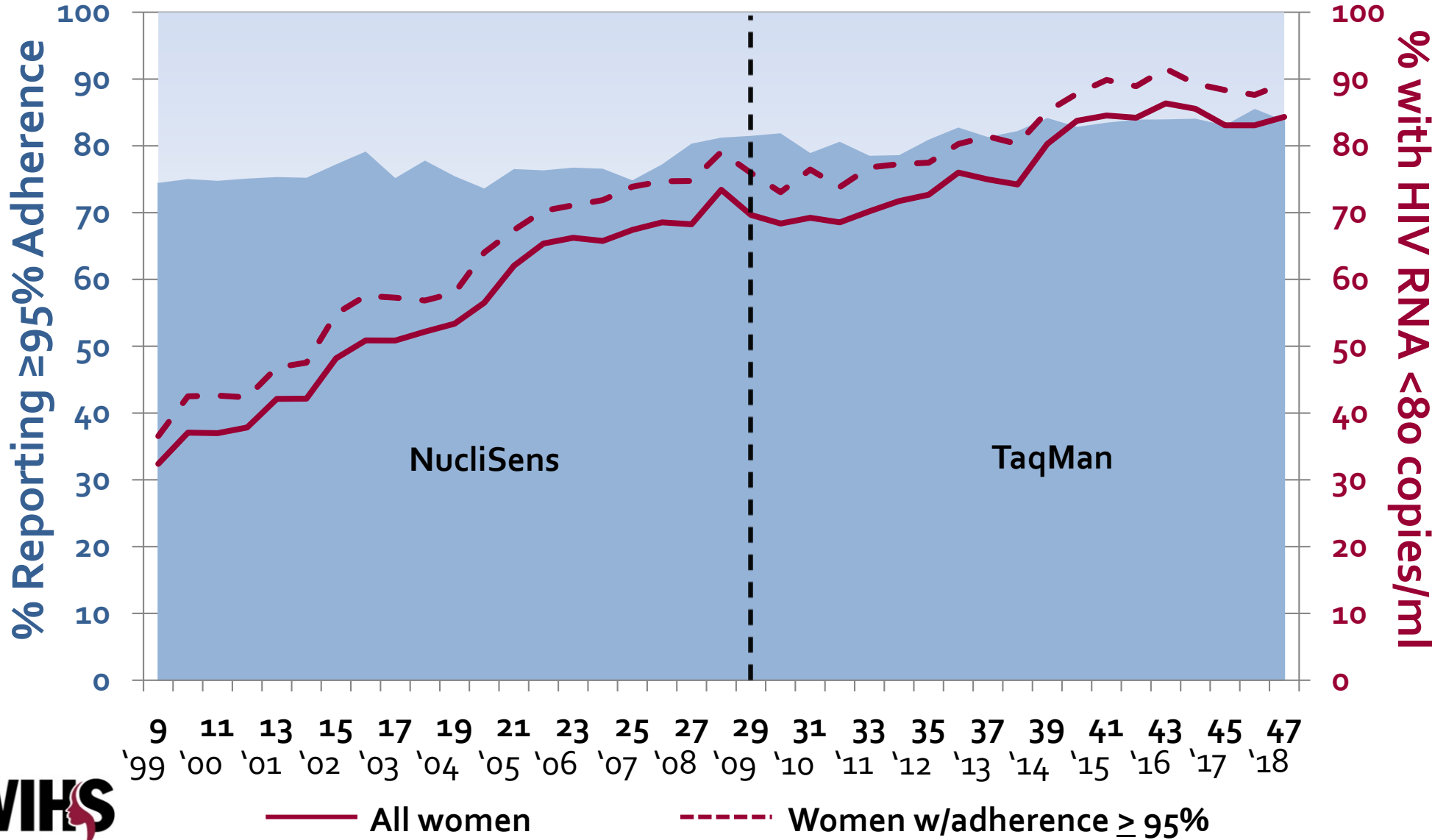


ART Exposure and Pathogenesis

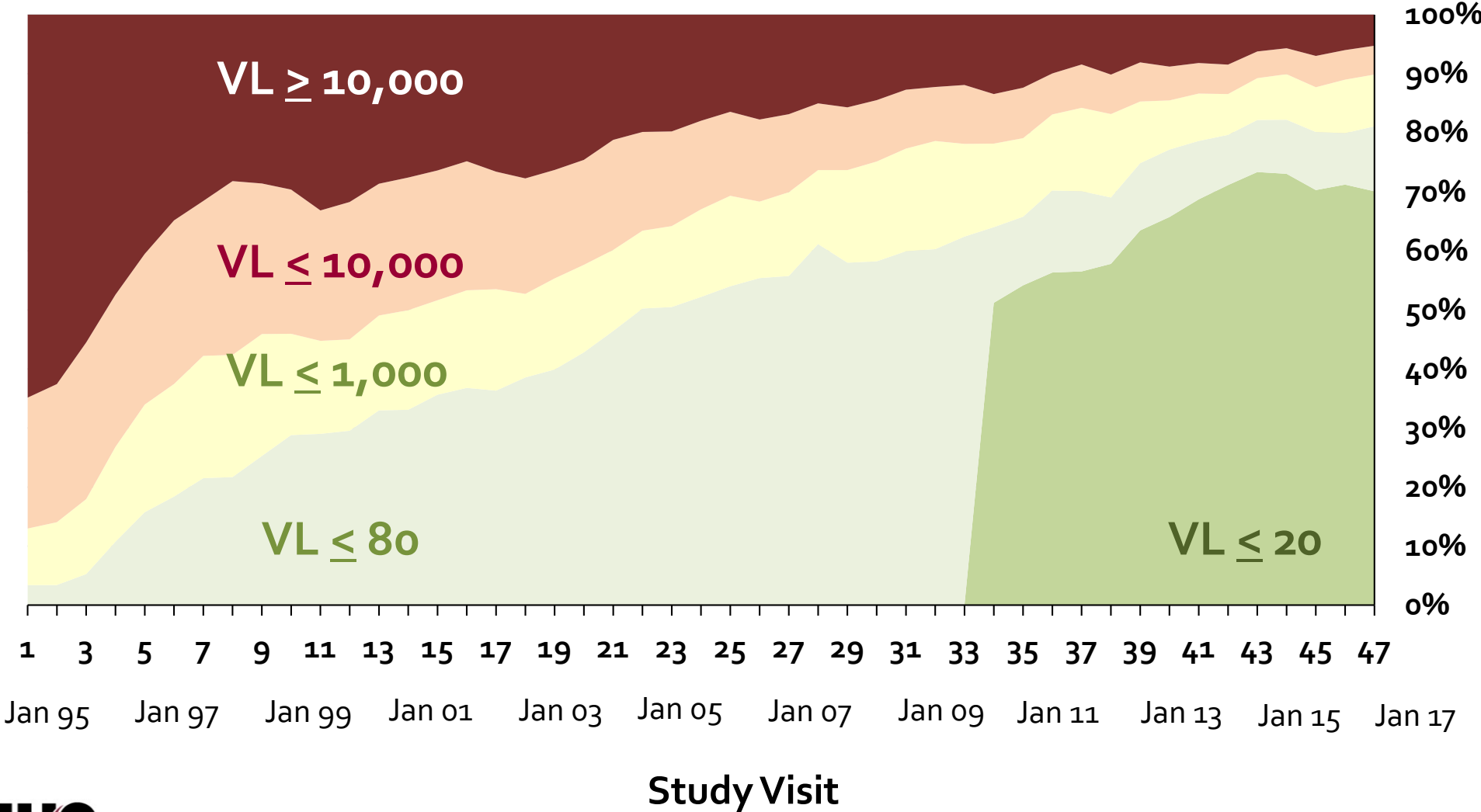
Antiretroviral Therapy Use Among WIHS HIV-infected Participants



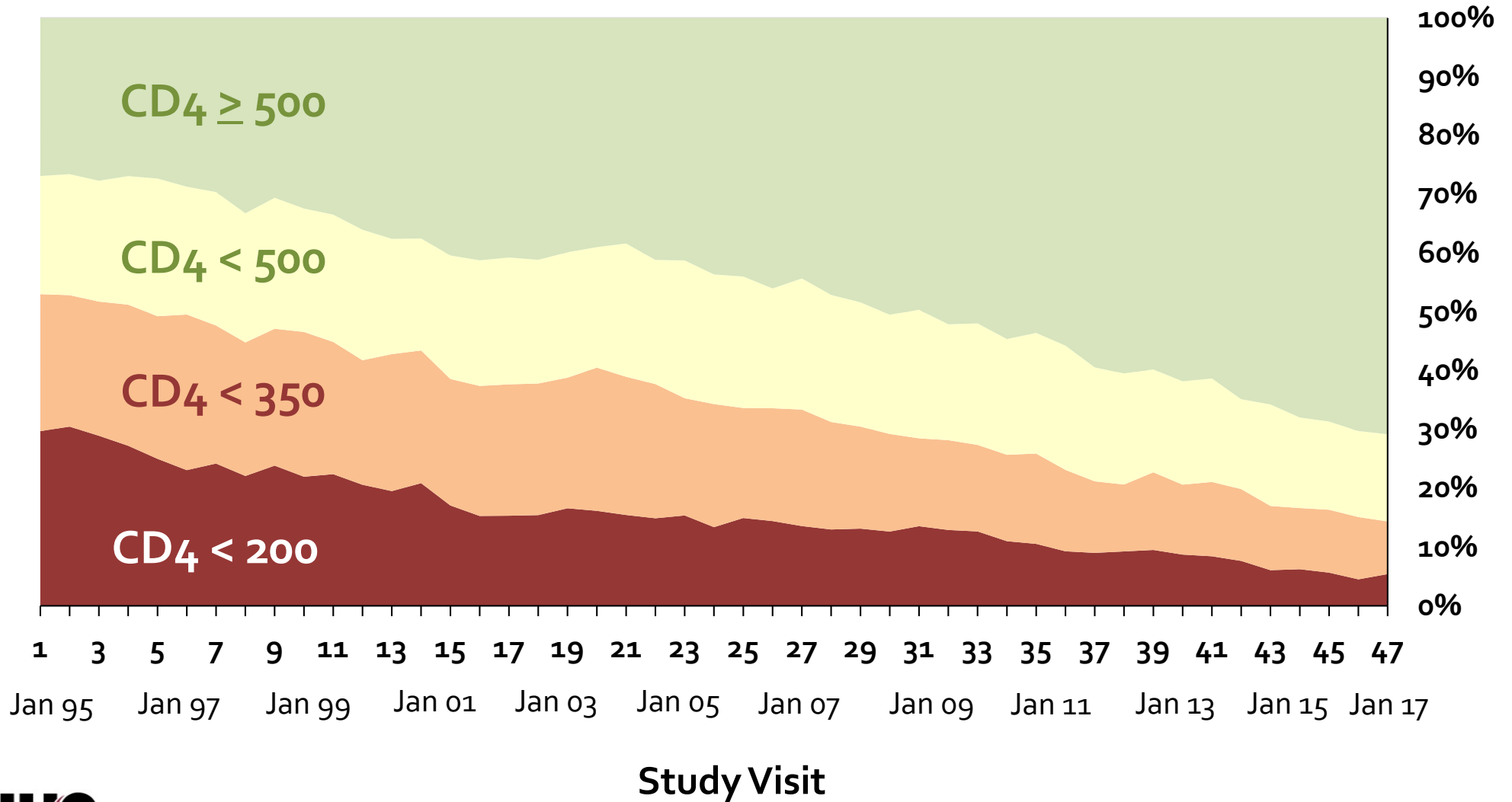
ARV Adherence and HIV RNA Among All Women on Therapy



Viral Load Among HIV+ Participants

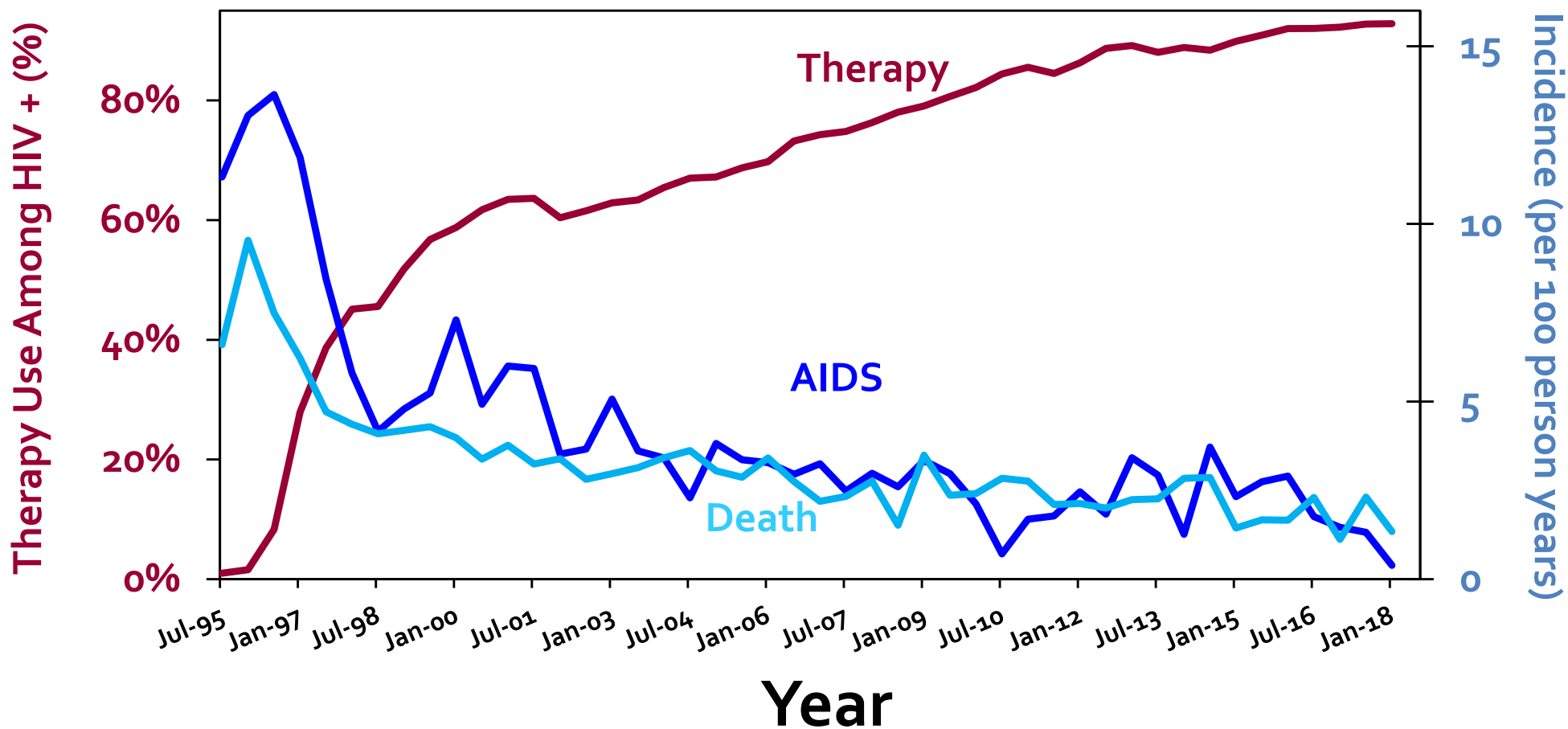


CD4 Cell Counts Among HIV+ Participants



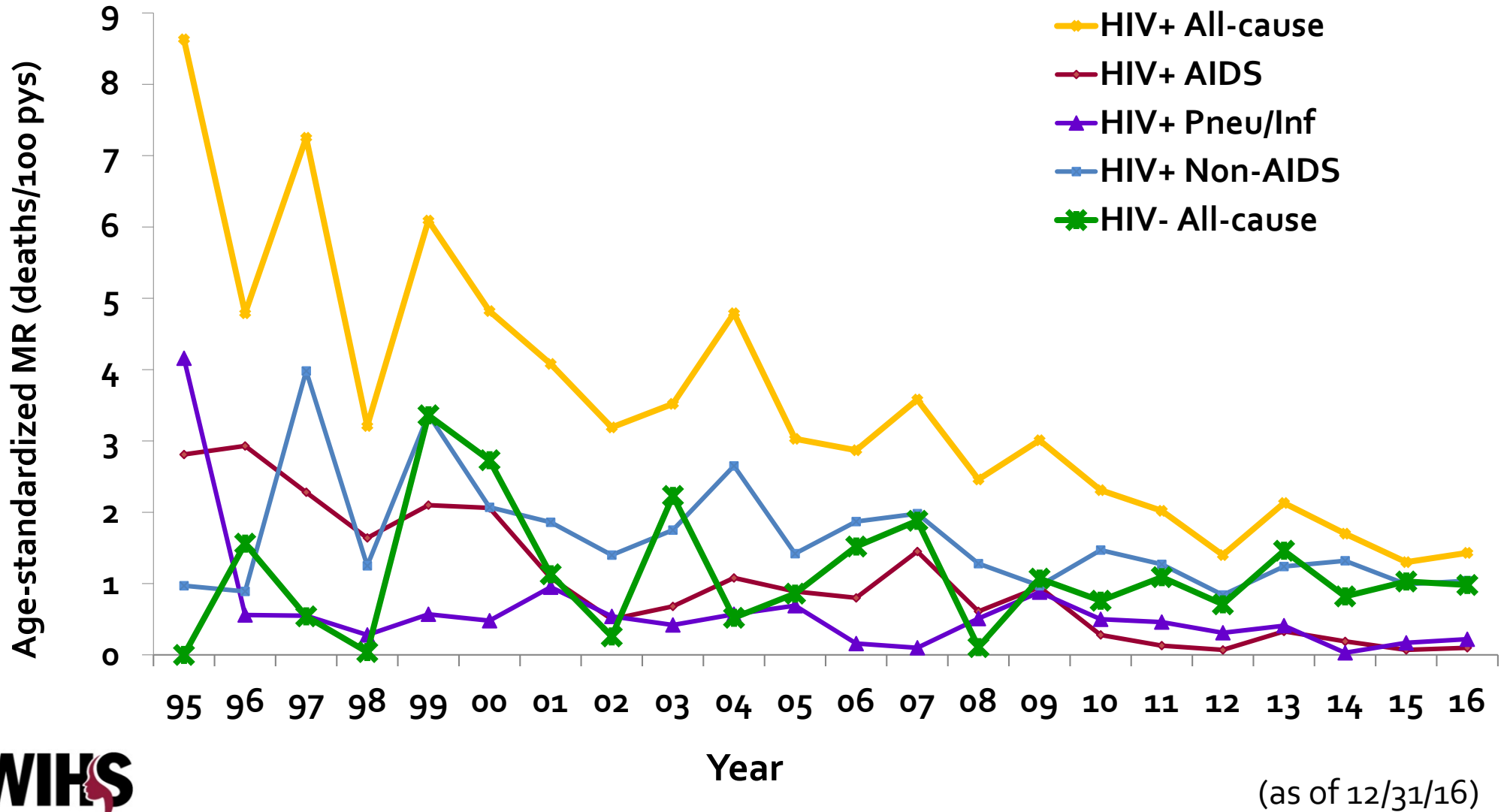
AIDS Outcomes And Deaths

WIHS Mortality, Self-Reported AIDS Incidence, and Use of Therapy

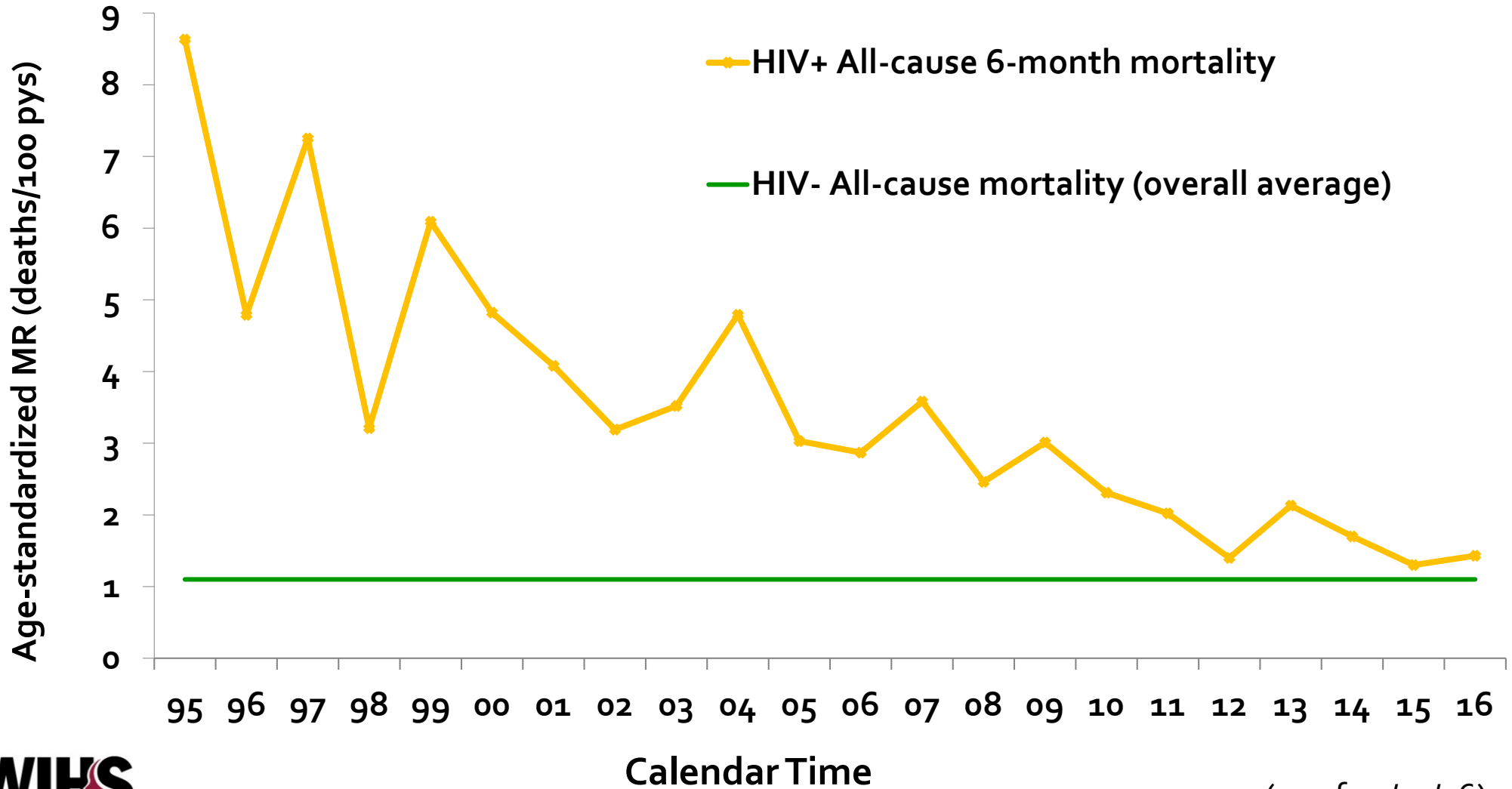


NDI data available through 12/31/16

Change in Age-Adjusted 6-Month Mortality Rates

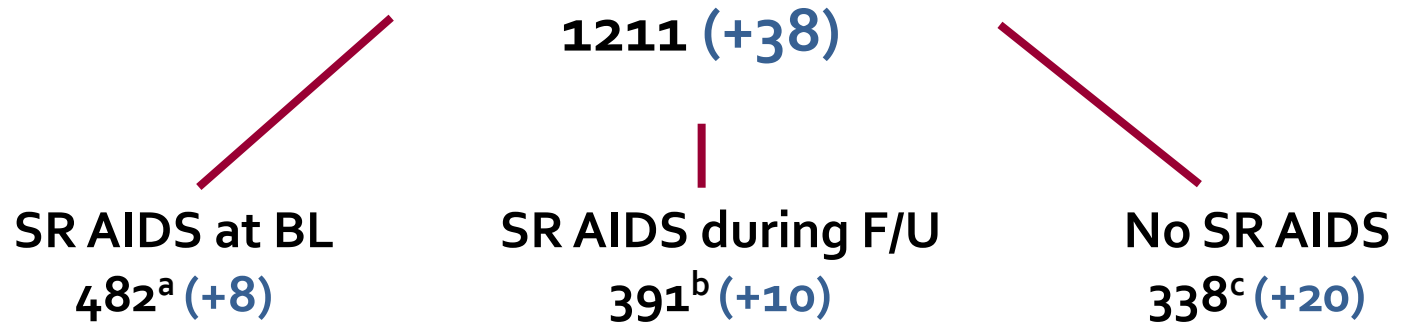


Change in Age-Adjusted 6-Month Mortality Rates



Causes of Death

Deaths among HIV+ Participants



	SR AIDS at BL 482 ^a (+8)	SR AIDS during F/U 391 ^b (+10)	No SR AIDS 338 ^c (+20)
AIDS death	229 (48%)	149 (38%)	101 (30%)
Pneumonia or Infection death	65 (13%)	65 (17%)	40 (12%)
Non-AIDS death	158 (33%)	143 (37%)	177 (52%)
Indeterminate/Missing	30 (6%)	34 (9%)	20 (7%)

Data based on NDI match through 12/31/16 (LA: 12/31/14) and through 3/31/18 for all sites via other reports

^a Includes 7 deaths among 01/02 recruits, 3 11/12 recruits, and 4 Southern recruits

^b Includes 58 deaths among 01/02 recruits, 6 11/12 recruit, and 6 HIV seroconverters (HIV SC)

^c Includes 58 deaths among 01/02 recruits, 14 11/12 recruits, 14 Southern recruits and 5 HIV SC (3 found at death)

Non-AIDS Outcomes And Deaths

Non-AIDS Causes of Death

Non-AIDS Deaths^d

594 (+64)

HIV+

478 (+44)

HIV-

116 (+20)

	HIV+	HIV-
Trauma or OD ^a	104 (+5) (22%)	28 (+6) (24%)
Malignancy	117 (+15) (24%)	24 (+5) (21%)
Liver disease ^b	68 (+2) (14%)	8 (+1) (7%)
CVD	73 (+9) (15%)	15 (+3) (13%)
All other non-AIDS causes ^c	116 (+13) (24%)	41 (+5) (35%)

Data based on NDI match through 12/31/16 (LA: 12/31/14) and through 3/31/18 via other reports

^a Includes 2 deaths among HIV seroconverters

^b Includes 2 deaths among HIV seroconverters (1 found at death); 56 HIV+ and 7 HIV- were HCV Ab+ at baseline

^c Includes 1 death among HIV seroconverters

^d Does not include 5 deaths (including 4 new) among HIV- with missing causes

Confirmed Incident Cancers through 3/31/2018

- **Sources of cancer confirmation**

- Medical record abstraction, cancer registry match, autopsy, biopsy, death certificate match

- **Excluded cancer records**

- Cancers documented solely by self-report/next-of-kin
- Benign tumors
- Most *in situ* tumors (except breast and melanoma)
- Basal cell and squamous cell skin cancers (not recorded in cancer registries)
- Prevalent cancers diagnosed before/at/shortly following enrollment

- **Cancer Classification**

- Data from completed forms were reviewed to determine (if possible) the topology and morphology for each diagnosed cancer, which was then classified according to Surveillance, Epidemiology, and End Results (SEER) Program “site-recode” definition for ICD-O-3/WHO 2008.

https://seer.cancer.gov/siterecode/icdo3_dwhohome/index.html

Confirmed Incident Cancers by HIV Status

Cancer	SEER Code(s)	HIV+	HIV-
All		283 (+16)	52 (+4)
Oral Cavity	20020-20090	11 (+1)	0
Colon	21041-21049	9	3
Rectum	21051-21052	7	0
Anus	21060	11 (+1)	0
Liver	21071	10	4
Pancreas	21100	8	0
Other Digestive Systems	21010-21030,21072,21080-21110,21130	7 (+1)	4
Lung and Bronchus	22030	42 (+3)	10 (+2)
Other Respiratory	22010-22020	7	1
Bones/ Joints	23000	0	0
Soft Tissues	24000	3	0
Melanoma	25010	4	0
Other non-epithelial skin ca	25020	0	0
Breast	26000	45 (+4)	16 (+2)

(+n) cancers documented during the past year

(Continued on next slide)

Confirmed Incident Cancers (continued)

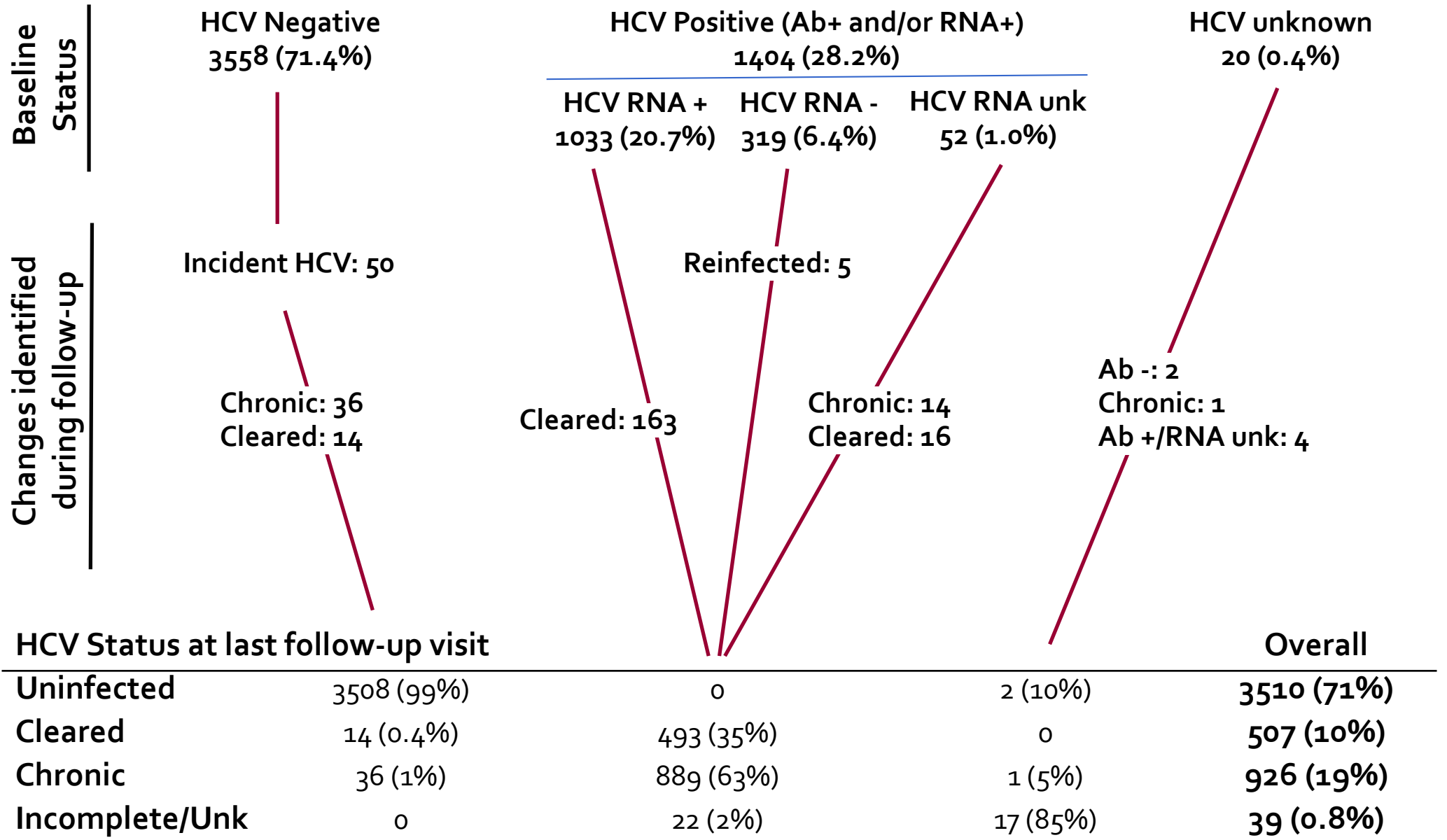
Cancer	SEER Code(s)	HIV+	HIV-
Cervix	27010	7 (+1)	0
Uterus	27020-27030	9 (+1)	3
Ovary	27040	1	0
Vagina	27050	3	0
Vulva	27060	6	0
Bladder/Ureter	29010,29030	1	0
Kidney and renal pelvis	29020	4 (+1)	0
Brain/CNS	31010, 31040	3	3
Thyroid/Pituitary	32010, 32020	4	2
Hodgkin's Disease	33011-33012	4	1
NHL	33041-33042	46	1
Multiple Myeloma	34000	5	0
Leukemia	35012, 35021-35023	3	2
Mesothelioma	36010	1	0
Kaposi's Sarcoma	36020	10	0
Miscellaneous/Unknown	37000	12 (+3)	2

(+n) cancers documented during the past year

Chronic Disease Indicators

Current Cohort (v46 or v47)	HIV+ N= 1585	HIV- N= 674
BMI Median (IQR) % BMI >30 [>40]	30 (26, 37) 51% [18%]	32 (27, 38) 58% [18%]
Hypertension (SBP \geq 140, DBP \geq 90, meds)	52%	50%
Diabetes (HbA _{1c} \geq 6.5%, FG \geq 126, meds)	23%	25%
Dyslipidemia (LDL>130, HDL<40)	31%	27%
Chronic Kidney Disease CKD-Epi eGFR <60 [<30]	13% [2%]	6% [1%]
Baseline Hepatitis C Ab+ (Baseline HCV RNA+)	20% (9%)	15% (7%)
Baseline Chronic Hepatitis B	3%	1%
Depressive Symptoms	28%	32%

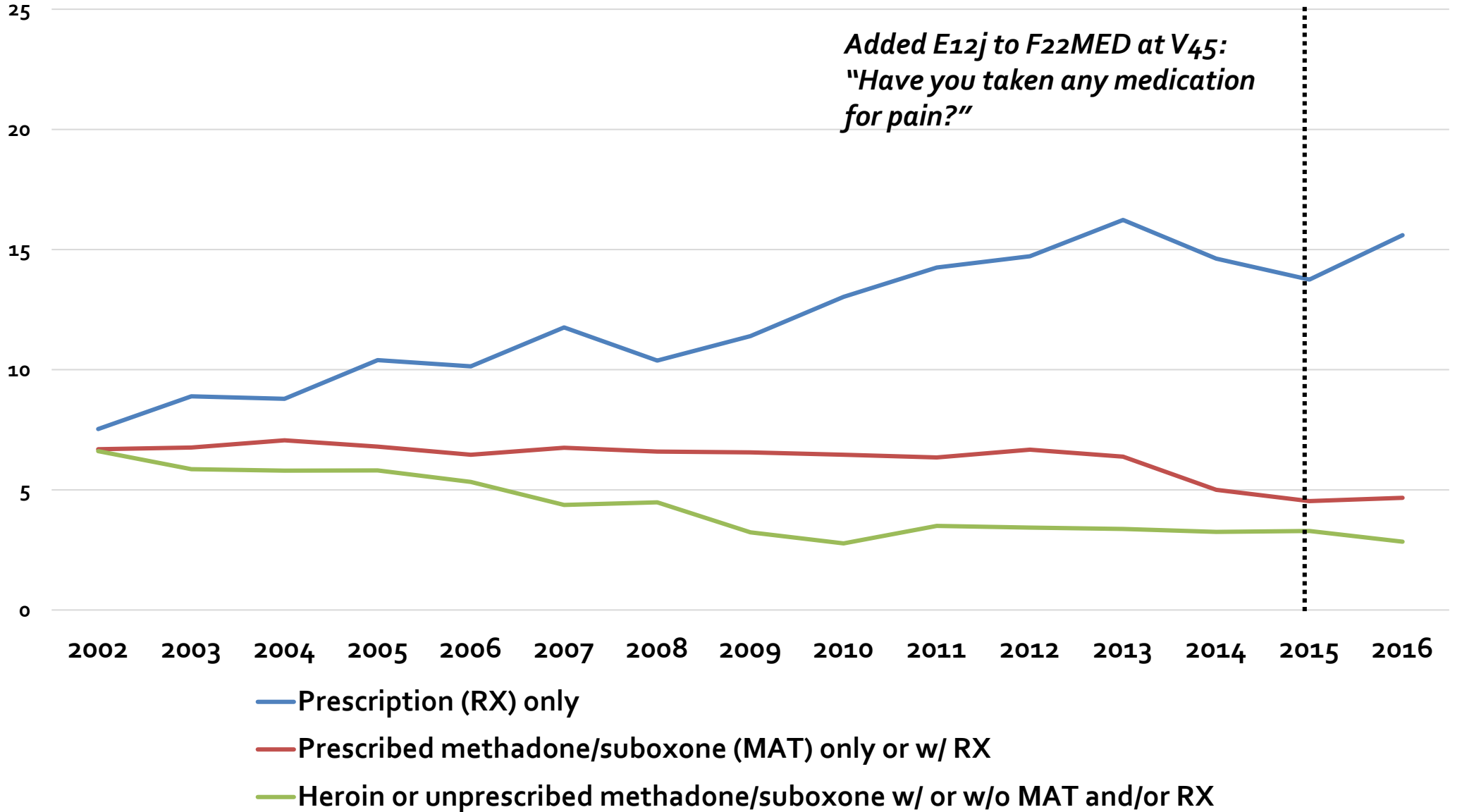
HCV Summary through V47



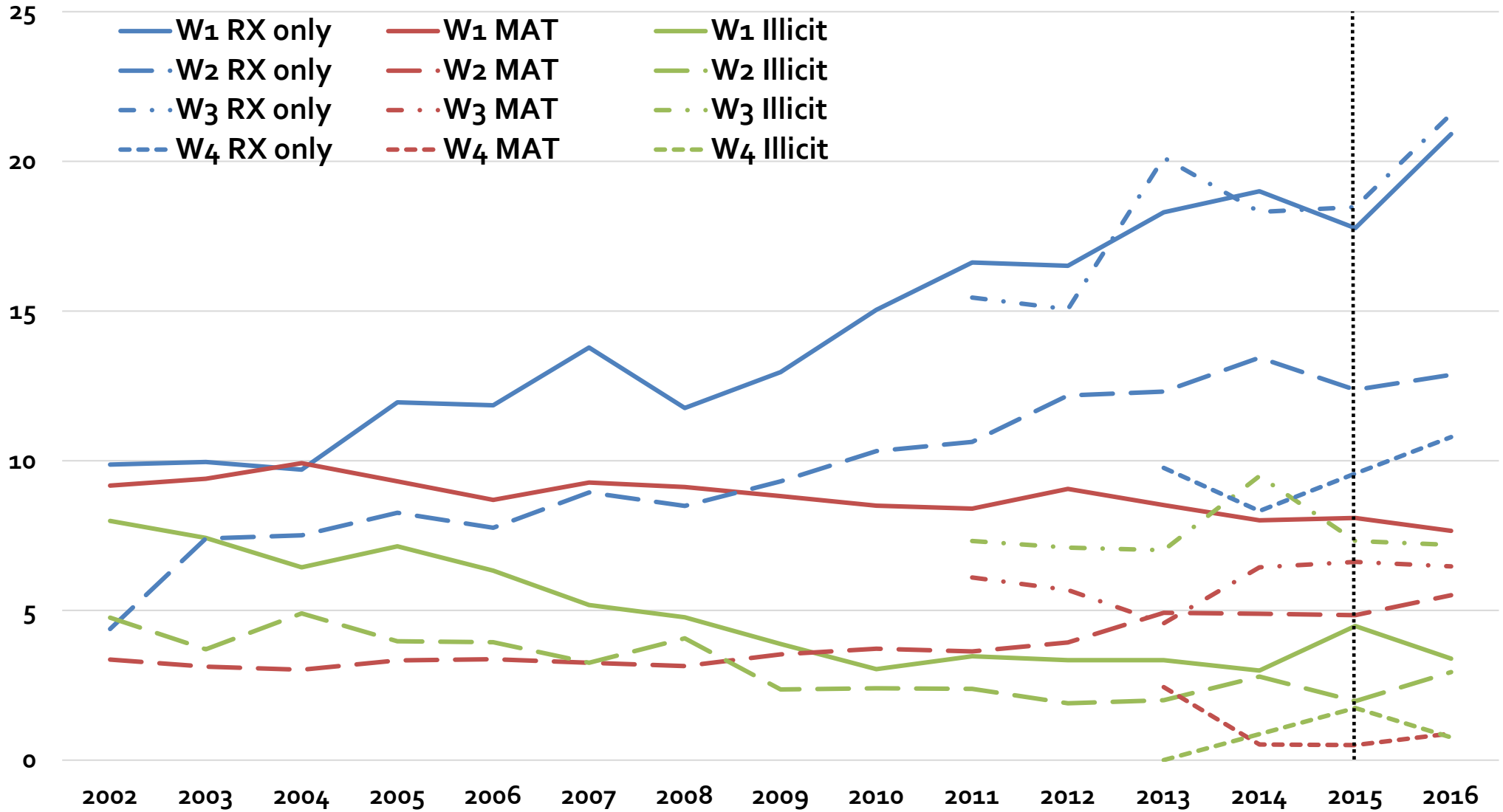
Substance Use

Current Cohort (v46 or v47)		HIV+ N= 1585	HIV- N= 674
Smoking:	Current	36%	44%
	Former	30%	29%
Injection Drug Use:	Current	<1%	1%
	Ever	18%	17%
Non-Injection Drug Use:	Current	25%	32%
	Ever	73%	81%
Recreational Rx Drug Use:	Current	0.7%	2%
Alcohol Use:			
>12 drinks/week		4%	10%
7-12 drinks/week		2%	4%

Prevalence of Opioid Use



Prevalence of Opioid Use



Reproductive Health & Behavior

Current Cohort (v46 or v47)	HIV+ N= 1585	HIV- N= 674
Hormonal contraceptive use (current)	4%	6%
Pregnancy		
Any time during WHS	19%	31%
In past year	1%	3%
Number male sex partners Median (IQR)		
Baseline	10 (5, 30)	12 (6, 40)
Current	1 (0, 1)	1 (0, 1)
Condom use		
No male partners	50%	36%
At least one male partner, always	27%	13%
At least one male partner, sometimes	10%	13%
At least one male partner, never	13%	38%
Self-reported STD*		
Any STD	3%	2%
Multiple STDs	<1%	0%

* Gonorrhea, syphilis, chlamydia, pelvic inflammatory disease, genital herpes, genital warts, or trichomonas

Pregnancies in WIHS

Retrospective Data	HIV+ N= 1911 ^a	HIV- N= 778
# Pregnant women	562 (+6)	350 (+6)
Number of pregnancies	1036 (+10)	879 (+17)
Live births	474 (46%)	370 (42%)
Miscarriages	221 (21%)	174 (20%)
Abortions	280 (27%)	304 (35%)
Other adverse outcomes ^b	58 (6%)	27 (3%)
Other outcomes	3 (<1%)	4 (<1%)
Age at reported pregnancy Median (IQR)	32 (28, 37)	31 (26, 35)
CD4+ Cell Count Median (IQR) ^c	459 (294, 657)	NA
HIV RNA Median (IQR) ^c	810 (<80, 12000)	NA
% on Therapy ^{c,d}	70%	NA

^a Susceptible to pregnancy while on study (sexually active, <46 years, no hyst/tl/ooph). Among active cohort, 123 HIV SN and 165 HIV SP are eligible for pregnancy; ^b Stillbirth or Ectopic Pregnancy; ^c At reported pregnancy, among HIV+ women only; ^d Any therapy at reported pregnancy

WIHS Repository Updates

Summary of WSAC Reviews

- 6,696 (7%) of 95,349 visits are restricted
- 207 requests including VIP specimens
 - 87 all specimens approved
 - 109 selected specimens approved
 - 9 no specimens approved
 - 2 reviews in progress
- 8,446 total VIP specimens requested
 - 7,485 specimens (89%) approved for release

WIHS Central Repository

DAIDS National Repository

Precision BioServices

Frederick, Maryland

Committed Specimens

As of 10/4/2018

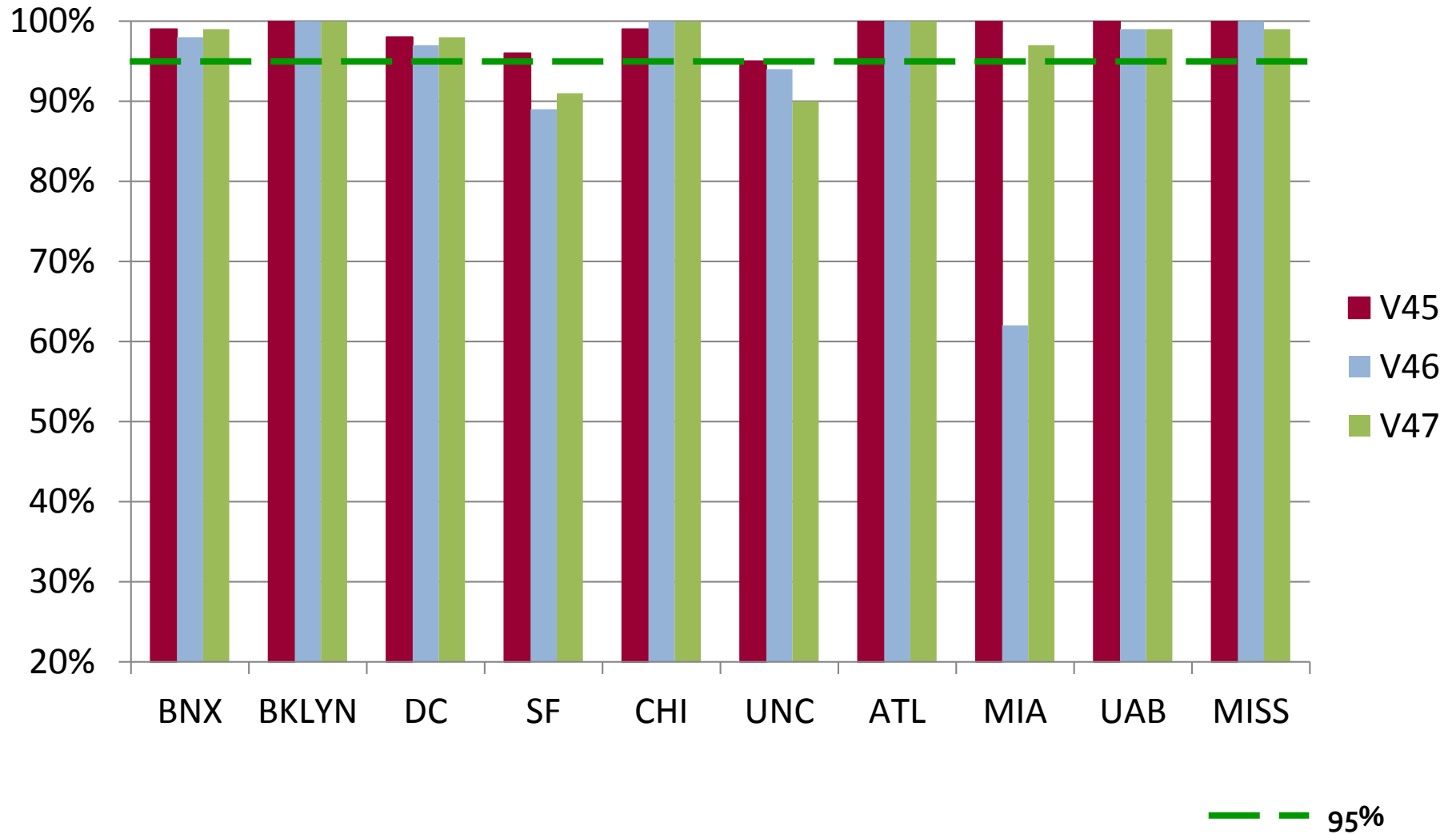
Total ever	3,243,248 (↑3%)
Not Available	354,727
Shipped	349,163 (↑2%)
	11% utilization
To be Shipped ^a	3
Unusable ^b	5,561 (↓0.1%)
Incoming Temp Storage	0
Currently Available	2,888,521



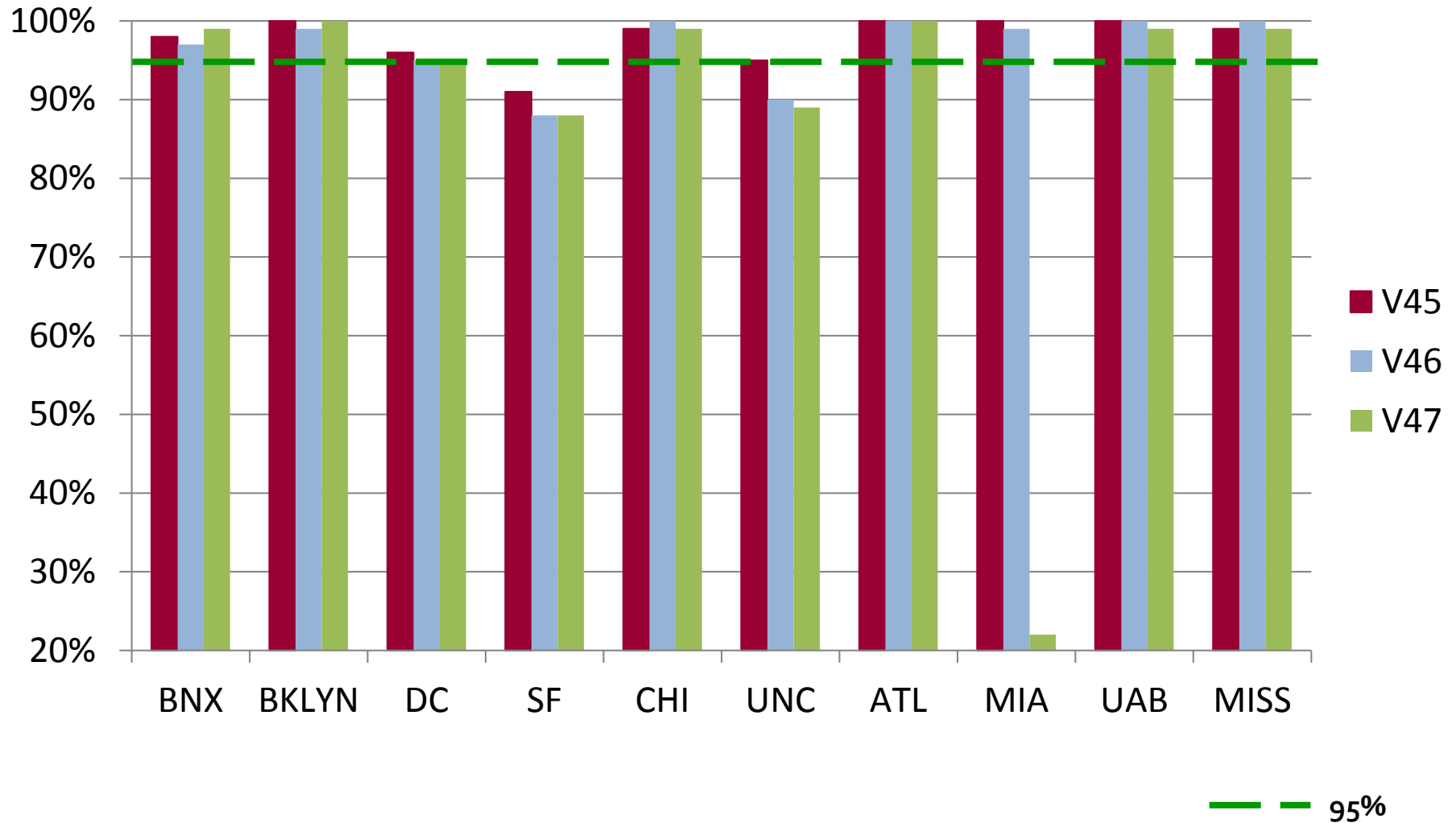
^a Less than four weeks since submitted for withdrawal

^b Discrepant, destroyed, broken, empty, lost, or missing

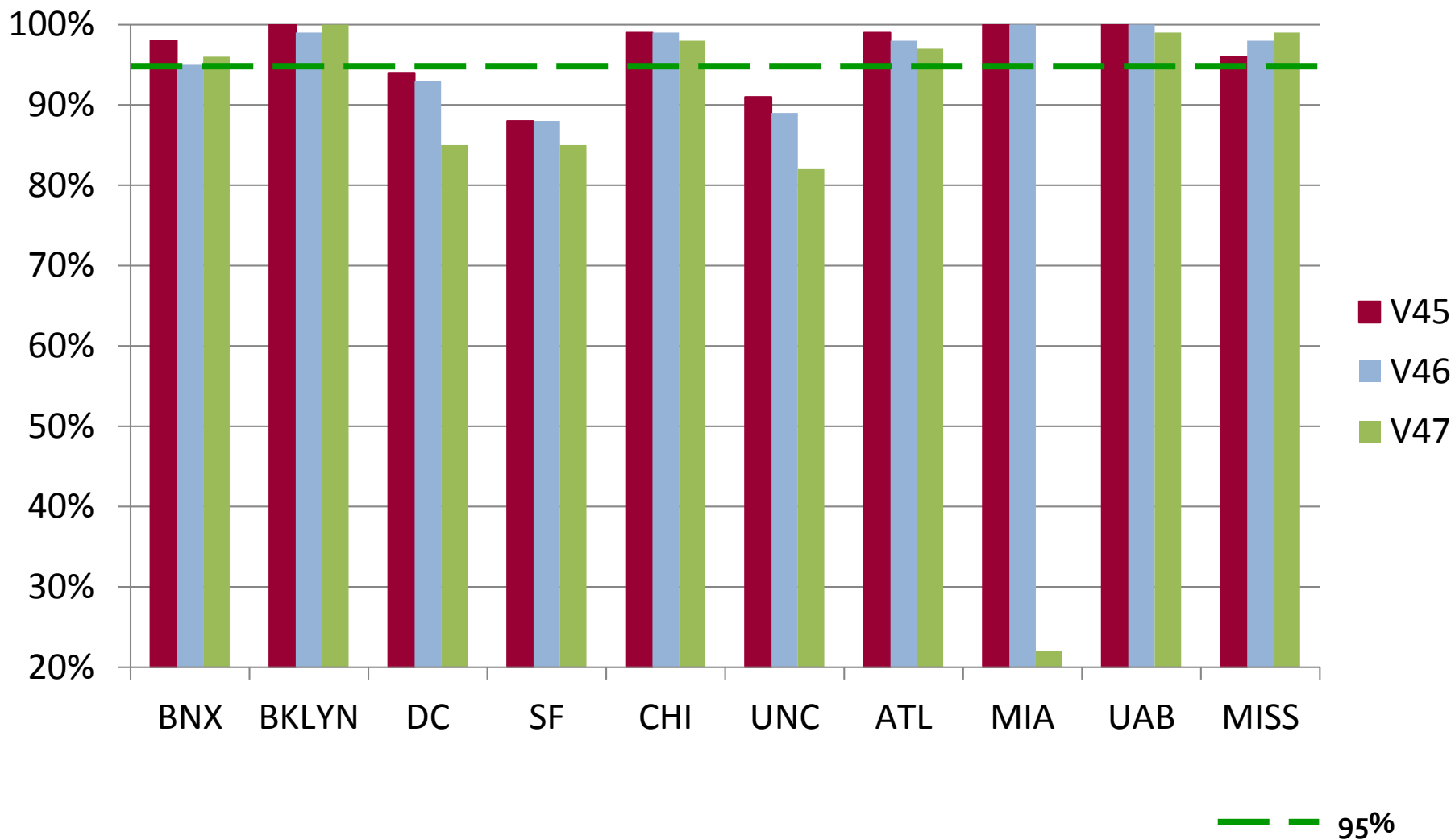
% of Expected Person-Visits with Committed Vials of Serum



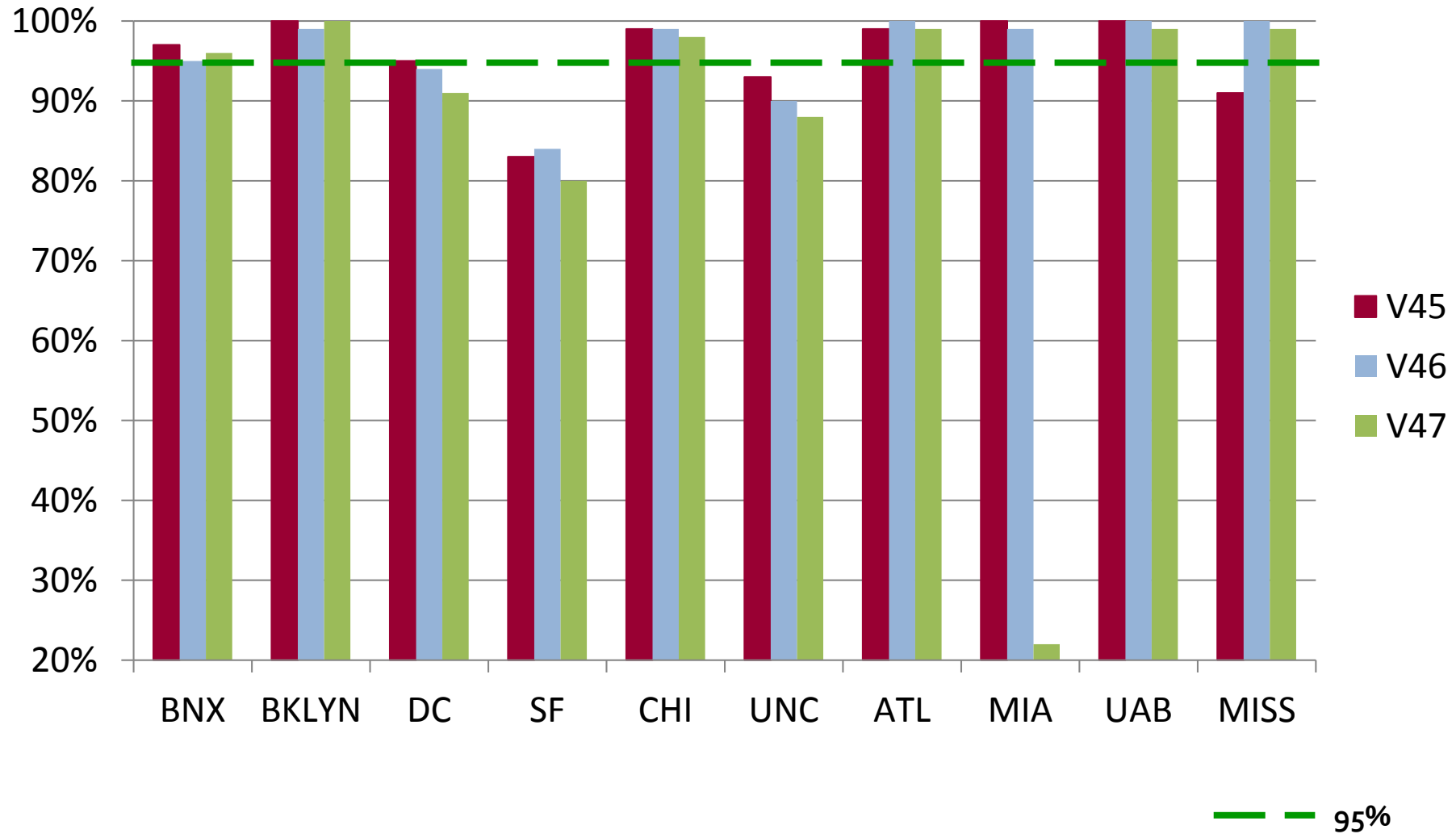
% of Expected Person-Visits with Committed Vials of Plasma



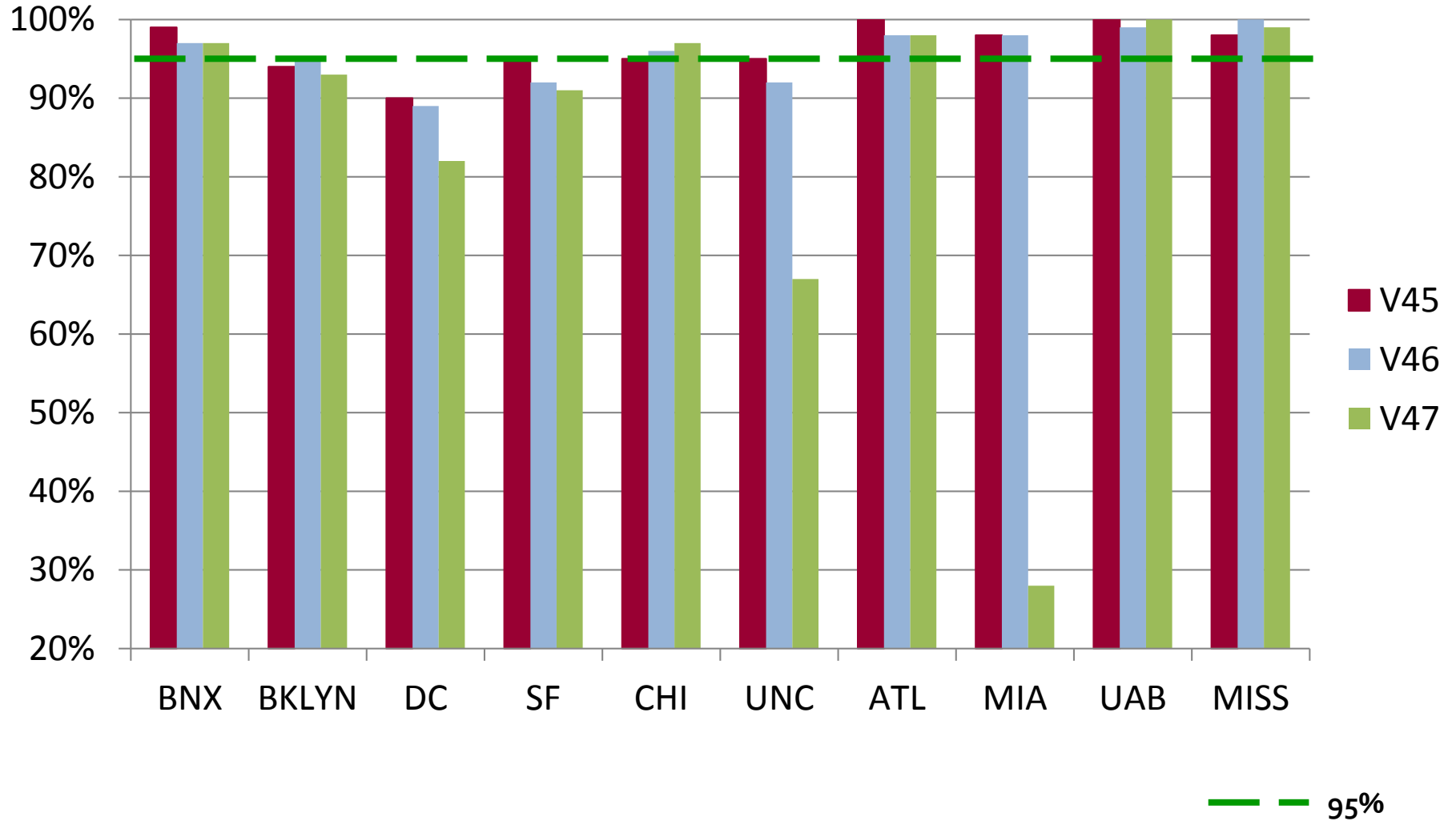
% of Expected Person-Visits with Committed Vials of Cells



% of Expected Person-Visits with Committed Vials of Cell Pellets



% of Expected Person-Visits with Committed Vials of CVL



Precision Bioservices Requests Shipped (1) to Investigators (9/28/2017 – 10/4/2018)

Readme	Investigator	Research Type	Specimen Type(s)	Total
W05050	Aouizerat	Genomics	CPT cells	191
W08013	Greenblatt	Sex Steroid	Serum	731
W10012	Aouizerat	Genomics	CPT cells	61
W12050	Augenbraun	Pathogenesis	CPT plasma	153
W13011	Shlipak	Renal	Urine supernatant	1,294
W14012	Colie	HPV	CVL	376
W14027	Seaberg	HCV RNA	Serum	135
W14054	Dittmer	Cancer/Path	CPT cell pellets	27
W14098	Price	Metabolic	CPT plasma, serum	16

Total Shipped: 6,671

Precision Bioservices Requests Shipped (2) to Investigators (9/28/2017 – 10/4/2018)

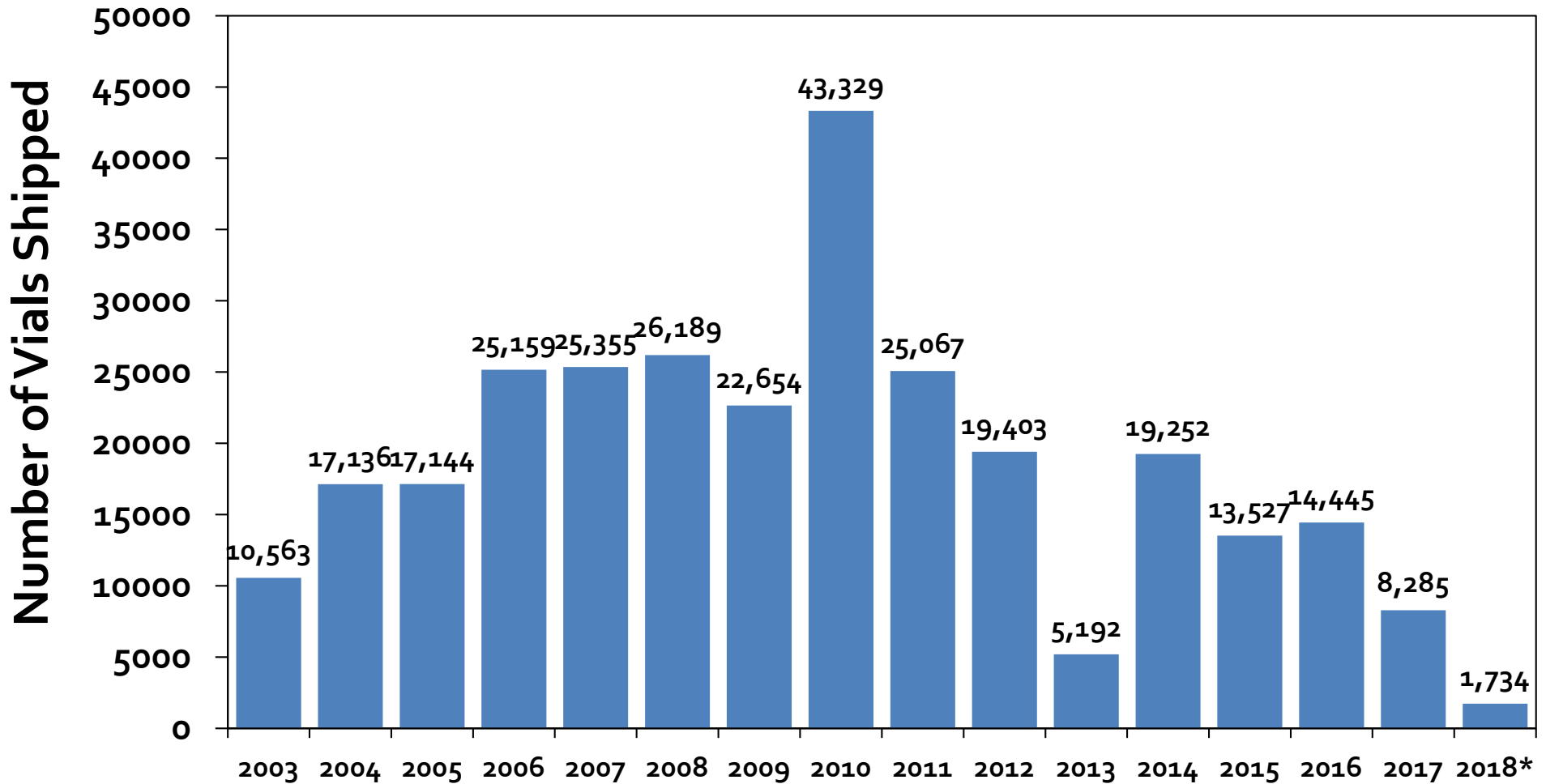
Readme	Investigator	Research Type	Specimen Type(s)	Total
W15021	Nekhai	Pathogenesis	CPT cell pellets	2,175
W15037	Faria de Oliveira	Behavioral	CPT cells	54
W15040	French	HCV RNA	Serum	228
W15058	Herold	Pathogenesis	CPT cells & plasma	44
W16021	Ley	Metabolic	CPT cells	67
W16026	Kovacs/Tien	HCV	Serum	341
W16054	Qi	CVD	Serum	193
W16058	Jao	Metabolic	Serum	22
W16066	D'Souza	HPV	Serum	62

Total Shipped: 6,671

Precision Bioservices Requests Shipped (3) to Investigators (9/28/2017 – 10/4/2018)

Readme	Investigator	Research Type	Specimen Type(s)	Total
W17029	Shivakoti	Pathogenesis	EDTA plasma	21
W17031	Rubin	Neurocog	CPT plasma	240
W17048	Shrestha	Genomics	CPT cells	20
W17054	Lee	Genomics	CPT cells	61
W18007	Tien	HCV	Serum	15
W18042	Tremblay	Metabolic	CPT cells	144

Vials Shipped from Precision Bioservices, 2003-2018



* 2018 includes shipments through 10/17/2018

