

HPTN 083 Final Results:

Pre-exposure Prophylaxis containing long-acting injectable cabotegravir is safe and highly effective for cisgender men and transgender women who have sex with men

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Authors

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for the HPTN 083 Study Team**

Disclosures

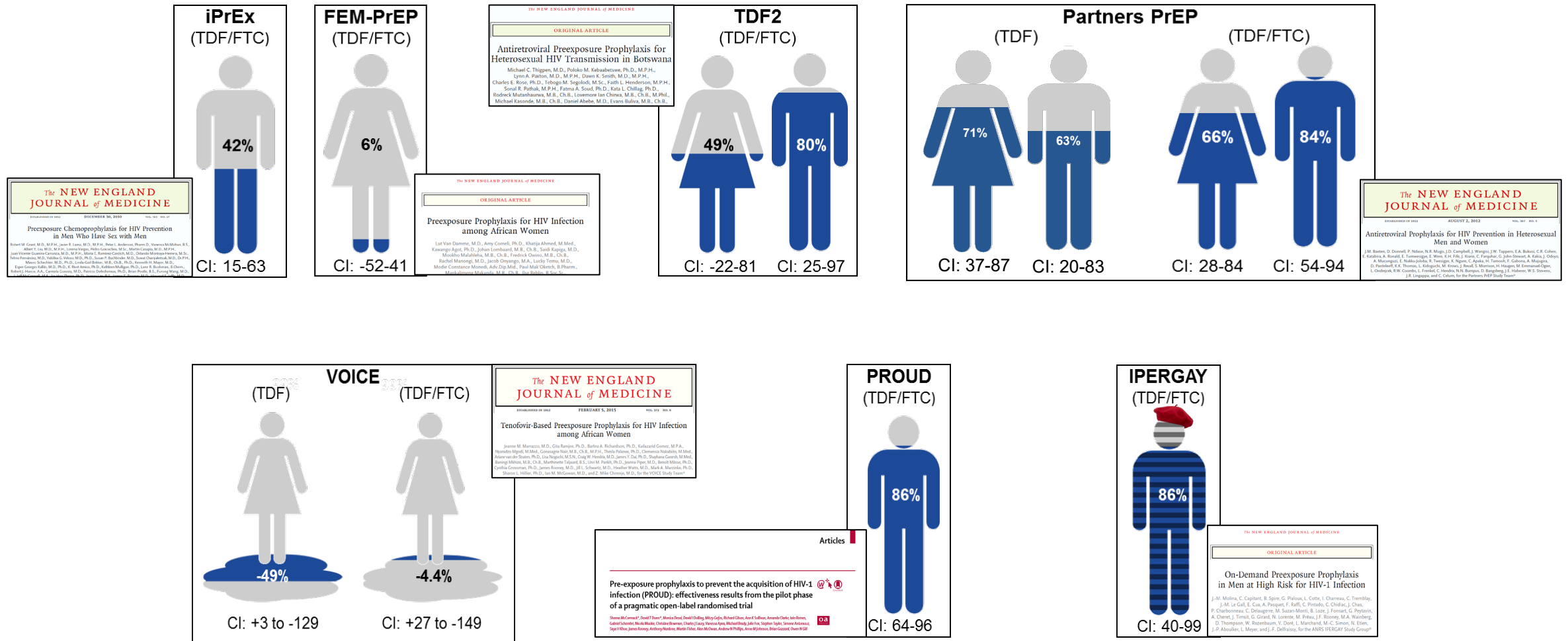
Raphael J. Landovitz has served as on scientific advisory boards for Gilead Sciences and Merck Inc, and has received honoraria from Roche, Inc.



Today's Agenda

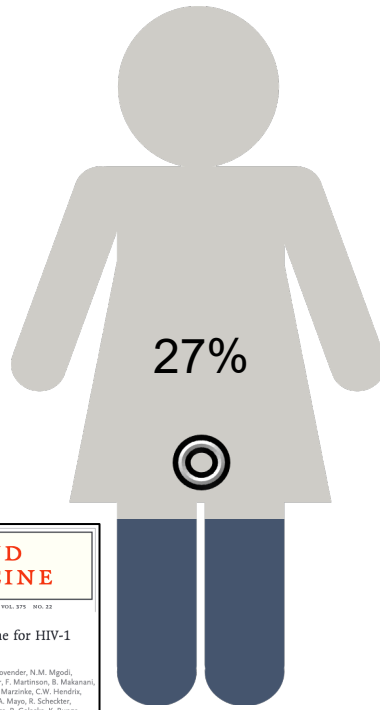
- **PrEP Background and Context**
- **HPTN 083 Study Design**
- **Statistical Methods**
- **Results**
 - **Population**
 - **HIV Incidence**
 - **Safety**
 - **Details of seroconversion events**
 - **Additional outcomes of interest**
- **Ongoing analyses**
- **Conclusions**

Effectiveness of TDF/FTC in Placebo-Controlled Clinical Trials



“PrEP 2.0”: Trials of Novel PrEP Agents

ASPIRE (Dapivirine)



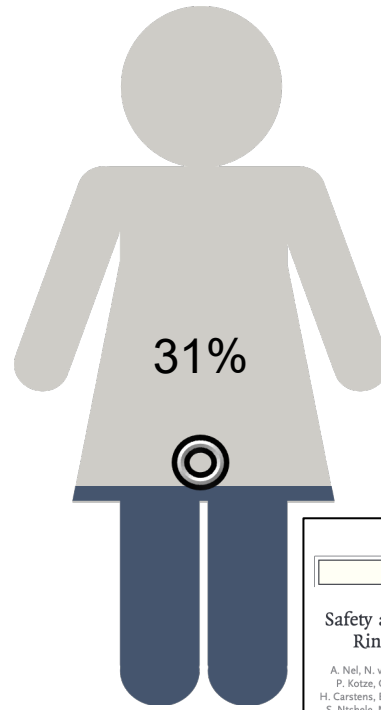
CI: 1 – 46

**The NEW ENGLAND
JOURNAL of MEDICINE**
ESTABLISHED IN 1812 DECEMBER 1, 2016 VOL. 375 NO. 22

Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women

J.M. Baeten, T. Palanee-Phillips, E.R. Brown, K. Schwartz, L.E. Soto-Torres, V. Govender, N.M. Mgodli, F. Maitso Kweema, G. Nair, F. Mhlanga, S. Siva, L.-G. Bekker, N. Jeenaarain, Z. Gaffoor, F. Martinson, B. Makani, A. Palheb, L. Naidoo, M. Hranik, B.A. Richardson, L.M. Parulek, J.W. Mellors, M.A. Marone, C.W. Hendrix, A. van der Straten, G. Ramjee, Z.M. Chirenje, C. Nakabwire, T.E. Taha, J. Jones, A. Mayo, R. Schacter, J. Barhanna, E. Lyant, C. Jacobson, P. Nkase, R. White, K. Peterson, D. Gormiga, R. Galaska, K. Rungu, D. Singh, D.W. Steidle, E.T. Montgomery, B.S. Mensch, K. Torgesen, C.I. Grossman, N. Chaboua, A. Nel, Z. Rosenberg, I. McGowan, and S. Hillier, for the MTN-025-ASPIRE Study Team*

Ring (Dapivirine)



CI: 1 – 51

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

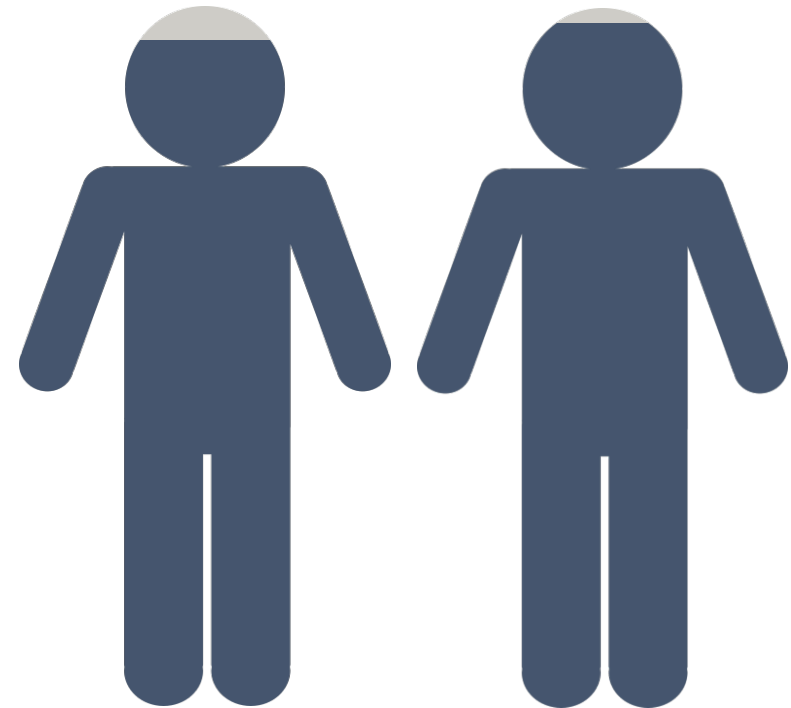
Safety and Efficacy of a Dapivirine Vaginal Ring for HIV Prevention in Women

A. Nel, N. van Niekerk, S. Kapiga, L.-G. Bekker, C. Gama, K. Gill, A. Kamali, P. Kotze, C. Louw, Z. Mabude, N. Miti, S. Kusemererwa, H. Tempelman, H. Carstens, B. Devlin, M. Isaacs, M. Malherbe, W. Mans, J. Nuttall, M. Russell, S. Ntshole, M. Smit, L. Solai, P. Spence, J. Steytler, K. Windle, M. Boremans, S. Ressler, J. Van Rooy, W. Parys, T. Vangeneugden, B. Van Baelen, and Z. Rosenberg, for the Ring Study Team*

DISCOVER

(TDF/FTC)

(TAF/FTC)



Incidence rate
0.30%

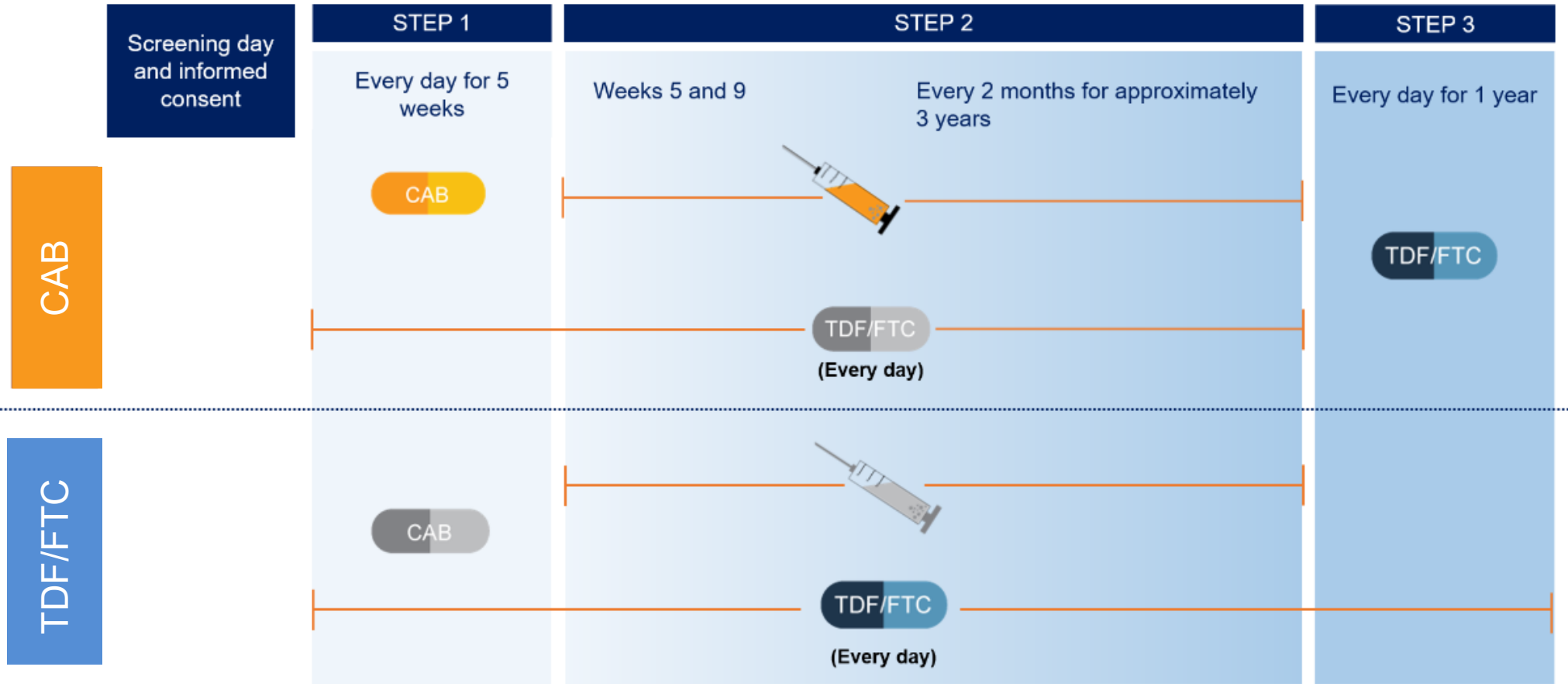
Incidence rate
0.16%

HPTN 083 Study Design

- **Phase 2b/3 randomized, double-blind, double-dummy @ 43 sites globally**
 - **MSM/TGW age 18+**
 - **Risk: any nCRAI, >5 partners, stimulant drug use, incident rectal or urethral STI (or incident syphilis) in past 6 months; or SexPro Score ≤ 16 (US only)**
 - **Generally good health**
 - **No HBV or HCV**
 - **No contraindication to gluteal injections, seizures, gluteal tattoos/skin conditions**
- **Planned enrollment 5000**
 - **$\geq 50\%$ under age 30**
 - **$\geq 10\%$ TGW**
 - **$\geq 50\%$ of US enrollment Black**
- **Primary efficacy endpoint: Incident HIV infections during blinded comparison**
- **Primary safety endpoint: G2 or higher clinical and laboratory AEs**

Please see Grinsztejn B. et al,
Abstract #OACLB0101

HPTN 083 Study Design



 TDF/FTC pill
  Cabotegravir (CAB) injection
  Placebo for TDF/FTC pill
  Placebo for cabotegravir (CAB) injection (20% Intralipid solution)

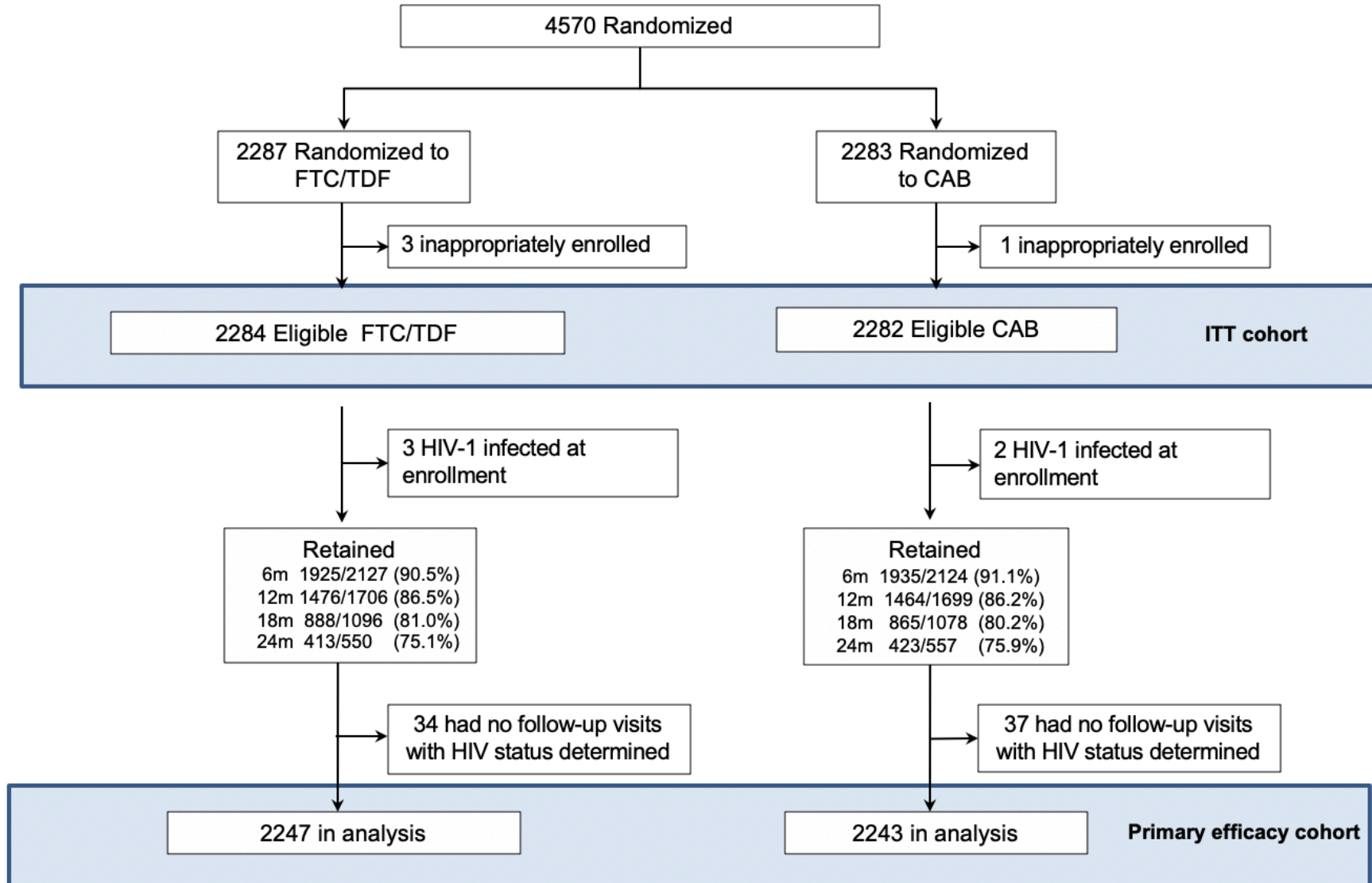
 Cabotegravir (CAB) pill
  Placebo for cabotegravir (CAB) pill



Statistical Design: Efficacy

- **Non-inferiority design**
 - **Non-inferiority margin 1.23**
 - **Alternative hypothesis of HR 0.75**
 - **Target background HIV Incidence ~4.5%**
 - **Anticipated TDF/FTC adherence by TFV plasma detectable ~57%**
- **Endpoint-driven (172 events) with pre-specified interim analyses at 25%, 50%, and 75% of endpoints**
 - **O'Brien-Fleming stopping boundaries for interim data analysis used to determine early stopping metrics**
- **DSMB recommended termination of blinded study after interim analysis on May 14, 2020 (25% endpoints accrued) for crossing pre-specified stopping bound**
- **Results include events occurring through May 14, 2020; participants unblinded, continuing on study**
 - **All to be offered CAB as soon as available at sites**

Participant Disposition



Study Population

	TOTAL (n=4566)	TDF-FTC (n=2284)	CAB (n=2282)
Gender Identity, n (%)			
MSM	3995 (87.5)	1981 (86.7)	2014 (88.3)
TGW	567 (12.4)	302 (13.2)	265 (11.6)
Age, median (IQR)			
	26 (22, 32)	26 (22, 32)	26 (22, 32)
Age, n (%)			
18-29	3079 (67.4)	1508 (66.0)	1571 (68.8)
30-39	1049 (23)	550 (24.1)	499 (21.9)
40-49	315 (6.9)	170 (7.4)	145 (6.4)
50-59	110 (2.4)	50 (2.2)	60 (2.6)
≥60	13 (0.3)	6 (0.3)	7 (0.3)
Region, n (%)			
United States	1698 (37.2%)	849 (37.2%)	849 (37.2%)
Latin America	1964 (43.0%)	984 (43.2%)	980 (42.9%)
Asia	752 (16.5%)	377 (16.5%)	375 (16.5%)
Africa	152 (3.3%)	74 (3.2%)	78 (3.4%)
Education, n (%)			
Post-Secondary (YES)	3477 (76.1)	1715 (75.1)	1762 (77.2)
Relationship Status, n (%)			
Single (YES)	3750 (82.1)	1863 (81.6)	1887 (82.7)

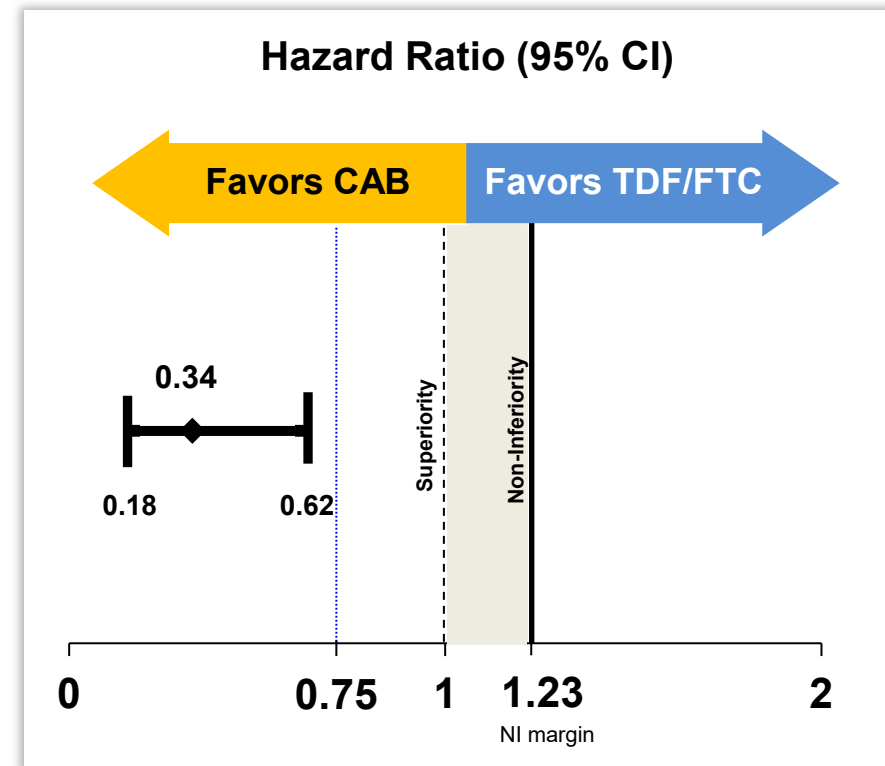
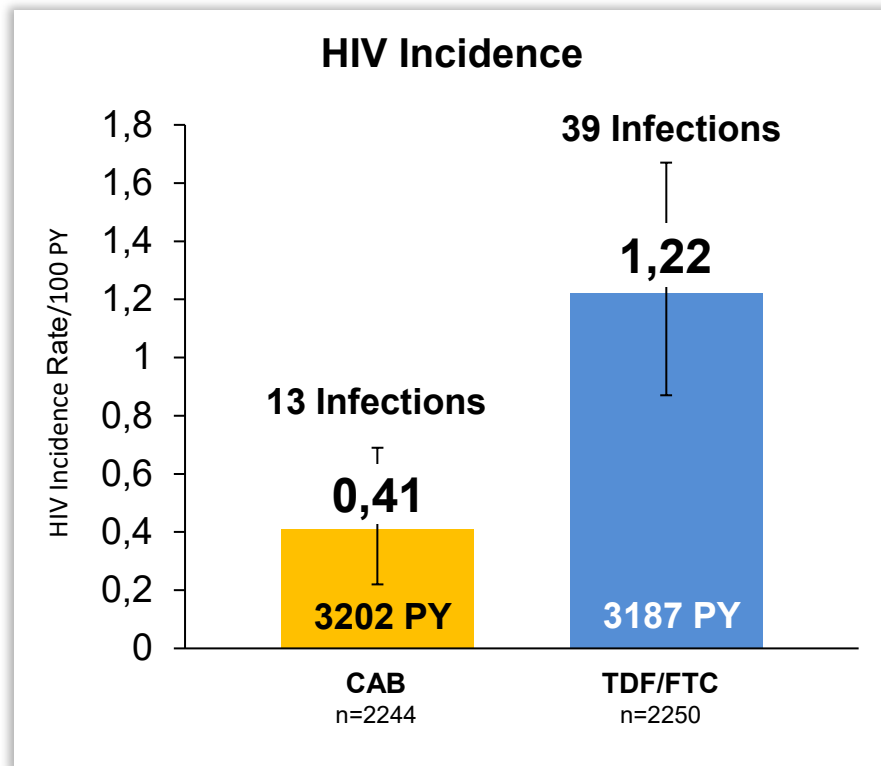
Study Population

	TOTAL (n=4566)	TDF-FTC (n=2284)	CAB (n=2282)
Race, n (%)			
United States			
Black/African American	844 (49.7)	433 (51.0)	411 (48.9)
White/Asian/Native/Other	854 (50.4)	416 (49.0)	438 (51.1)
Latin America			
Black/Afro-Caribbean	395 (20.1)	196 (19.9)	199 (20.3)
Native	858 (43.7)	425 (43.2)	433 (44.2)
White/Asian/Other	711 (59.6)	363 (36.8)	348 (35.5)
Asia			
Asian	749 (99.6)	375 (99.5)	374 (99.7)
Other	3 (0.4)	2 (0.5)	1 (0.3)
Africa			
Black	119 (78.3)	57 (77.0)	62 (79.5)
Other	5 (3.3)	3 (4.1)	2 (2.6)
Ethnicity, n (%)			
United States: Latinx	303(17.8)	154 (18.1)	149 (17.6)
Latin America: Latinx	1805 (91.9)	912 (92.7)	893 (91.1)

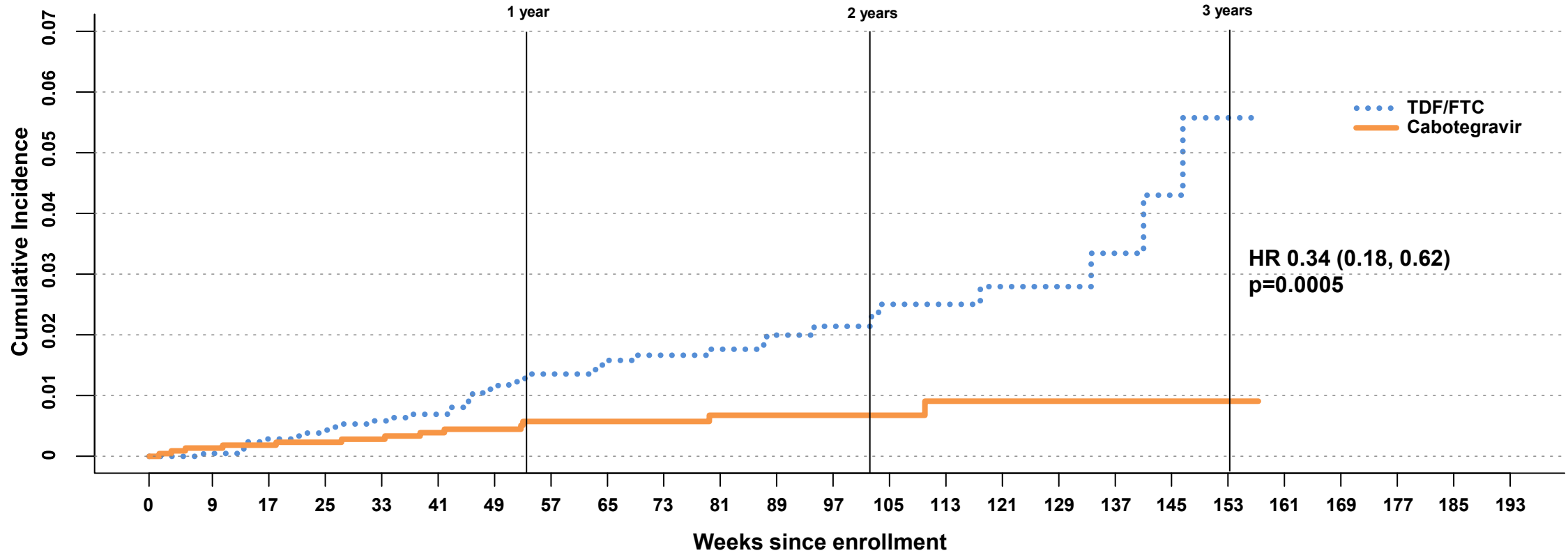
HIV Incidence

CAB vs. TDF/FTC

52 HIV infections in 6389 PY of follow-up
1.4 (IQR 0.8-1.9) years median per-participant follow-up
Pooled incidence 0.81 (95%CI 0.61-1.07) per 100 PY



HIV Incidence – ITT



Number at risk

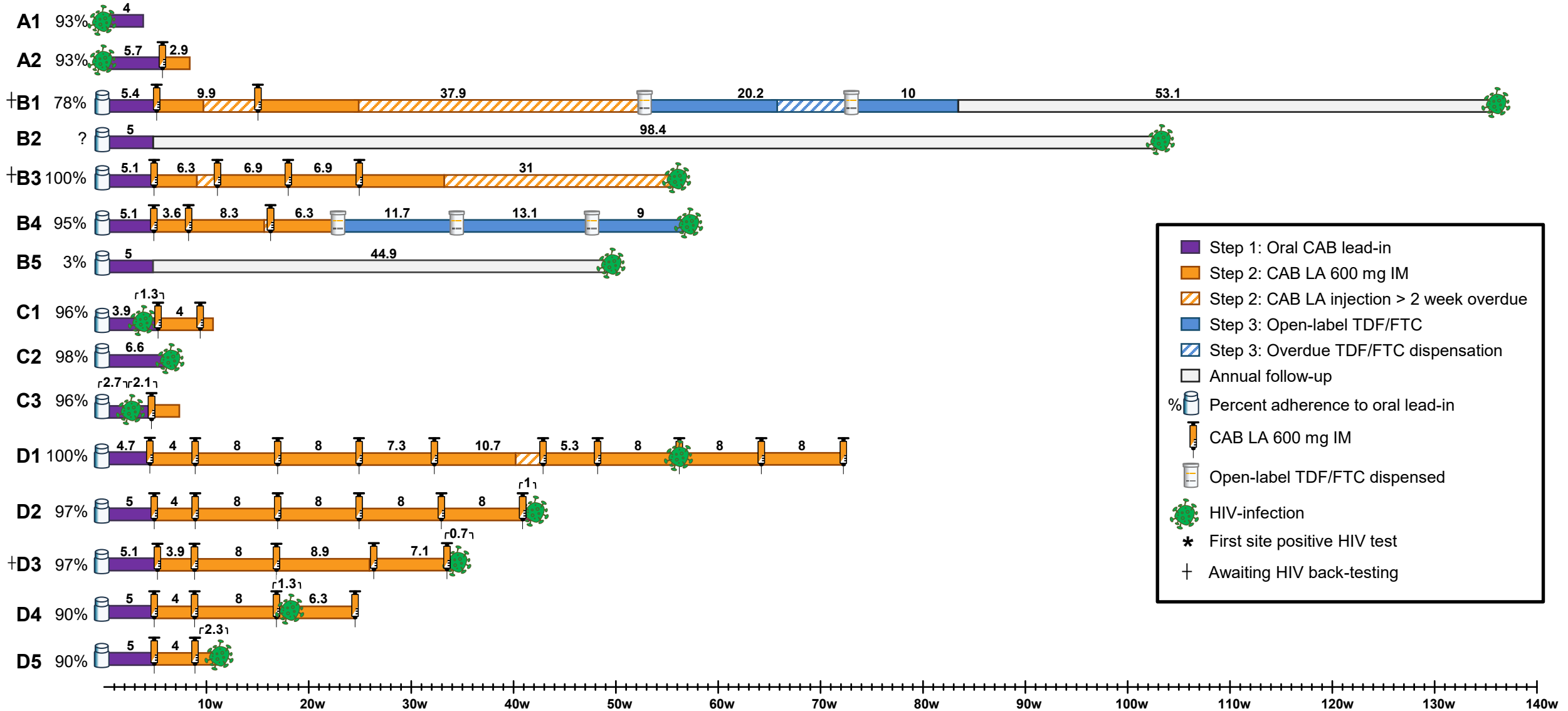
TDF/FTC	2247	2133	2081	2019	1913	1764	1624	1494	1294	1132	965	816	643	516	400	310	230	149	85	33	0	0	0	0	0
Cabotegravir	2243	2138	2092	2032	1921	1776	1632	1488	1312	1119	957	795	644	503	401	318	243	172	111	42	0	0	0	0	0

Cumulative number of events

TDF/FTC	0	1	6	8	12	14	22	25	27	29	30	32	33	35	35	36	36	37	38	39	0	0	0	0	0
Cabotegravir	0	3	4	5	6	8	9	11	11	11	12	12	12	12	13	13	13	13	13	13	0	0	0	0	0

13 Incident HIV Infections

Cabotegravir



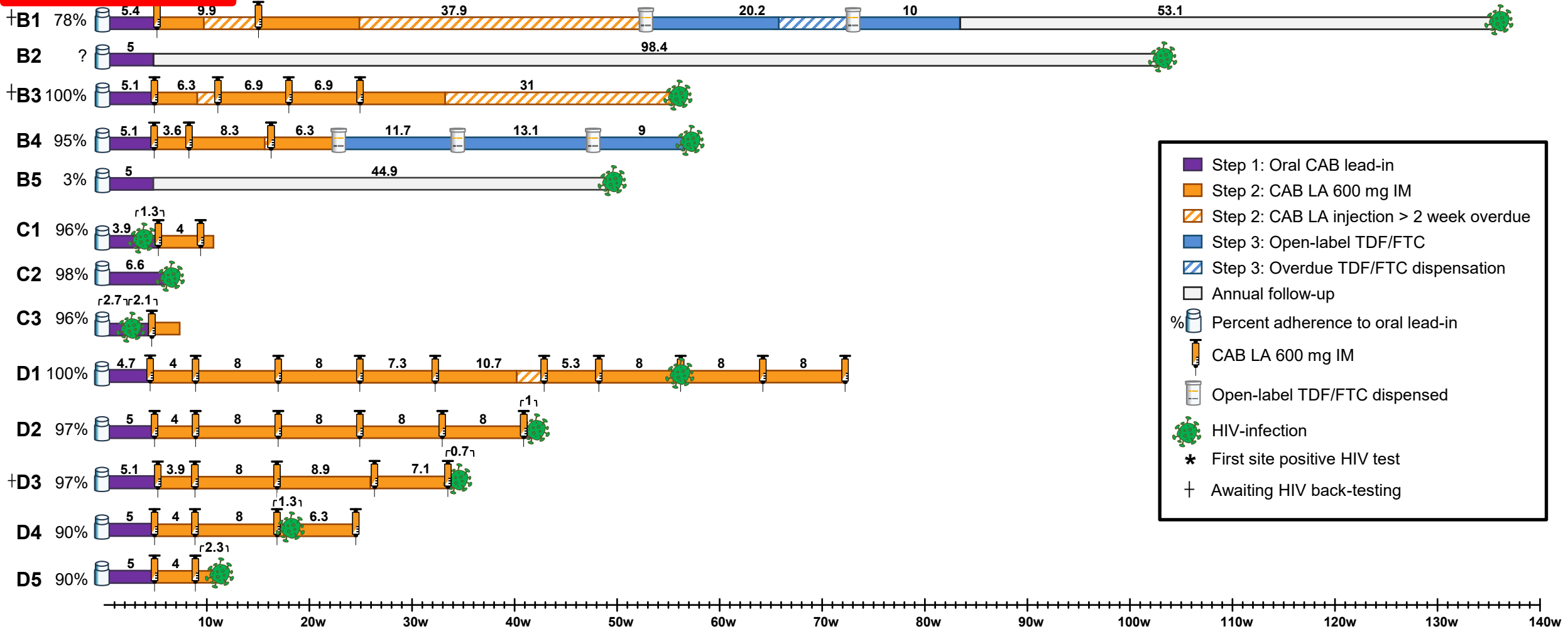
- Step 1: Oral CAB lead-in
- Step 2: CAB LA 600 mg IM
- Step 2: CAB LA injection > 2 week overdue
- Step 3: Open-label TDF/FTC
- Step 3: Overdue TDF/FTC dispensation
- Annual follow-up
- % Percent adherence to oral lead-in
- CAB LA 600 mg IM
- Open-label TDF/FTC dispensed
- HIV-infection
- * First site positive HIV test
- + Awaiting HIV back-testing

13 Incident HIV Infections

Cabotegravir

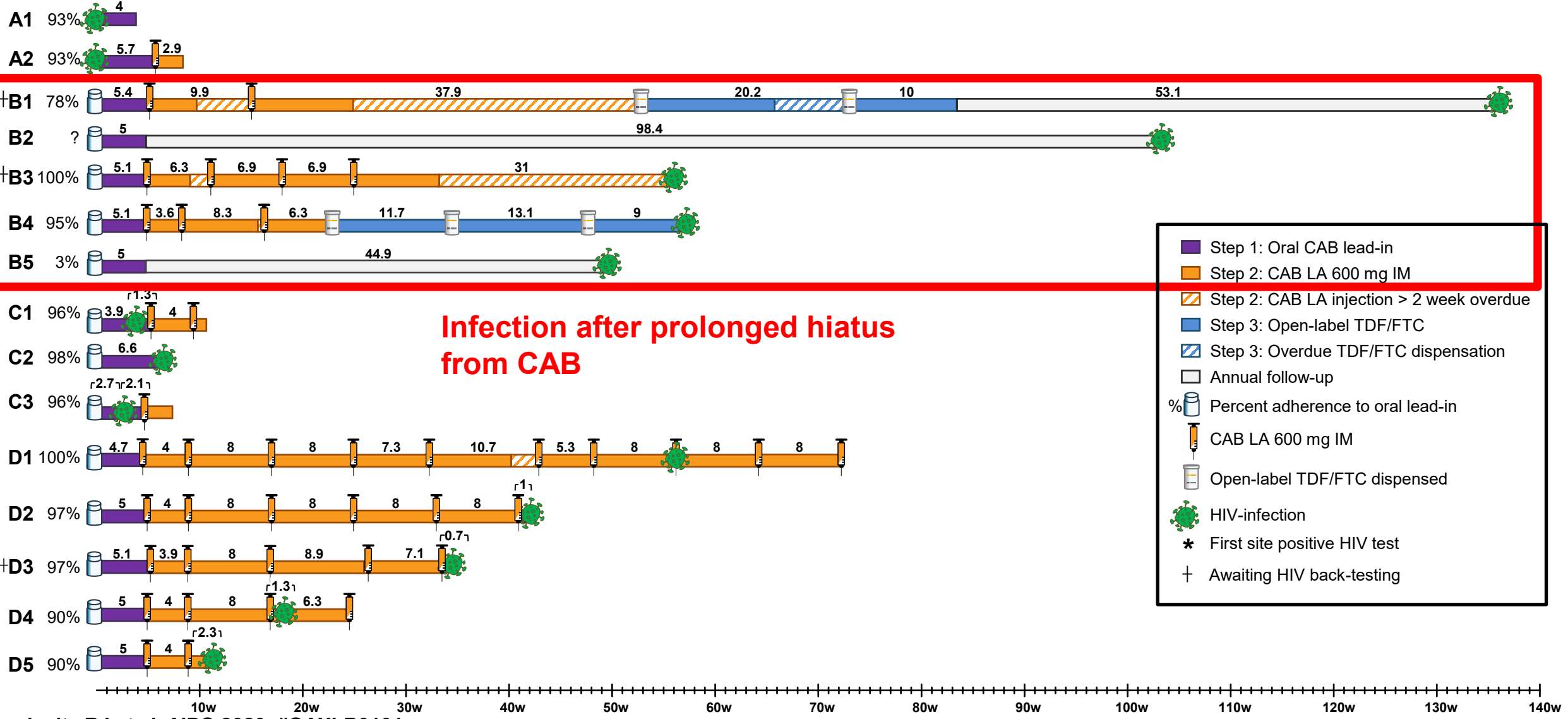
Infection prior to administration of study product

A1 93%
A2 93%



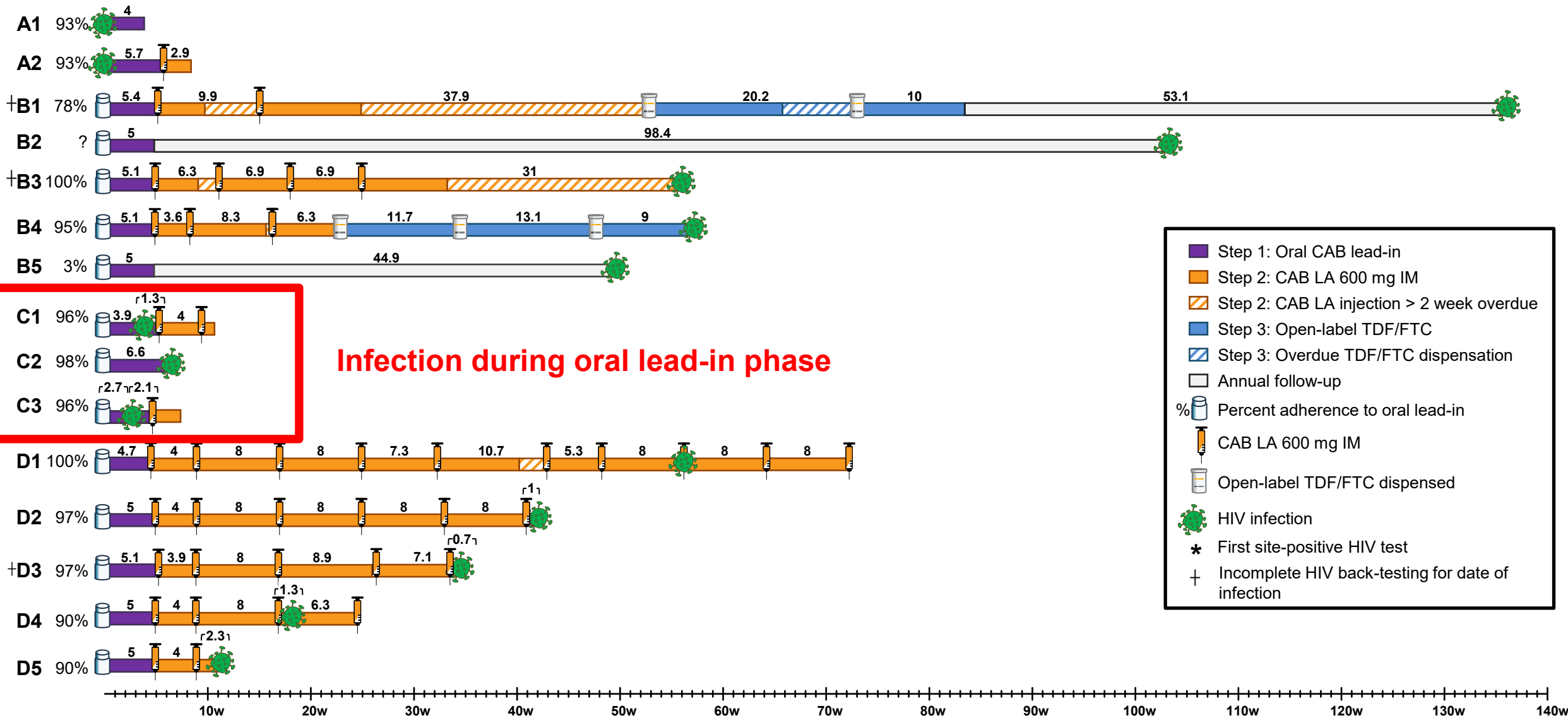
13 Incident HIV Infections

Cabotegravir



13 Incident HIV Infections

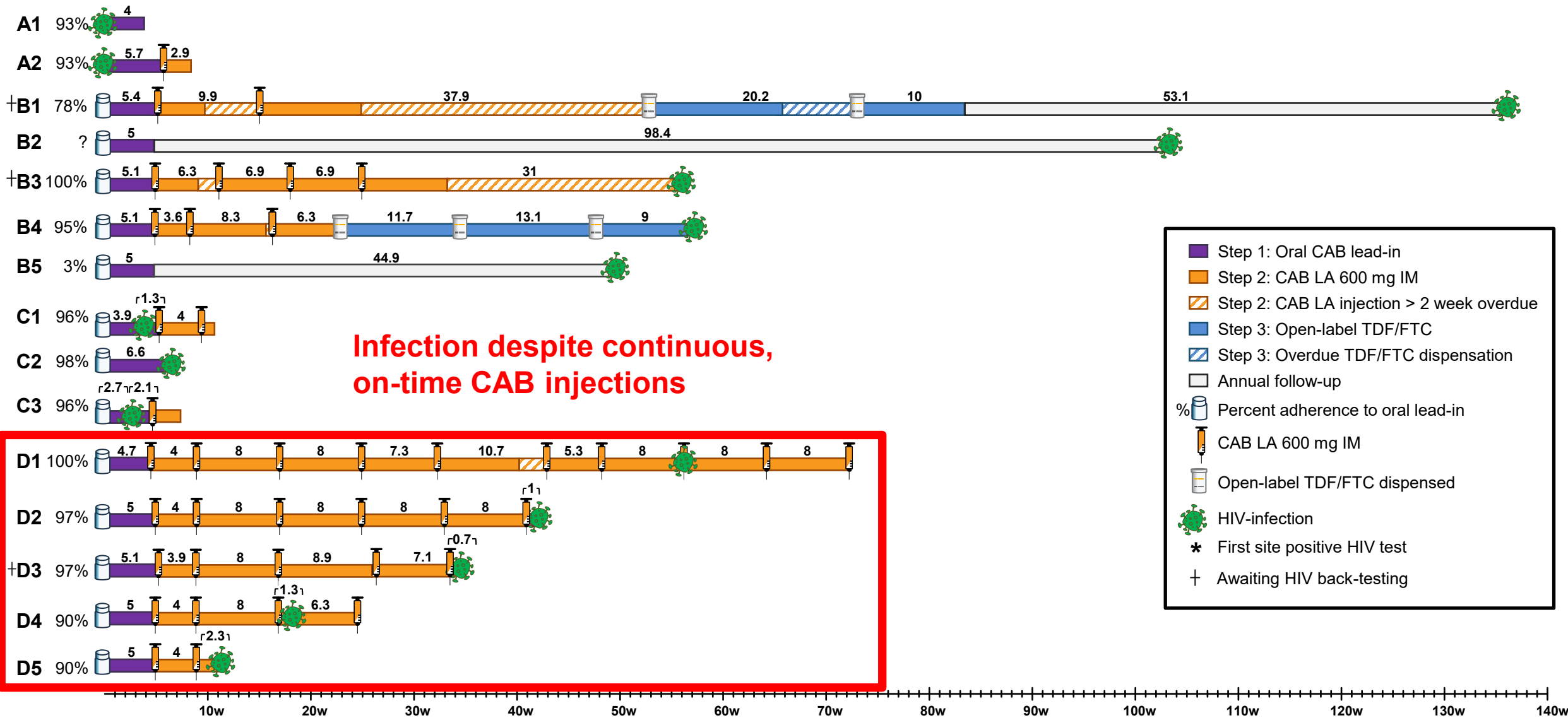
Cabotegravir



- Step 1: Oral CAB lead-in
- Step 2: CAB LA 600 mg IM
- Step 2: CAB LA injection > 2 week overdue
- Step 3: Open-label TDF/FTC
- Step 3: Overdue TDF/FTC dispensation
- Annual follow-up
- % Percent adherence to oral lead-in
- CAB LA 600 mg IM
- Open-label TDF/FTC dispensed
- HIV infection
- * First site-positive HIV test
- + Incomplete HIV back-testing for date of infection

13 Incident HIV Infections

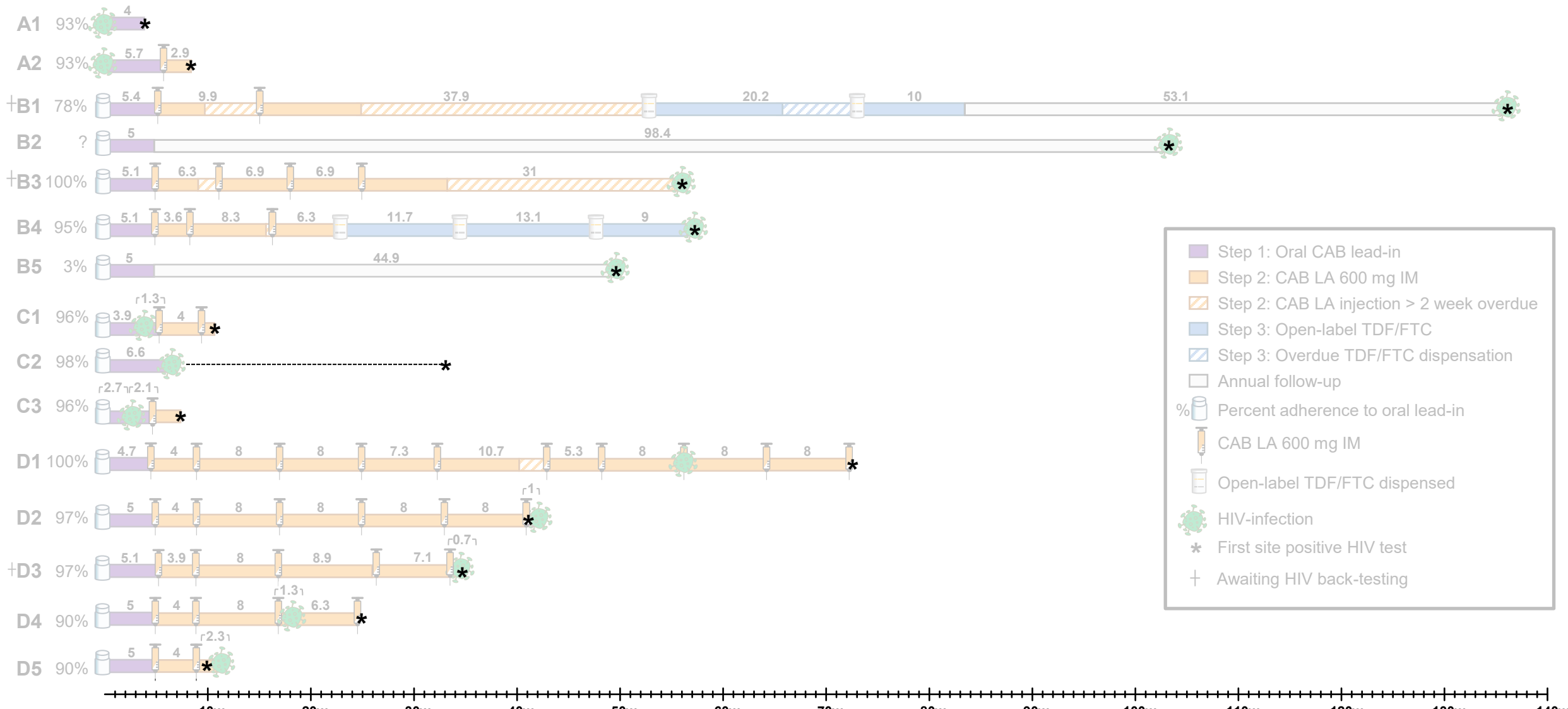
Cabotegravir



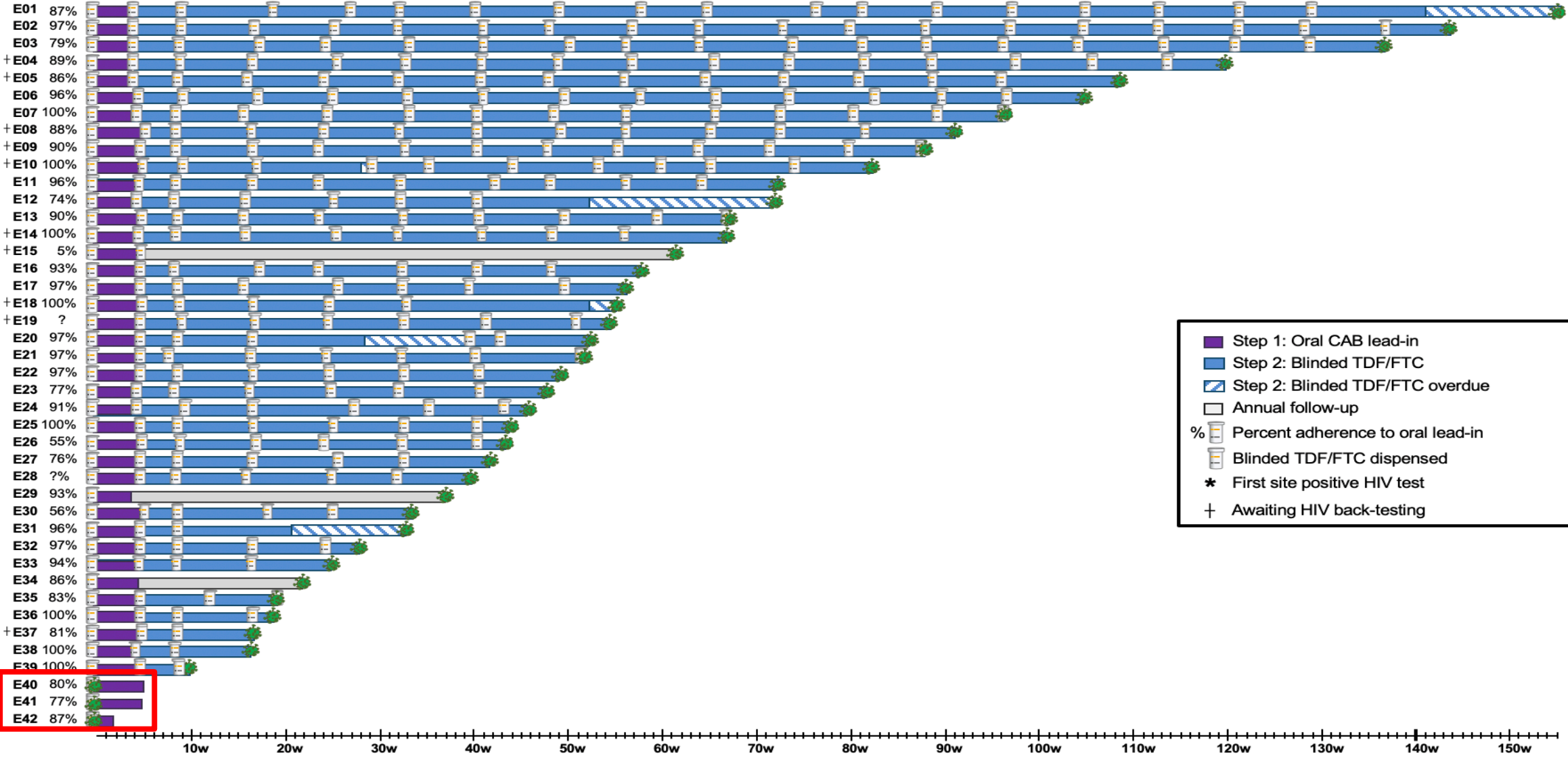
- Step 1: Oral CAB lead-in
- Step 2: CAB LA 600 mg IM
- Step 2: CAB LA injection > 2 week overdue
- Step 3: Open-label TDF/FTC
- Step 3: Overdue TDF/FTC dispensation
- Annual follow-up
- % Percent adherence to oral lead-in
- CAB LA 600 mg IM
- Open-label TDF/FTC dispensed
- 🦠 HIV-infection
- * First site positive HIV test
- + Awaiting HIV back-testing

13 Incident HIV Infections

Cabotegravir



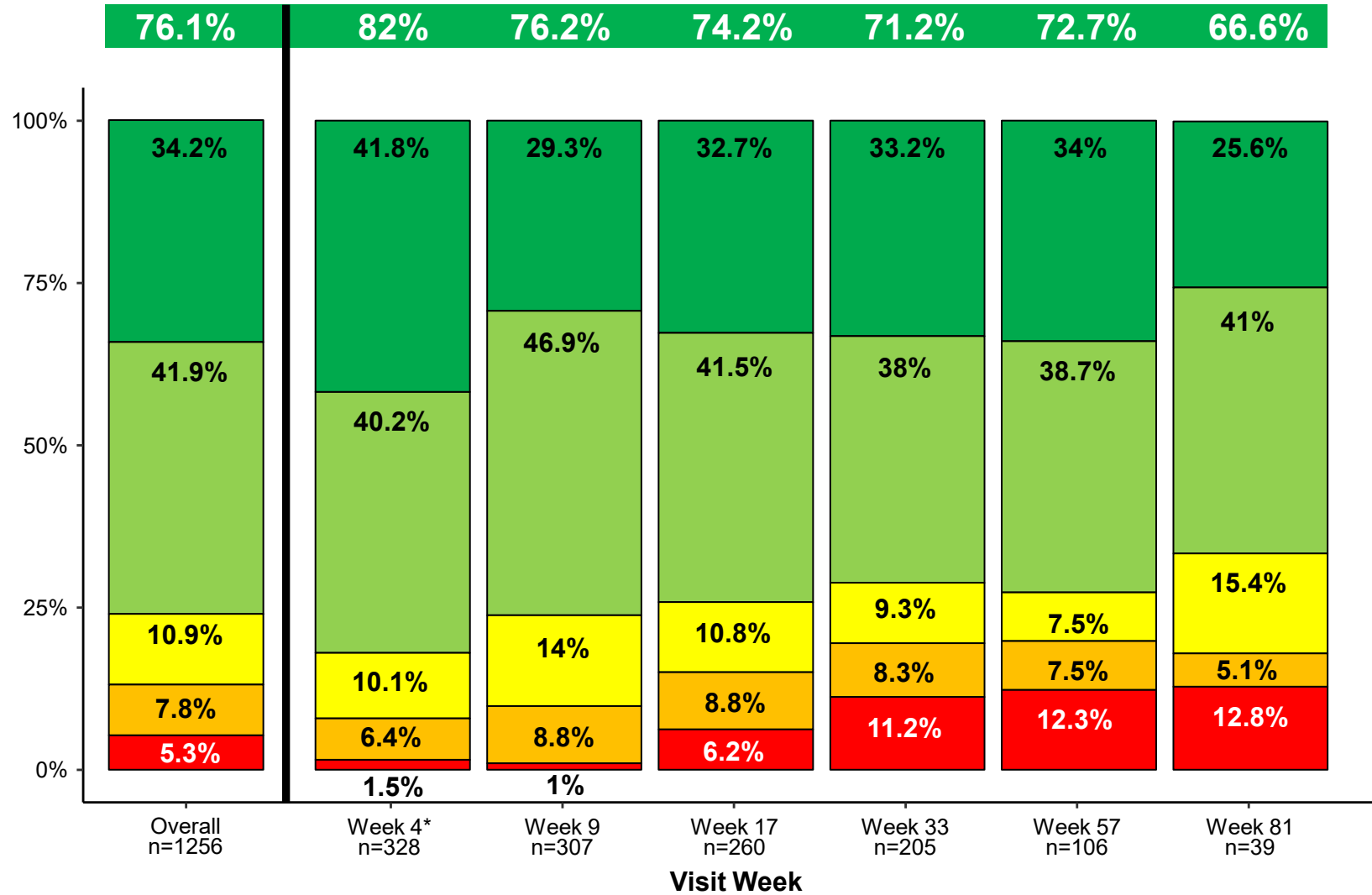
39 Incident HIV Infections TDF/FTC



- Step 1: Oral CAB lead-in
- Step 2: Blinded TDF/FTC
- Step 2: Blinded TDF/FTC overdue
- Annual follow-up
- % Percent adherence to oral lead-in
- Blinded TDF/FTC dispensed
- * First site positive HIV test
- + Awaiting HIV back-testing

DBS TFV-DP

Randomly selected “adherence” subset



Number of participants: 372
Number of samples assayed: 1256

- 7 doses/week (≥1250 fmol/punch)
- 4 – 7 doses/week (700 - <1250 fmol/punch)
- 2 – 4 doses/week (350 - <700 fmol/punch)
- <2 doses/week (LLOQ - <350 fmol/punch)
- No detectable drug (BLQ)

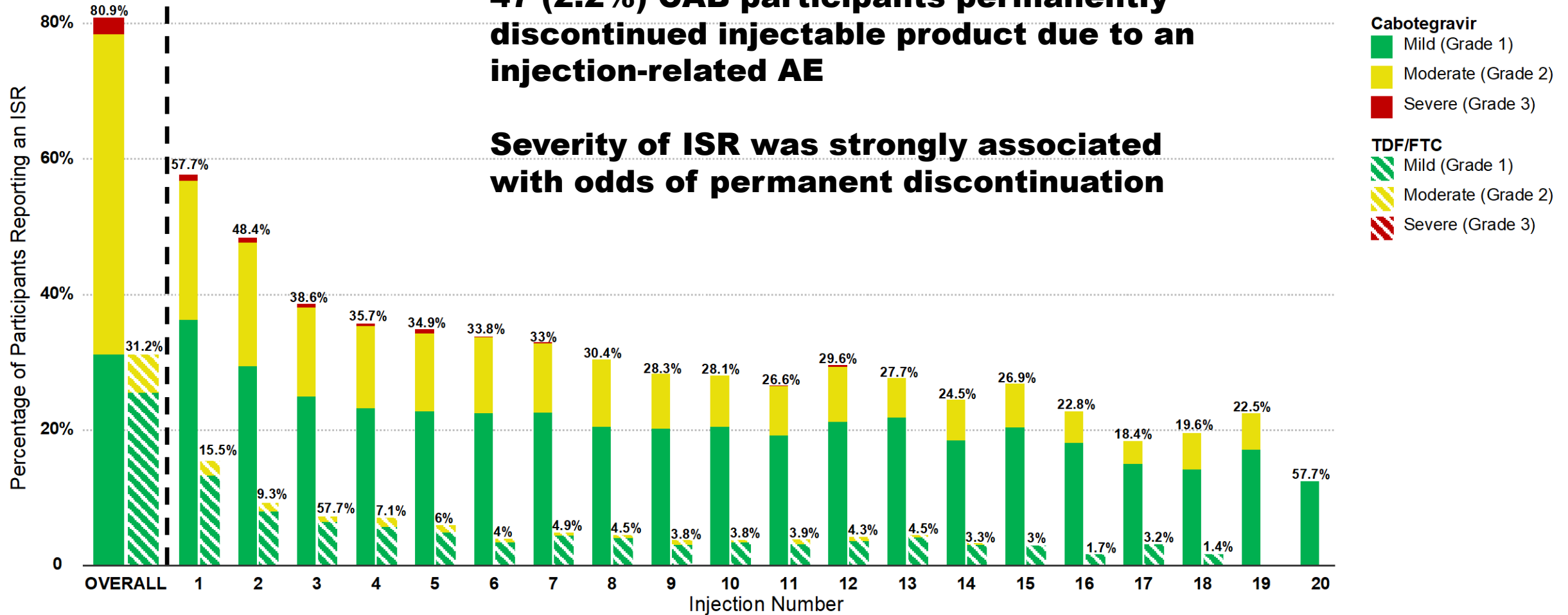
Plasma TFV
87% >0.3 ng/mL
75% >40 ng/mL

Each participant selected for adherence testing may have up to 8 samples included in this summary.
* Category values for Week 4 adjusted for days on therapy, as steady state not yet achieved

Injection Site Reactions

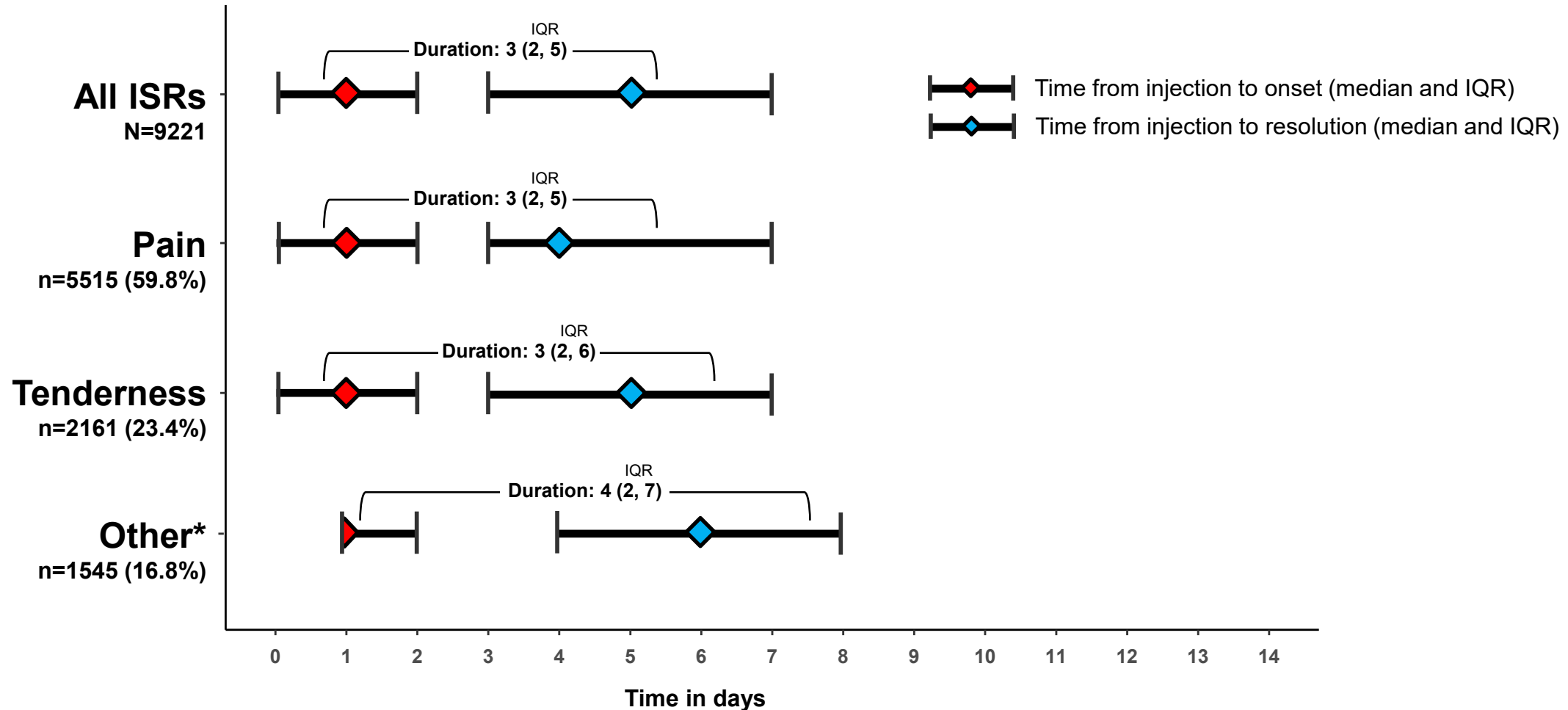
47 (2.2%) CAB participants permanently discontinued injectable product due to an injection-related AE

Severity of ISR was strongly associated with odds of permanent discontinuation



Cabotegravir, n	2117	2117	2037	1938	1872	1761	1620	1464	1360	1200	1034	877	744	604	465	372	298	234	168	111	8
TDF/FTC, n	2081	2081	2014	1940	1869	1760	1606	1463	1355	1193	1037	903	760	596	482	370	288	220	146	89	6

ISR Timing/Duration



*Other injection site reactions include induration, nodule, hematoma, bruising, discoloration, swelling, erythema, itching, warmth, anesthesia, hemorrhage, and abscess

Grade 2+ Adverse Events Reported in $\geq 5\%$

	TOTAL (n=4566)	TDF-FTC (n=2284)	CAB (n=2282)	p-value
Participants with grade 2+ AEs, n (%)	4202 (92.1%)	2106 (92.3%)	2096 (91.9%)	
Creatinine clearance decreased	3204 (70.2%)	1642 (72.0%)	1562 (68.5%)	0.01
CPK increased	937 (20.5%)	460 (20.2%)	477 (20.9%)	0.52
Nasopharyngitis	828 (18.1%)	388 (17.0%)	440 (19.3%)	0.04
Creatinine increased	775 (17.0%)	412 (18.1%)	363 (15.9%)	0.06
Upper Respiratory Infection	510 (11.2%)	255 (11.2%)	255 (11.2%)	0.99
Musculoskeletal discomfort	507 (11.1%)	253 (11.1%)	254 (11.1%)	0.95
Lipase increased	495 (10.9%)	252 (11.0%)	243 (10.7%)	0.68
Headache	448 (9.8%)	216 (9.5%)	232 (10.2%)	0.42
AST/SGOT increased	382 (8.4%)	197 (8.6%)	185 (8.1%)	0.53
ALT/SGPT increased	347 (7.6%)	191 (8.4%)	156 (6.8%)	0.05
Blood glucose increased	323 (7.1%)	117 (5.1%)	206 (9.0%)	<0.001
Amylase increased	316 (6.9%)	166 (7.3%)	150 (6.6%)	0.36
Diarrhoea	306 (6.7%)	158 (6.9%)	148 (6.5%)	0.56
Rash	253 (5.5%)	139 (6.1%)	114 (5.0%)	0.11
Hypoglycaemia	241 (5.3%)	123 (5.4%)	118 (5.2%)	0.75
Pyrexia*	181 (4.0%)	60 (2.6%)	121 (5.4%)	<0.001

*70% of pyrexia events in CAB were within 7 days of an injection (event probability 0.65%)
16% of pyrexia events in TDF/FTC were within 7 days of an injection (event probability 0.05%)

Adverse Events: Grade 3+

Reported in $\geq 2\%$

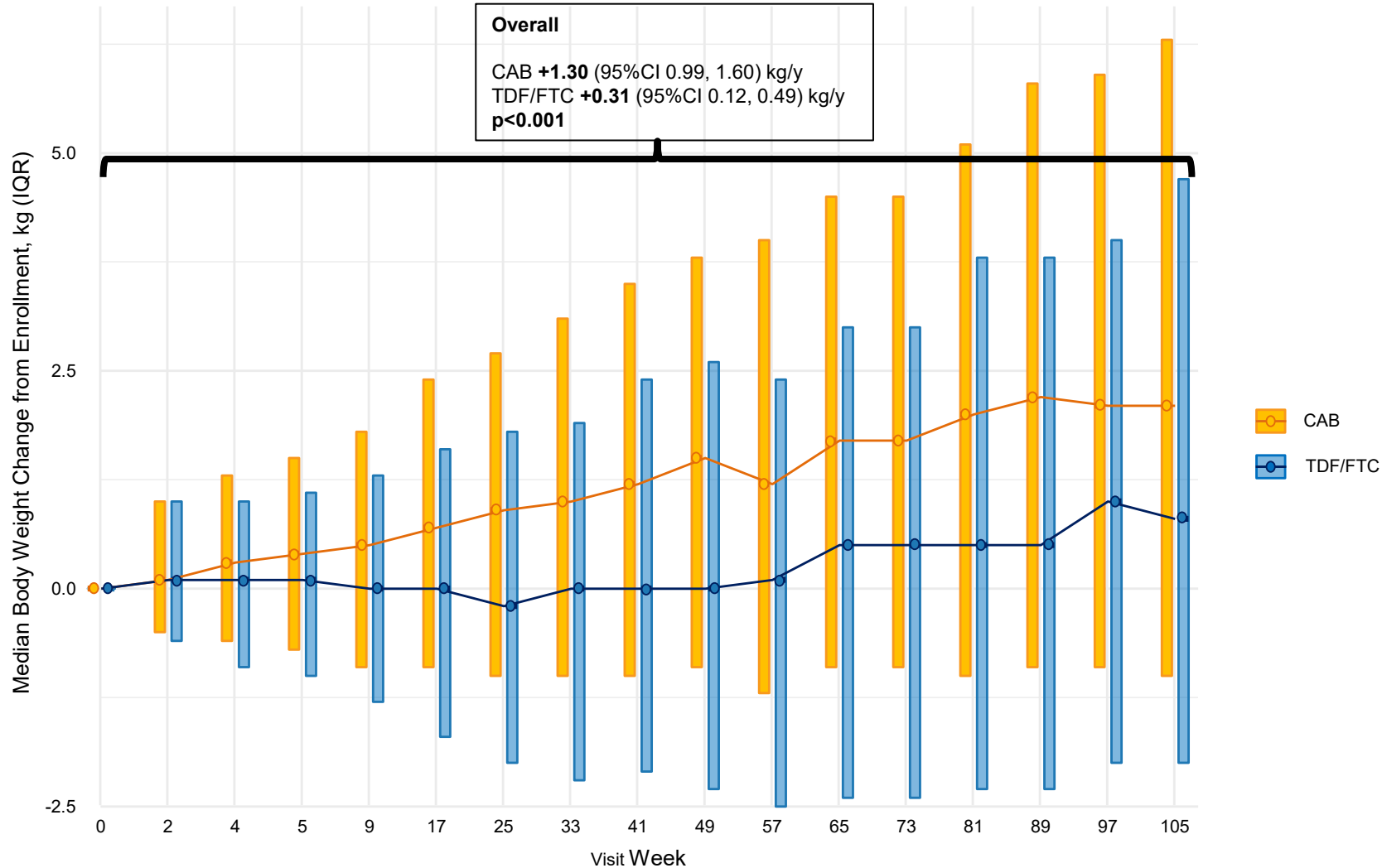
	TOTAL (n=4566)	TDF-FTC (n=2284)	CAB (n=2282)	p-value
Participants with grade 3+ AEs, n (%)	1490 (32.7%)	766/2282 (33.6%)	724/2280 (31.8%)	
CPK increased	633 (13.9%)	309 (13.5%)	324 (14.2%)	0.51
Creatinine clearance decreased	348 (7.6%)	190 (8.3%)	158 (6.9%)	0.08
Lipase increased	152 (3.3%)	76 (3.3%)	76 (3.3%)	0.99
Creatinine increased	152 (3.3%)	75 (3.3%)	77 (3.4%)	0.87
AST/SGOT increased	122 (2.7%)	69 (3.0%)	53 (2.3%)	0.14
Participants with EAEs and SAEs, n (%)	240 (5.3%)	122 (5.4%)	118 (5.2%)	
Participant deaths, n (%)	11 (0.24%)	7 (0.3%)	4 (0.2%)	

Prevalent and Incident STIs

	TOTAL (n=4566)	TDF-FTC (n=2284)	CAB (n=2282)
Prevalent at baseline, n (%)			
Syphilis	241 (5.3)	115 (5.1)	126 (5.5)
Gonorrhea _{urine}	29 (0.6)	17 (5.1)	12 (0.5)
Gonorrhea _{rectal}	297 (6.5)	150 (6.6)	147 (6.5)
Chlamydia _{urine}	122 (2.7)	57 (2.5)	65 (2.9)
Chlamydia _{rectal}	502 (11)	255 (11.2)	247 (10.9)
Incidence, n (rate per 100 py)			
Syphilis	908 (16.5)	451 (16.4)	457 (16.5)
Gonorrhea _{urine}	128 (2.4)	57 (2.1)	71 (2.6)
Gonorrhea _{rectal}	592 (10.9)	295 (10.9)	297 (11)
Chlamydia _{urine}	241(4.4)	124 (4.6)	117 (4.3)
Chlamydia _{rectal}	906 (16.7)	481 (17.8)	425 (15.7)

Changes in Weight

Median of changes from baseline (IQR)



Cabotegravir Is Not Associated With Weight Gain in Human Immunodeficiency Virus-uninfected Individuals in HPTN 077

Raphael J Landovitz¹, Sahar Z Zangeneh², Gordon Chau², Beatriz Grinsztejn³, Joseph J Eron⁴, Halima Dawood⁵, Manyu Magnus⁶, Albert Y Liu⁷, Ravindre Panchia⁸, Mina C Hosseinipour⁹, Ryan Kofron¹, David A Margolis¹⁰, Alex Rinehart¹⁰, Adeola Adeyeye¹¹, David Burns¹¹, Marybeth McCauley¹², Myron S Cohen⁴, Judith S Currier¹

HPTN 077: Over 41 weeks

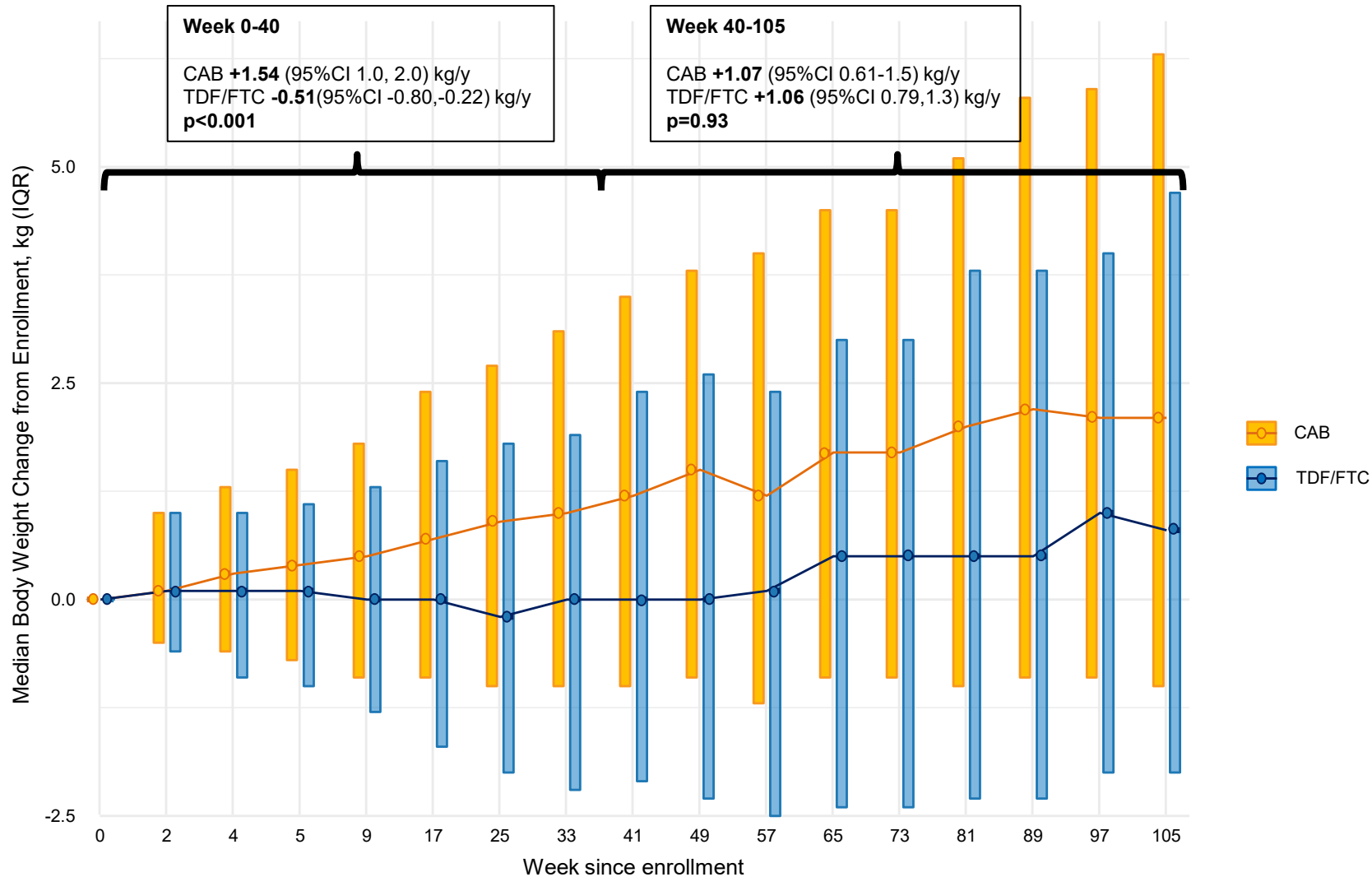
CAB **+1.48** (95%CI 0.15, 2.8) kg/y
 PBO **+1.57** (95%CI -1.35, 4.49) kg/y
 $p = 0.95$

Landovitz RJ et al. CID 2019.



Changes in Weight

Median of changes from baseline



Cabotegravir Is Not Associated With Weight Gain in Human Immunodeficiency Virus-uninfected Individuals in HPTN 077

Raphael J Landovitz¹, Sahar Z Zangeneh², Gordon Chau², Beatriz Grinsztejn³, Joseph J Eron⁴, Halima Dawood⁵, Manya Magnus⁶, Albert Y Liu⁷, Ravindre Panchia⁸, Mina C Hosseinipour⁹, Ryan Kofron¹, David A Margolis¹⁰, Alex Rinehart¹⁰, Adeola Adeyeye¹¹, David Burns¹¹, Marybeth McCauley¹², Myron S Cohen⁴, Judith S Currier¹

HPTN 077: Over 41 weeks

CAB +1.48 (95%CI 0.15, 2.8) kg/y
PBO +1.57 (95%CI -1.35, 4.49) kg/y
p=0.95

Landovitz RJ et al. CID 2019.



Ongoing work

- **Drug concentrations of each PrEP agent at time of infection detection**
 - **For CAB, PK profiles since inception to suppression**
 - **For TDF/FTC, TFV plasma and TFV-DP from peri - infection detection**
- **Resistance profiles of HIV acquired after SP exposure**
 - **At first detection**
 - **Over time until suppression on ART**

Conclusions

- **Both agents were highly effective for HIV prevention**
- **The PrEP regimen containing CAB-LA was superior to a daily oral regimen of TDF/FTC in HPTN 083, with a 66% reduction in risk of HIV infection observed in participants receiving CAB compared to TDF/FTC**
- **CAB-LA was well tolerated despite injection site reactions**
- **Peri-infection drug concentrations and detailed resistance profiles are needed to fully understand and contextualize results**
- **CAB is the first long-acting injectable agent to demonstrate robust HIV prevention efficacy in MSM/TGW**
- **Awaiting results for cisgender women (HPTN 084)**

HPTN 083 Recognition

It TRULY took a metropolis

Sponsor

- U.S. National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA), and the National Institute of Child Health and Human Development (NICHD) all components of the U.S. National Institutes of Health (NIH)
- Additional funding from ViiV Healthcare

HIV Prevention Trials Network (HPTN)

- Laboratory Center (Johns Hopkins University)
- Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchinson Cancer Research Center
- Leadership and Operations Center, FHI 360
- HPTN Leadership

Pharmaceutical Support

- ViiV Healthcare
- Gilead Sciences, Inc.

DAIDS

- Adeola Adeyeye
- Carl Dieffenbach
- Sheryl Zwierski
- David Burns
- Melissa Kin
- Katie Shin
- Eileen Pouliot
- Nancy Cogliano
- Linda Ehler
- Usha Sharma

HPTN Leadership

- Myron Cohen
- Wafaa El-Sadr
- Deborah Donnell
- Sue Eshleman
- Nirupama Sista
- Kathy Hinson

Leadership & Operations (LOC)

Study Team

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