Treatment Revolution

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Disclosures

Travel Support: Gilead Sciences

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Education/Consulting: Gilead Sciences, ViiV Healthcare, Bristol Myers-Squibb, Merck

1. Current Guidelines

2. Third Agent/Anchor Drug

3. Backbone

4. Future Directions

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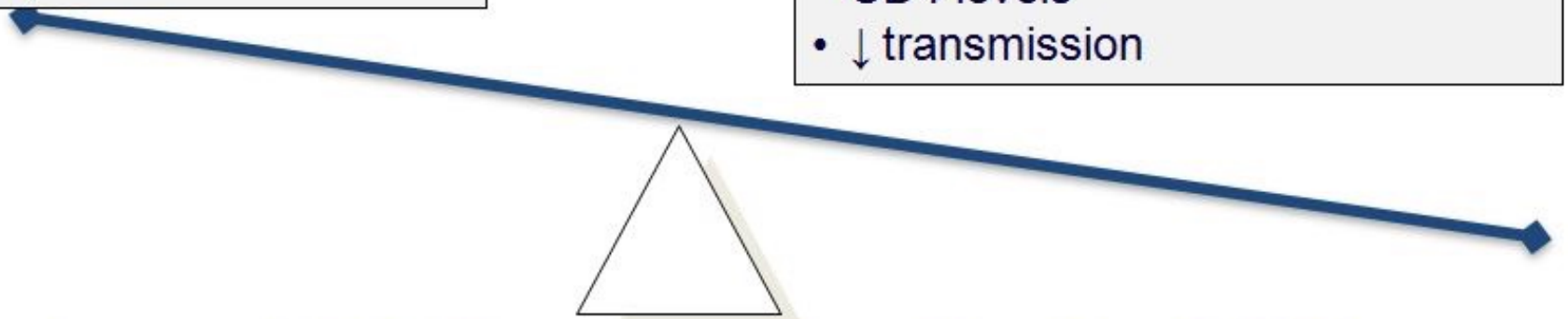
When to Start Therapy: Balance Now Favors Earlier ART

- Drug toxicity
- Preservation of limited Rx options
- Risk of resistance (and transmission of resistant virus)

- ↑ potency, durability, simplicity, safety of current regimens
- ↓ emergence of resistance
- ↓ toxicity with earlier therapy
- ↑ subsequent treatment options
- Risk of uncontrolled viremia at all CD4 levels
- ↓ transmission



Delayed ART **Early ART**

START Study: Randomized Comparison of Immediate vs Delayed ART

Treatment-naive pts with CD4+ cell count > 500 cells/mm³

(N = 4685)

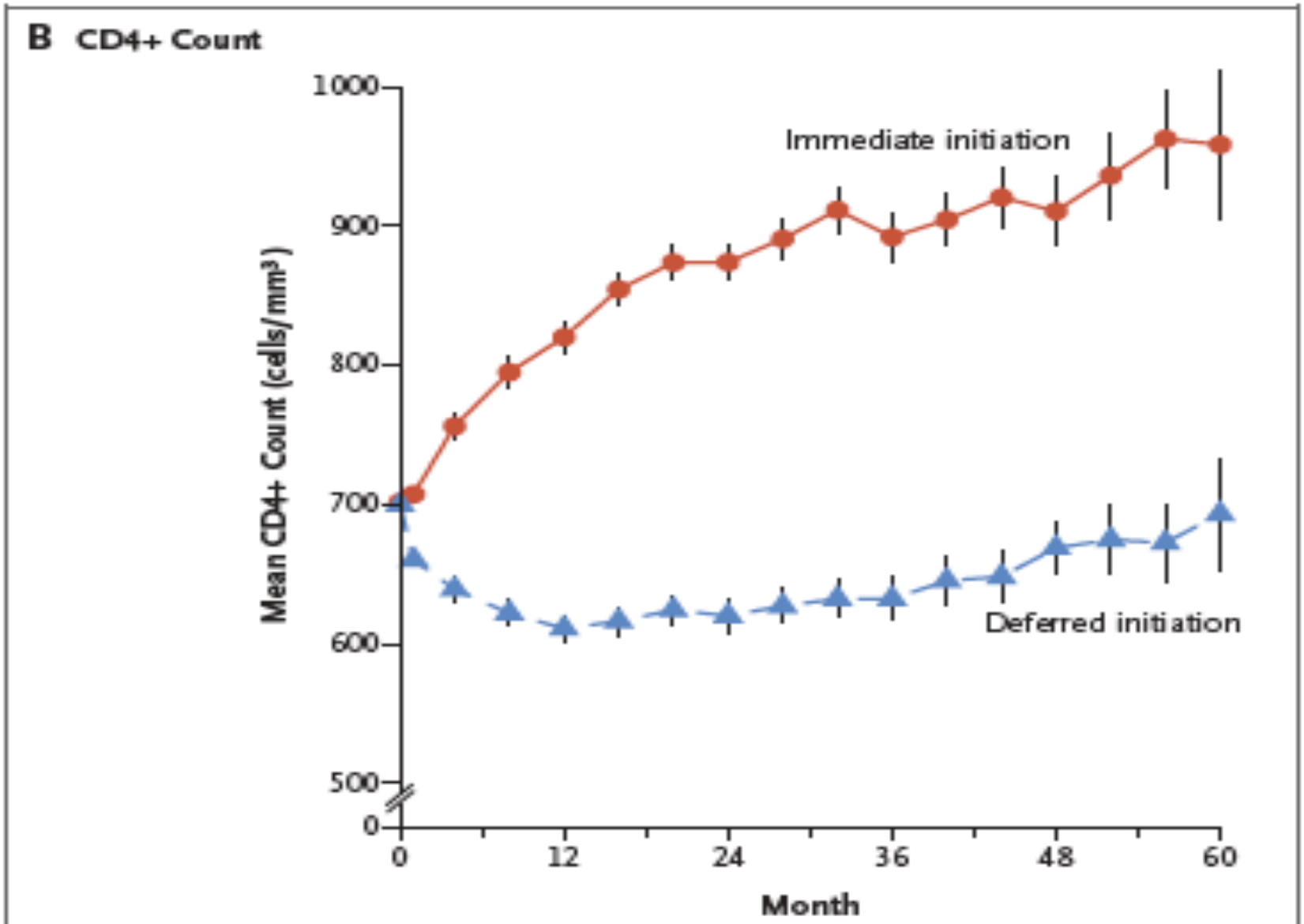
- **Immediate treatment**
- **Defer treatment until CD4+ cell count ≤ 350 cells/mm³**

Study endpoints (over 6 yrs)

- Fatal AIDS or nonfatal serious AIDS events (CV, liver, renal, and cancer)
- Non-AIDS–related death

- Study stopped in May 2015 due to excess of events (86 vs 41) in the deferred treatment arm
- Most common AIDS-related illnesses among study participants were pulmonary TB, Kaposi's sarcoma, and non-Hodgkin's lymphoma; the most common serious non-AIDS–related illnesses were cancer, heart attack, and deaths due to various causes

NIH. Press release. May 27, 2015.



No. of Patients						
Immediate initiation	2326	2205	1853	1075	574	157
Deferred initiation	2359	2190	1829	1077	549	162

START Study: Primary and Secondary Endpoints

End Point	Immediate-Initiation Group (N=2326)		Deferred-Initiation Group (N=2359)		Hazard Ratio (95% CI)	P Value
	No.	No./100 person-yr	No.	No./100 person-yr		
Composite Primary End Point	42	0.60	96	1.38	0.43 (0.30-0.62)	<0.001
Components of the Primary End Point						
Serious AIDS-Related Event	14	0.20	50	0.72	0.28 (0.15-0.50)	<0.001
Serious Non-AIDS-Related Event	29	0.42	47	0.67	0.61 (0.38-0.97)	0.04
Death From Any Cause	12	0.17	21	0.30	0.58 (0.28-1.17)	0.13
Tuberculosis	6	0.09	20	0.28	0.29 (0.12-0.73)	0.008
Kaposi's Sarcoma	1	0.01	11	0.16	0.09 (0.01-0.71)	0.02
Malignant Lymphoma	3	0.04	10	0.14	0.30 (0.08-1.10)	0.07
Cancer Not Related to AIDS	9	0.13	18	0.26	0.50 (0.22-1.11)	0.09
Cardiovascular Disease	12	0.17	14	0.20	0.84 (0.39-1.81)	0.65

Lundgren J, et al; 8th IAS, Vancouver, Canada, July 19-22, 2015; Abst. MOSY0301.

When to Start: *Australian Commentary on DHHS Guidelines*

Antiretroviral therapy **(ART) is recommended for all HIV-infected individuals**, irrespective of CD4 count, to reduce the risk of disease progression.

The decision to start ART should take into account both **personal health benefits** and risks, and **reduction in transmission risk**

Clinicians should regularly discuss the current **state of knowledge** regarding when to start ART with all **individuals** with HIV who are **not yet on treatment**

All decisions to start ART should be made by the individual with HIV, in consultation with their health care providers and on the basis that they are fully informed and supported in their decision making

What to Start: Choice of ART Regimen

Previously:

Raltegravir + Truvada or Kivexa

or

Atripla (Efavirenz + Truvada)

Now:

Triumeq (Dolutegravir + Kivexa

or

Genvoya (Elvitegravir/cobicistat + F/TAF)

What to Start: July 2016 Updates on Recommended Regimens for First-line ART

Regimen	DHHS[1]	IAS-USA[2]
DTG/ABC/3TC	Preferred/recommended	Preferred/recommended
DTG + TAF/FTC	Preferred/recommended	Preferred/recommended
DTG + TDF/FTC	Preferred/recommended	Alternative
EVG/COBI/TAF/FTC	Preferred/recommended	Preferred/recommended
EVG/COBI/TDF/FTC	Preferred/recommended	Alternative
RAL + TAF/FTC	Preferred/recommended	Preferred/recommended
RAL + TDF/FTC	Preferred/recommended	Alternative
DRV + RTV + TAF/FTC	Preferred/recommended	Alternative
DRV + RTV + TDF/FTC	Preferred/recommended	Alternative

- DHHS[1]
  - Recommended regimens include 3 INSTIs and 1 boosted PI
  - Primary change since Jan 2016 update is addition of TAF/FTC
- IAS-USA[2]
  - All recommended regimens include INSTI + TAF/FTC or ABC/3TC
  - Major changes since 2014 update include removal of NNRTIs, boosted PIs, and TDF

1. DHHS Guidelines. July 2016.
2. Günthard HF, et al. JAMA. 2016;316:191-210.

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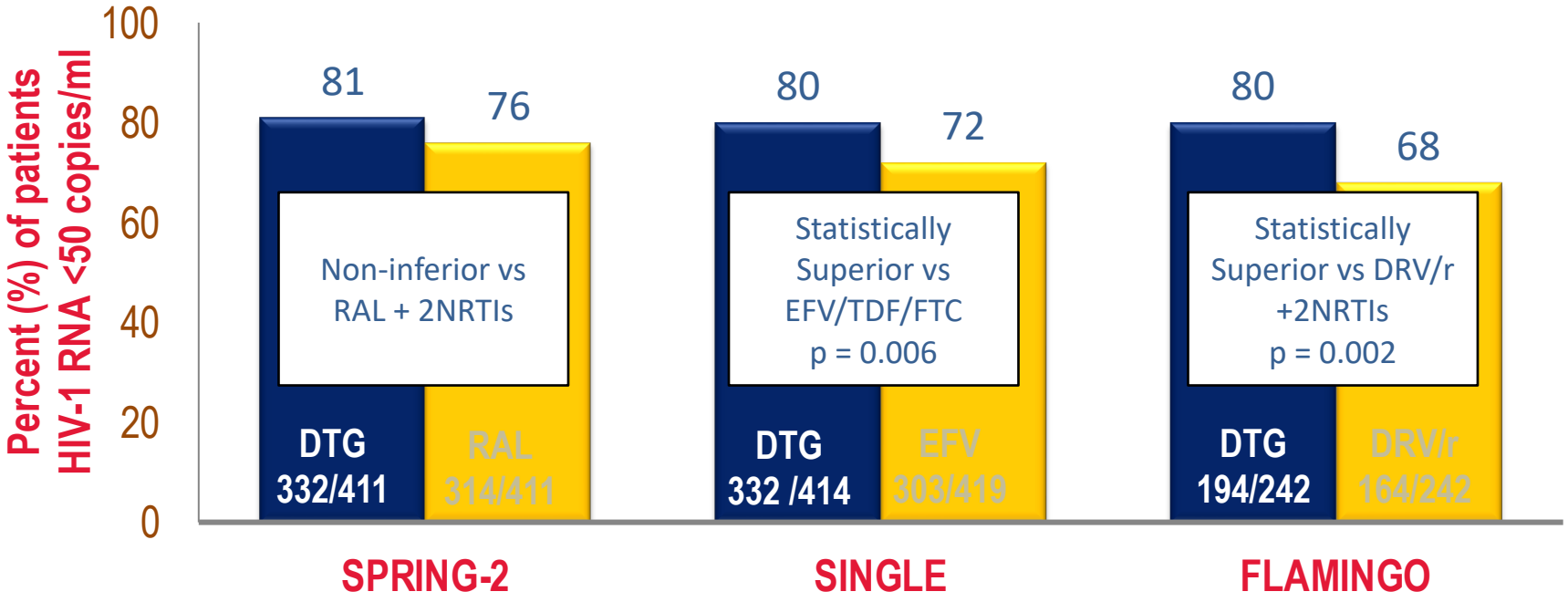
DTG Phase III Treatment-Naïve studies Snapshot Responders: <50 c/mL HIV-1 RNA (week 96)

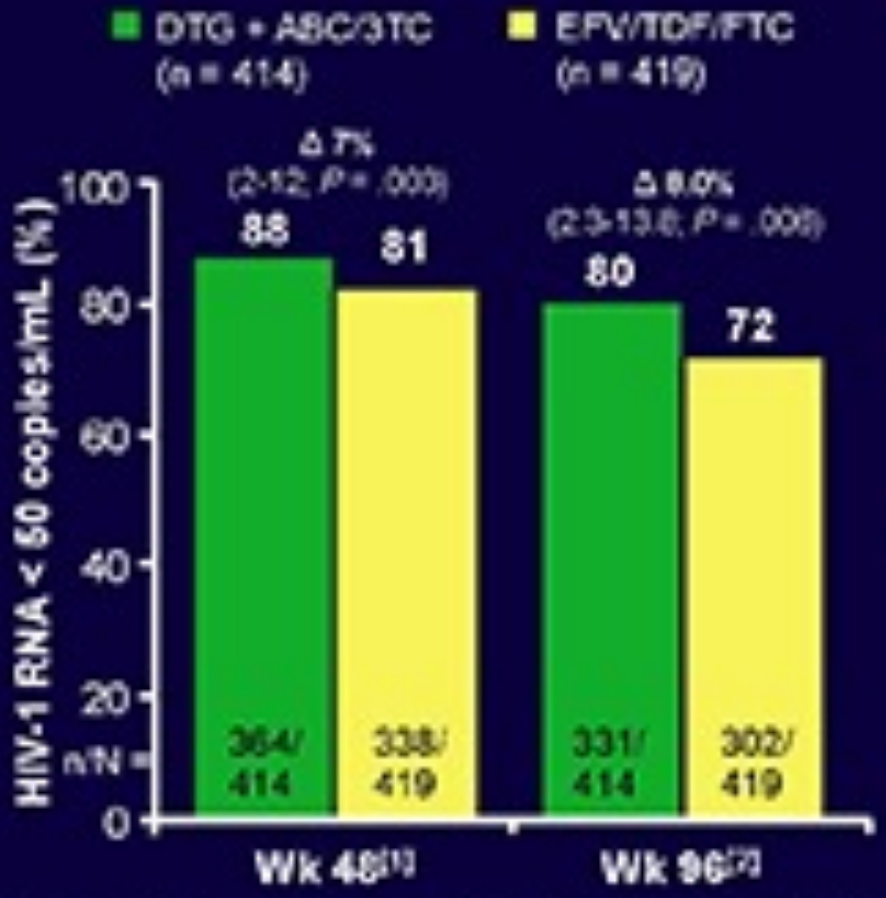


- In SPRING-2, DTG was non-inferior to RAL based on the Snapshot algorithm at Week 96 (adjusted difference in proportion [95% CI; DTG-RAL] 4.5 [-1.1, 10.0])[1]
- In FLAMINGO, DTG was superior to DRV/r at Week 96 (adjusted difference in proportion [95% CI; DTG-DRV/r] 12.4 [4.7, 20.2], *P*=0.002)[2]
- In SINGLE, DTG + ABC/3TC was superior to EFV/TDF/FTC at Week 96 (adjusted difference in proportion [95% CI; DTG-EFV/TDF/FTC] 8.0 [2.3, 13.8], *P*=0.006)[3] and at Week 144 (71% vs 63%, adjusted difference: 8.3 [2.0, 14.6], *P*=0.01)[3]

1. Raffi F, et al. Lancet Infect Dis 2013;13:927–35; 2. Molina JM, et al. Lancet HIV 2015; 3: e127-36; 3. Walmsley S et al. JAIDS 2015 ePub ahead of print: DOI: 10.1097/QAI.0000000000000790

Granier et al. CROI 2015; Seattle WA; Poster 550

SINGLE: DTG + ABC/3TC Superior to EFV/TDF/FTC at Both Wk 48 and 96



- Treatment-related study d/c: 3% in DTG vs 11% in EFV arm
  - No new treatment-related AEs in either arm btwn Wks 48-96
- VF at Wk 96: 25 (6%) in each arm
- 0 pts with resistance in DTG arm; 1 pt with NRTI and 6 pts with NNRTI resistance in EFV arm
- CD4+ cell count increase at Wk 96 greater with DTG: +325 vs +281 cells/mm^3 (P = .004)

1. Walmsley S, et al. N Engl J Med. 2013;369:1807-1818.
2. Walmsley S, et al. CROI 2014. Abstract 543.

Table 4. Advantages and Disadvantages of Currently Available Integrase Strand Transfer Inhibitors

	Dolutegravir	Elvitegravir	Raltegravir
Year of US Food and Drug Administration approval	2013	2012	2007
Advantages	Superior to efavirenz and ritonavir-boosted darunavir in comparative clinical trials[36,37] Once-daily dosing Coformulated with abacavir/lamivudine as part of a complete initial regimen Dolutegravir (not coformulated) pill size is small Lowest risk of resistance with virologic failure[36,37,40,43] Relatively few drug interactions Can be taken with or without food Superior to raltegravir in treatment-experienced patients	Superior to ritonavir-boosted atazanavir in comparative clinical trial in HIV-infected women[38] Once-daily dosing Coformulated with tenofovir disoproxil fumarate/emtricitabine or tenofovir alafenamide/emtricitabine as a complete regimen	Superior to ritonavir-boosted atazanavir and ritonavir-boosted darunavir in comparative clinical trial[39] Longest safety record Fewest drug interactions Can be taken with or without food
Disadvantages	Only available coformulation is with abacavir/lamivudine Raises serum creatinine owing to inhibition of tubular secretion of creatinine Higher rates of insomnia and headache than comparators in some studies[36,37] Largest tablet among coformulated single-pill regimens	Requires pharmacokinetic boosting with cobicistat or ritonavir for once-daily dosing Most drug interactions Cobicistat raises serum creatinine owing to inhibition of tubular secretion of creatinine Should be taken with food	Currently must be taken twice daily (formulation consisting of 2 pills given once daily in development) Not coformulated as part of a complete regimen

Table 5. Advantages and Disadvantages of Initial Antiretroviral Therapy Options for Patients in Whom InSTIs Are Not an Option[a]

	Darunavir (Boosted With Cobicistat or Ritonavir) Plus TAF/Emtricitabine, TDF/Emtricitabine, or Abacavir/Lamivudine[b]	Efavirenz/TDF/Emtricitabine	Rilpivirine/TAF (or TDF)/Emtricitabine
Advantages	Low risk of resistance with virologic failure, even with intermittent adherence	High efficacy in patients with baseline HIV RNA >100 000 copies/mL Extensive experience in patients with concomitant tuberculosis Widely available globally	Lowest risk of rash among NNRTI-based therapies Low risk of metabolic adverse effects Smallest tablet among single-pill regimens
Disadvantages	Requires pharmacokinetic boosting; many drug interactions Ritonavir-boosted darunavir inferior to raltegravir and dolutegravir in separate comparative clinical trials[37,39] Results of comparative, fully powered studies of cobicistat-boosted darunavir as initial therapy are not yet available	Relatively high rate of rash No single-tablet form available with TAF High rates of neuropsychiatric adverse effects Increased risk of suicidality in 1 study[55]; avoid in patients with history of depression	Not recommended for patients with HIV RNA >100 000 copies/mL or CD4 cell count <200/μL owing to increased risk of virologic failure Must be taken with a meal to optimize absorption Should not be administered with proton pump inhibitors; stagger dosing if given with an H_2 blocker

Abbreviations: InSTI, integrase strand transfer inhibitor; NNRTI, nonnucleoside reverse transcriptase inhibitor; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

[a] Nonnucleoside reverse transcriptase inhibitor–based regimens should not be used without baseline resistance data because of the possible presence of transmitted NNRTI-resistant virus. In the rare circumstance in which maraviroc might be included in initial therapy, initiation should not occur before confirmation of CC chemokine receptor 5 tropism.

[b] Cautions on the use of abacavir and TAF or TDF are described in the text.

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Issues with Current Backbone Agents

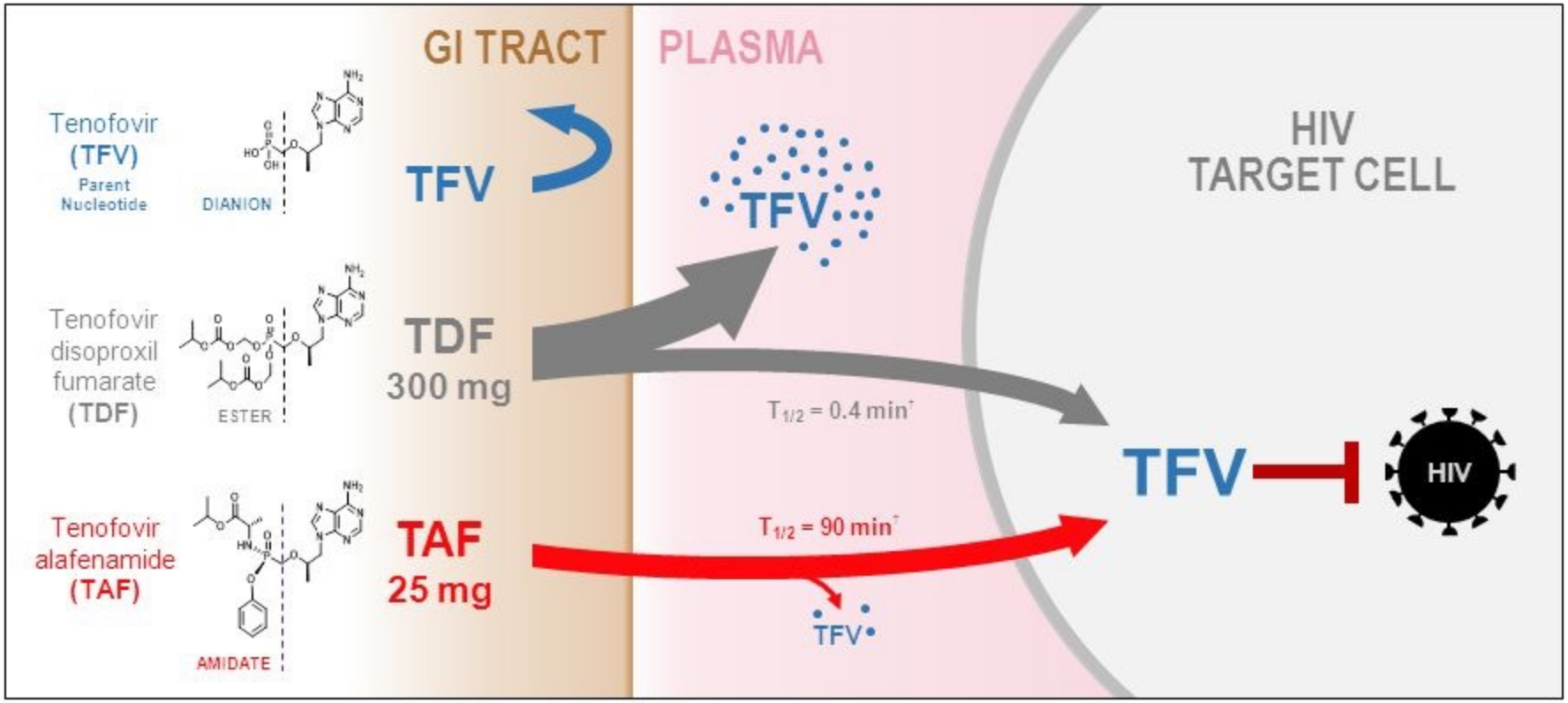
Kivexa (Abacavir/lamivudine-3TC)

- Abacavir component can cause hypersensitivity (allergic) reaction – need to check HLA B*5701 (8% positive)
- Association of abacavir with myocardial infarction

Truvada (Tenofovir-TDF/emtricitabine-FTC)

- Tenofovir-TDF can cause renal impairment (Fanconi syndrome or creatinine creep)
- Low bone density and tenofovir TDF

Tenofovir Alafenamide (TAF): Novel Prodrug of Tenofovir

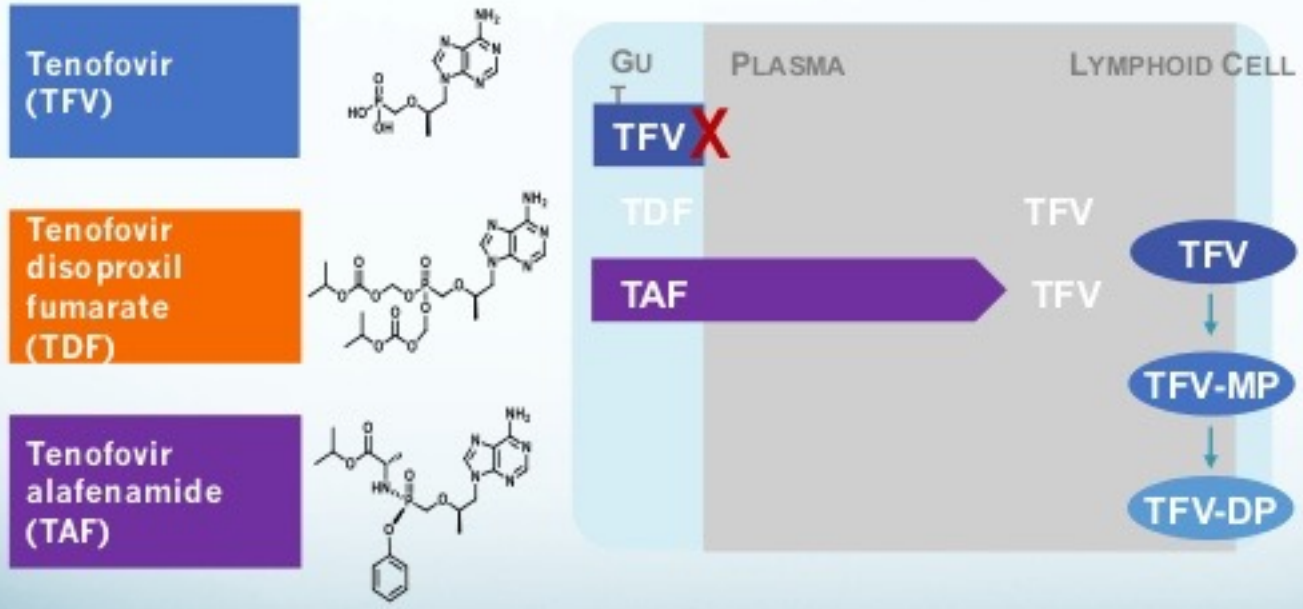


- **91% lower plasma TFV levels minimize renal and bone effects while maintaining high potency for suppressing HIV**

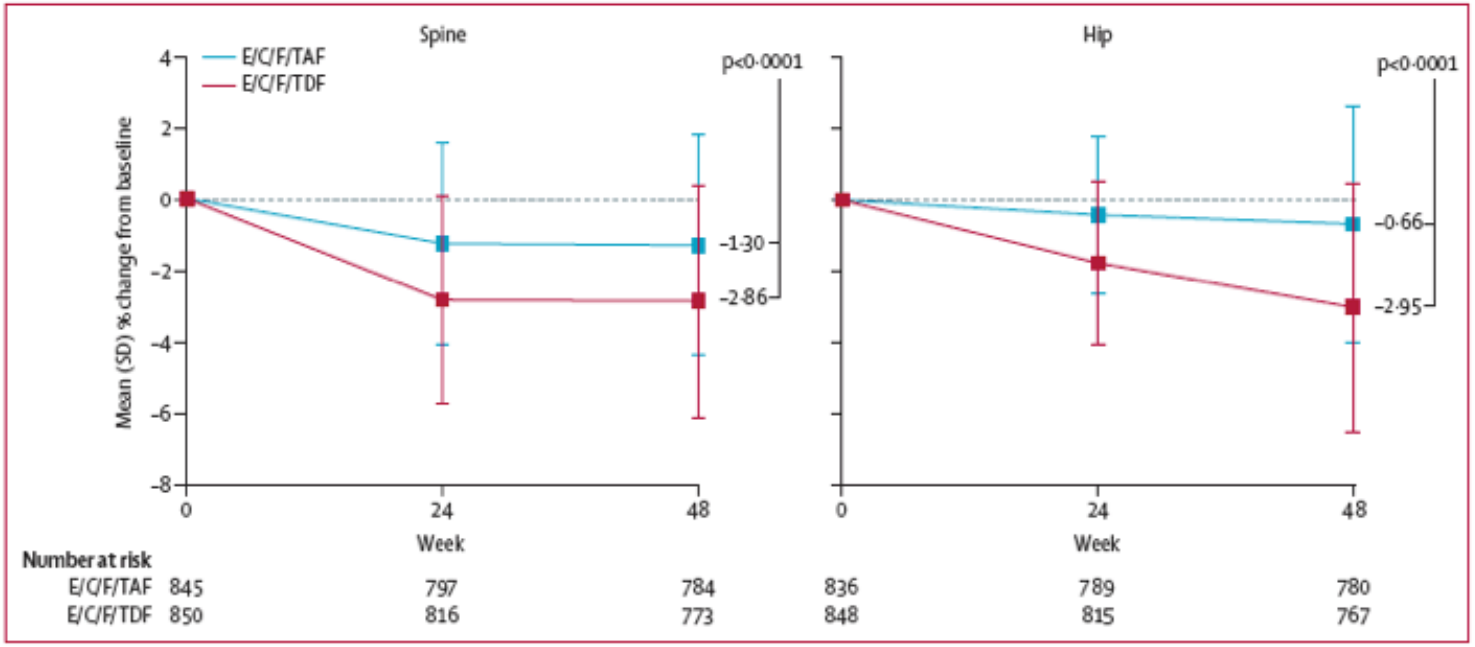
† $T_{1/2}$ based on *in vitro* plasma data.

1. Lee W et. *Antimicr Agents Chemo* 2005;49(5):1898-1906. 2. Birkus G et al. *Antimicr Agents Chemo* 2007;51(2):543-550. 3. Babusis D, et al. *Mol Pharm* 2013;10(2):459-66. 4. Ruane P, et al. *J Acquir Immune Defic Syndr* 2013; 63:449-5. 5. Sax P, et al. *JAIDS* 2014. 2014;67(1):52-8. 6. Sax P, et al. *Lancet* 2015;385:2606-15.

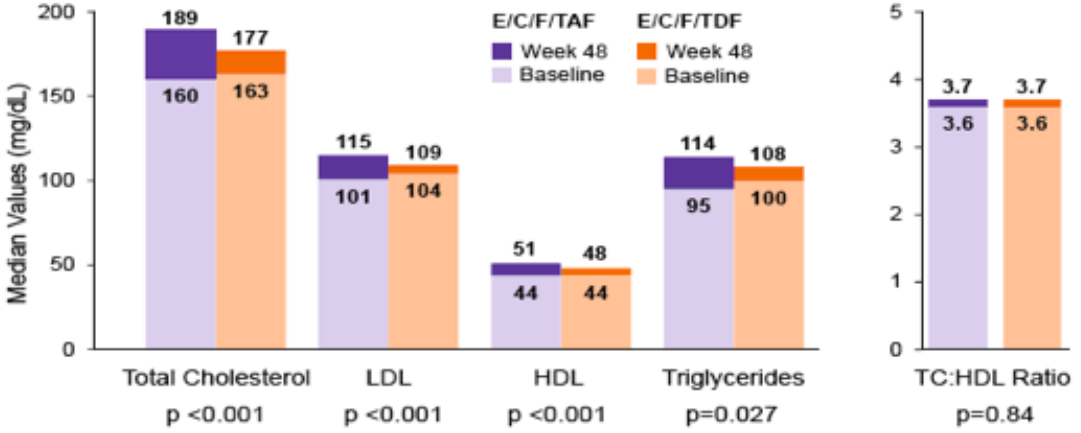
What is Tenofovir Alafenamide?



Paul Sax CROI 2015 Abstract 143LB via Chuck Hicks

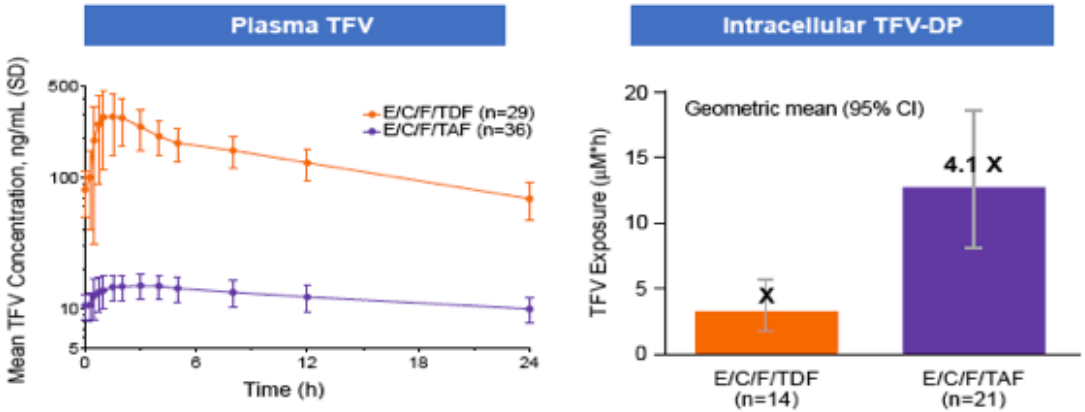


Appendix Figure 4. Fasting Lipids at Week 48



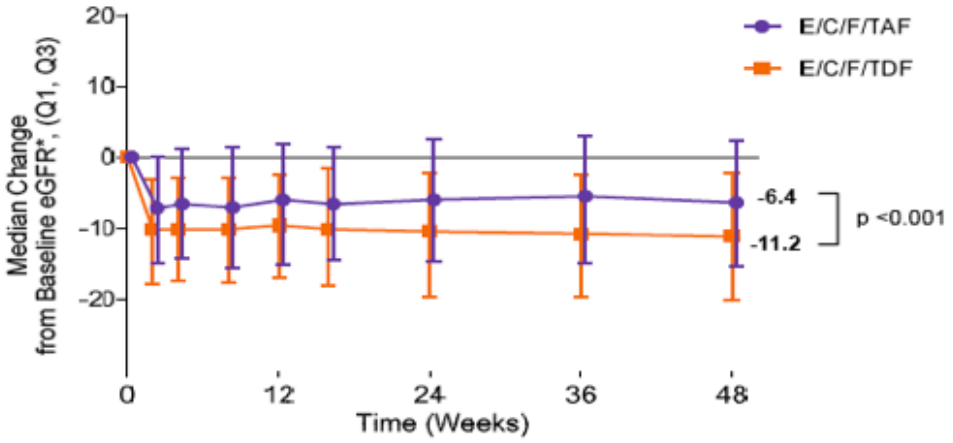
Patients initiating lipid-modifying medications: 3.6% E/C/F/TAF vs 2.9% E/C/F/TDF (p=0.42).

Appendix Figure 1. Plasma TFV and Intracellular TFV-DP Levels



Steady State TFV PK	E/C/F/TDF n=29	E/C/F/TAF n=36	% Reduction
Mean AUC_{tau}, ng*h/mL (%CV)	3,410 (25)	297(20)	91

Appendix Figure 2a. Change in eGFR (Cockcroft-Gault)



*Cockroft-Gault (mL/min).

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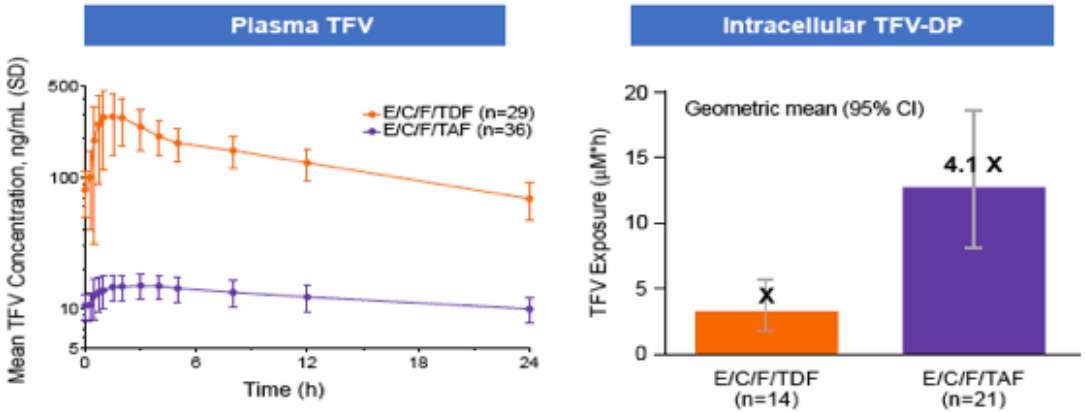

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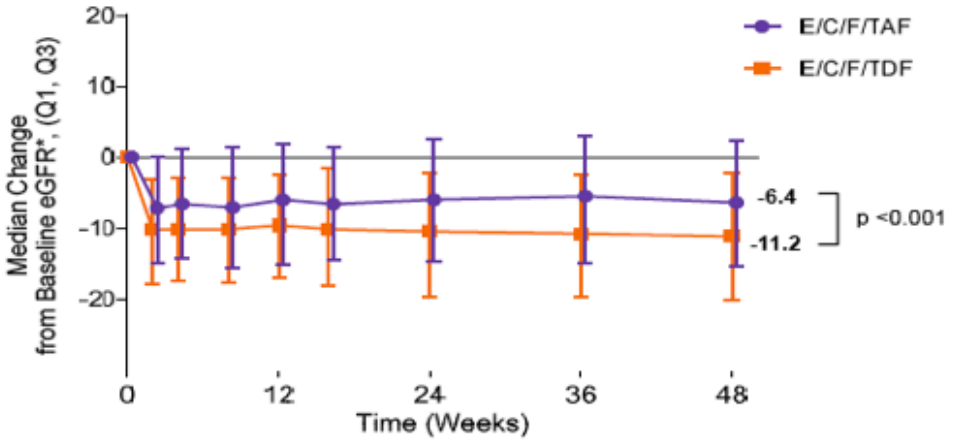

*Cockroft-Gault (mL/min).

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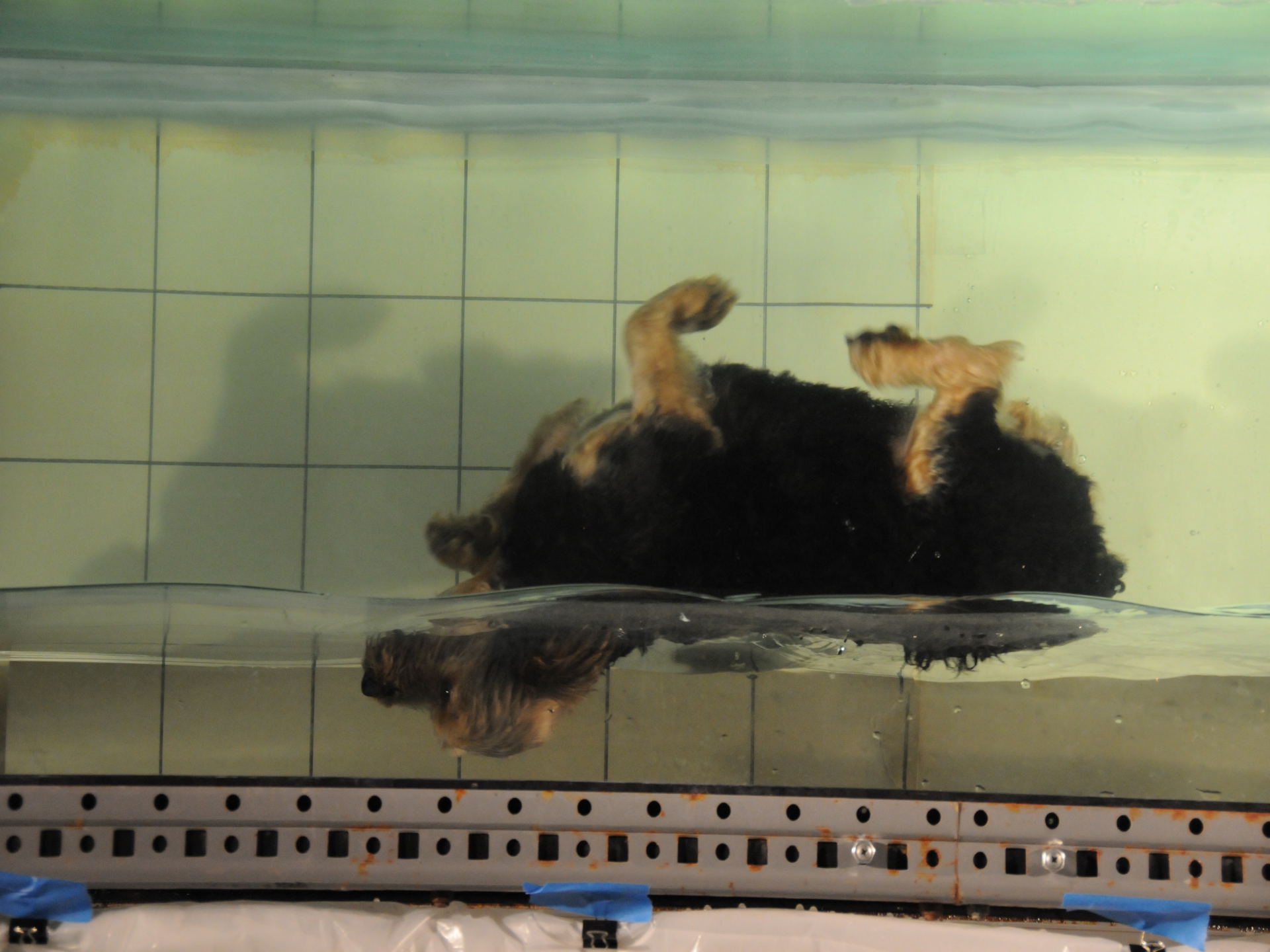
Future Directions

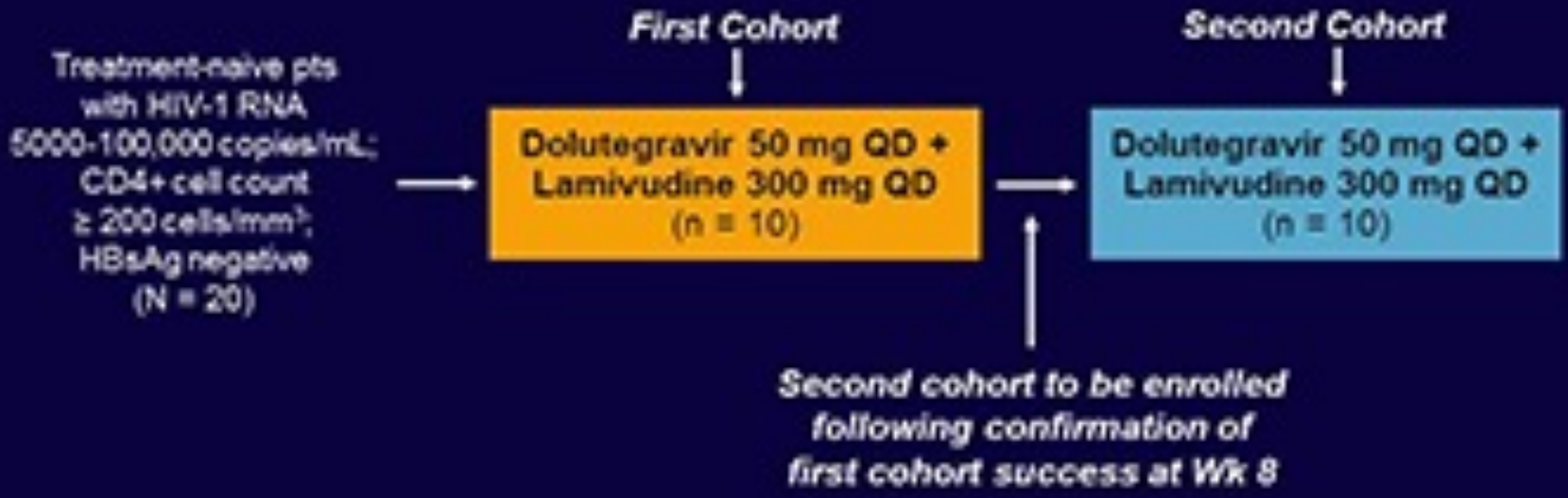
1. Dual agents (2 drugs instead of 3)

2. Injectable agents



PADDLE: Dolutegravir + Lamivudine in Treatment-Naive Pts

- Open-label, single-arm phase IV exploratory trial
  - Primary endpoint: HIV-1 RNA < 50 copies/mL at Wk 48 (ITT-e, FDA snapshot analysis)



Figueroa MI, et al. EACS 2015. Abstract 1066.

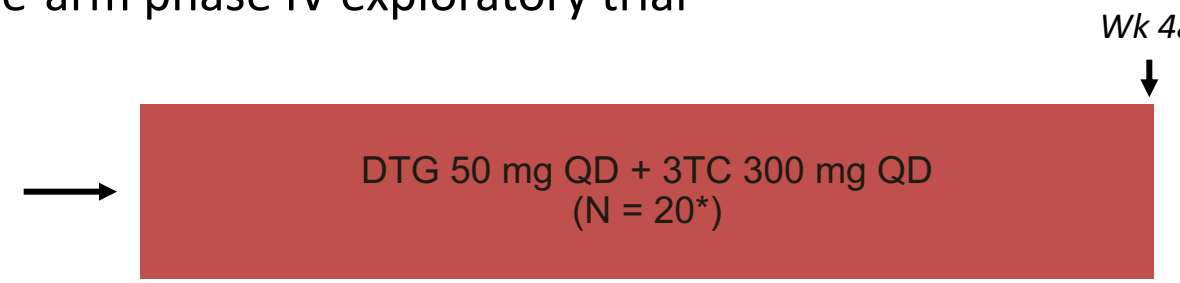
Viral Suppression at Week 24

#	SCR	BSL	Day 2	Day 4	Day 7	Day 10	W.2	W.3	W.4	W.6	W.8	W.12	W.24
1	5.584	10.909	3.701	383	101	71	<50	<50	<50	<50	<50	<50	<50
2	8.887	10.233	5.671	318	<50	<50	<50	<50	<50	<50	<50	<50	<50
3	67.335	151.569	37.604	1.565	1.178	266	97	53	<50	<50	<50	<50	<50
4	99.291	148.370	11.797	3.303	432	179	178	55	<50	<50	<50	<50	<50
5	34.362	20.544	4.680	1.292	570	168	107	<50	<50	<50	<50	<50	<50
6	16.024	14.499	3.754	1.634	162	<50	<50	<50	<50	<50	<50	<50	<50
7	37.604	18.597	2.948	819	61	<50	<50	<50	<50	<50	<50	<50	<50
8	25.071	24.368	6.264	1.377	Not done	268	105	<50	<50	<50	<50	<50	<50
9	14.707	10.832	Not done	516	202	<50	<50	<50	<50	<50	<50	<50	<50
10	10.679	7.978	5.671	318	<50	<50	<50	<50	<50	<50	<50	<50	<50
11	50.089	273.676	160.974	68.129	3.880	2.247	784	290	288	147	<50	<50	<50
12	13.508	64.103	3.496	3.296	135	351	351	84	67	<50	<50	<50	<50
13	28.093	33.829	37.350	26.343	539	268	61	<50	<50	<50	<50	<50	<50
14	15.348	15.151	3.994	791	198	98	<50	61	64	<50	<50	<50	<50
15	23.185	23.500	15.830	4.217	192	69	<50	<50	<50	Not done	<50	<50	<50
16	11.377	3.910	370	97	143	<50	<50	<50	<50	<50	<50	<50	<50
17	39.100	25.828	11.879	1.970	460	147	52	<50	<50	<50	<50	<50	<50
18	60.771	73.069	31.170	2.174	692	358	156	<50	<50	<50	<50	<50	<50
19	82.803	106.320	35.517	2.902	897	352	168	76	<50	<50	<50	<50	<50
20	5.190	7.368	3.433	147	56	<50	<50	<50	<50	<50	<50	<50	<50

From Week 8 onwards all patients had pVL < 50 copies/mL

PADDLE: Dolutegravir + Lamivudine for Treatment-Naive Pts

- Open-label, single-arm phase IV exploratory trial



*10 pts enrolled initially; additional 10 pts enrolled after confirming virologic success of first cohort at Wk 8.
†Primary endpoint.

- 18/20 pts achieved HIV-1 RNA < 50 c/mL at Wk 48
  - 1 pt committed suicide (deemed unrelated to study drugs)
  - 1 pt experienced PDVF at Wk 36 (BL HIV-1 RNA > 100,000 c/mL); resuppressed HIV-1 RNA without ART change by discontinuation visit (Wk 52)
  - 3 other pts with BL HIV-1 RNA > 100,000 c/mL suppressed at Wk 48

Cahn P, et al. AIDS 2016. Abstract FRAB0104LB.

Slide credit: clinicaloptions.com

Switch to DTG + RPV in Suppressed Pts With Multiple Previous Treatment Failures

- Open-label cohort study based in clinical practice setting (N = 38)
  - DTG 50 mg/day + RPV 25 mg/day for pts with long-term virologic suppression but virologic failure on > 1 previous ART regimens

Baseline Characteristic , %	Switch to DTG + RPV (N = 38)	
Regimen at time of switch	▪ NRTI + NNRTI + PI	85
	▪ NRTI + NNRTI + PI + INSTI	53
Reasons for switch to DTG + RPV	▪ Drug–drug interaction	38
	▪ Toxicity	33
	▪ Simplification	25
Pre-existing resistance mutations	▪ NRTI: 65; NNRTI: 37; PI: 32; INSTI: NA	

- DTG + RPV associated with improved liver function tests, improved lipid profile, and stable kidney function at Wk 48

Díaz A, et al. AIDS 2016. Abstract TUPDB0106.

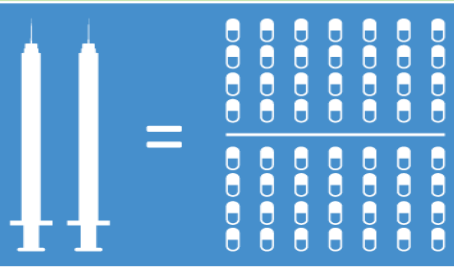
Slide credit: clinicaloptions.com

HIV MEDS TAKEN AS A SHOT

ARE INJECTABLE ARVs THE FUTURE?

ARV= AntiRetroViral

- ☑ EASIER
- ☑ MORE CONVENIENT
- ☑ CHEAPER
- ☑ BETTER TOLERATED



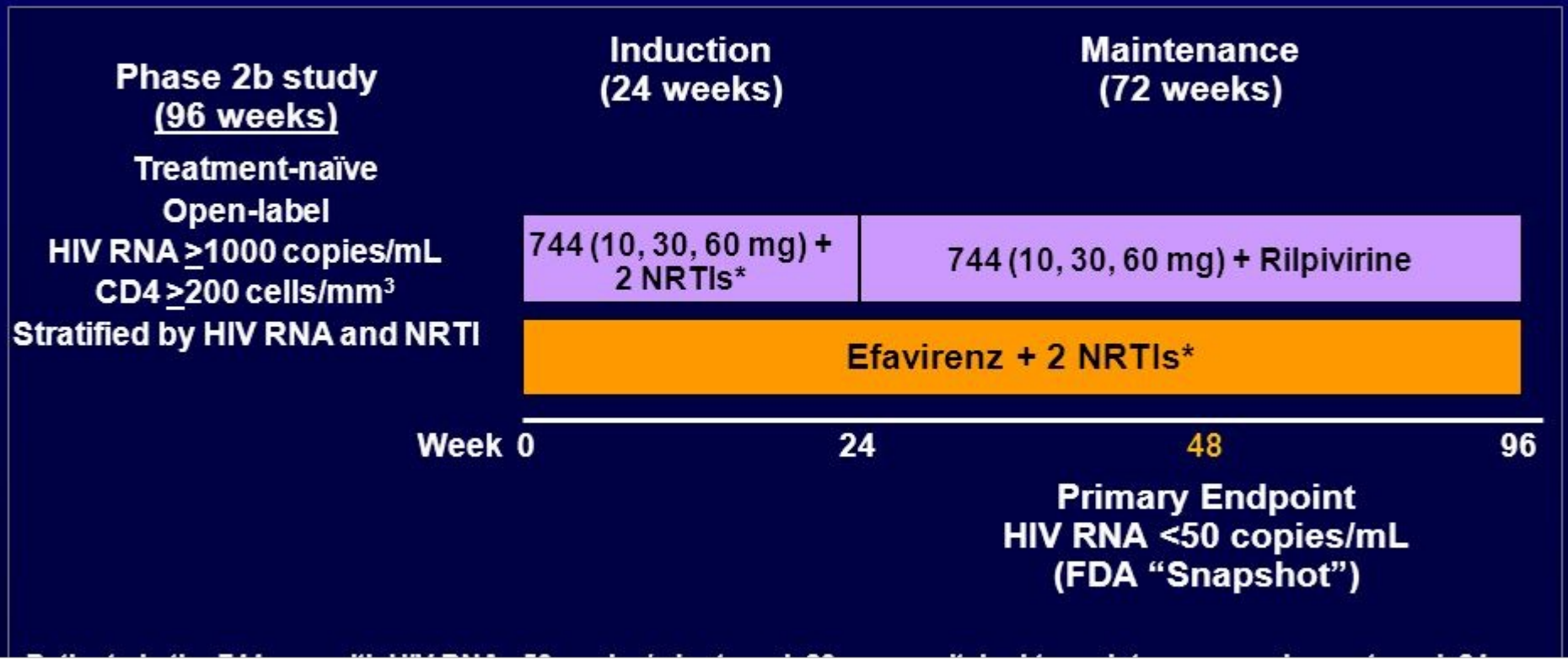
IN THE LATTE-2 STUDY:
2 SHOTS EVERY 4 OR 8 WEEKS TAKES THE PLACE OF DAILY ARV PILL.

IN BOTH INJECTION GROUPS, MORE THAN 90% OF PEOPLE REMAINED UNDETECTABLE.

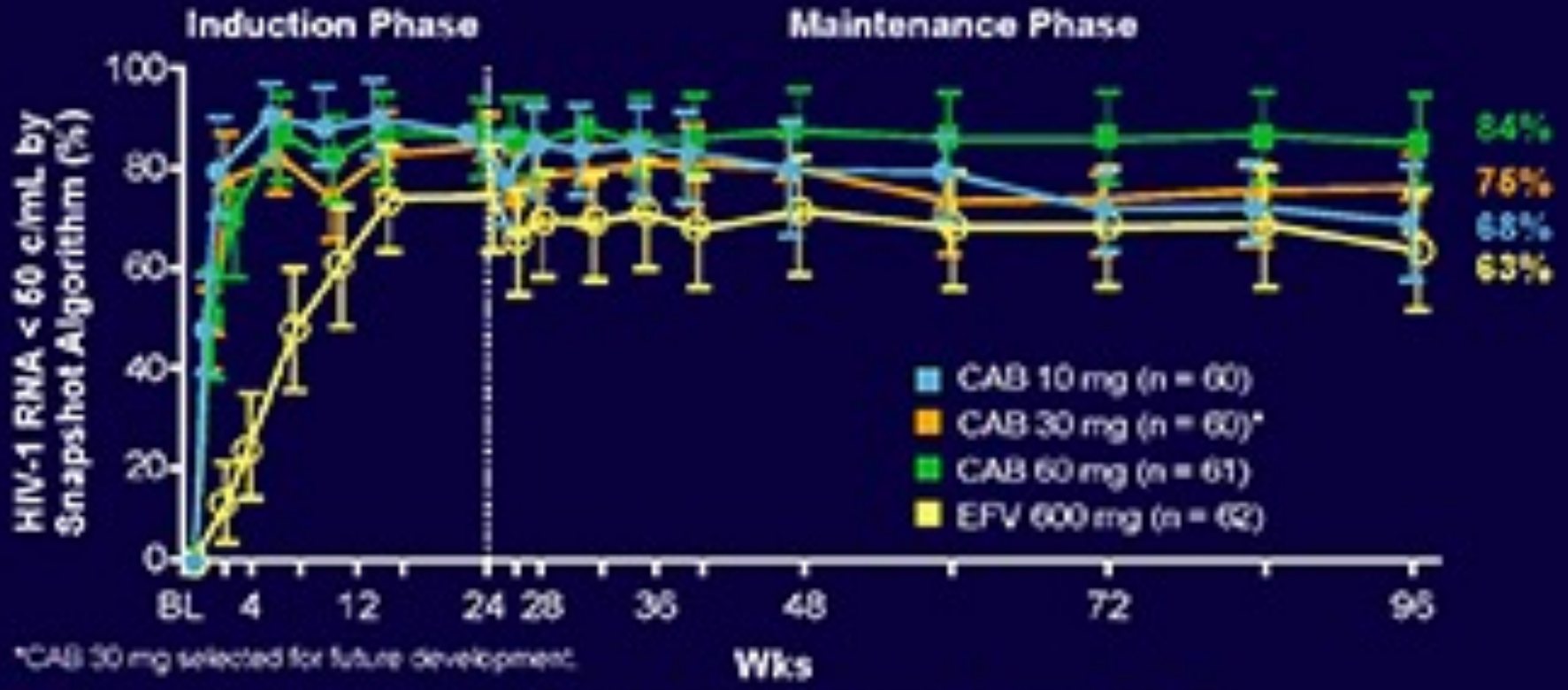
ALTHOUGH PAINFUL, PARTICIPANTS **PREFERRED** THE INJECTIONS.
SOME SAID THE INJECTIONS REDUCED THEIR FEELINGS OF STIGMA, AND GAVE THEM RELIEF FROM THE DAILY REMINDER OF LIVING WITH HIV.

BETA A PUBLICATION OF SAN FRANCISCO AIDS FOUNDATION

LATTE Study: 744 + Rilpivirine as 2-Drug Oral Maintenance Therapy



LATTE: Virologic Success Through Maintenance Wk 96



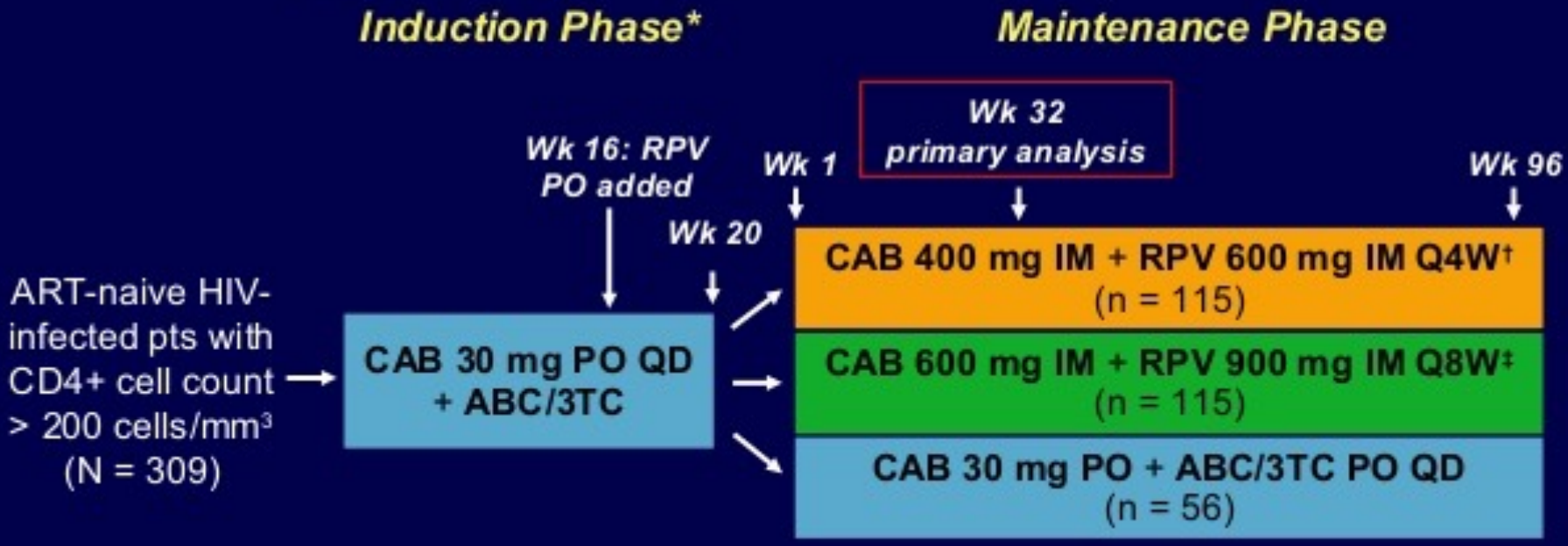
*CAB 30 mg selected for future development.

- 6 pts in CAB arms with PDVF at Wk 96; 4 additional pts since Wk 48
  - 3 pts in CAB 10-mg arm with treatment-emergent NNRTI resistance; 1 of these with both NNRTI + INSTI RAMs but decreased ARV exposure in PK analysis

Margolis D, et al. CROI 2015. Abstract 554LB. Reproduced with permission.

LATTE-2: Cabotegravir IM + Rilpivirine IM for Long-Acting Maintenance ART

- Multicenter, open-label phase IIb study
  - Cabotegravir: integrase inhibitor

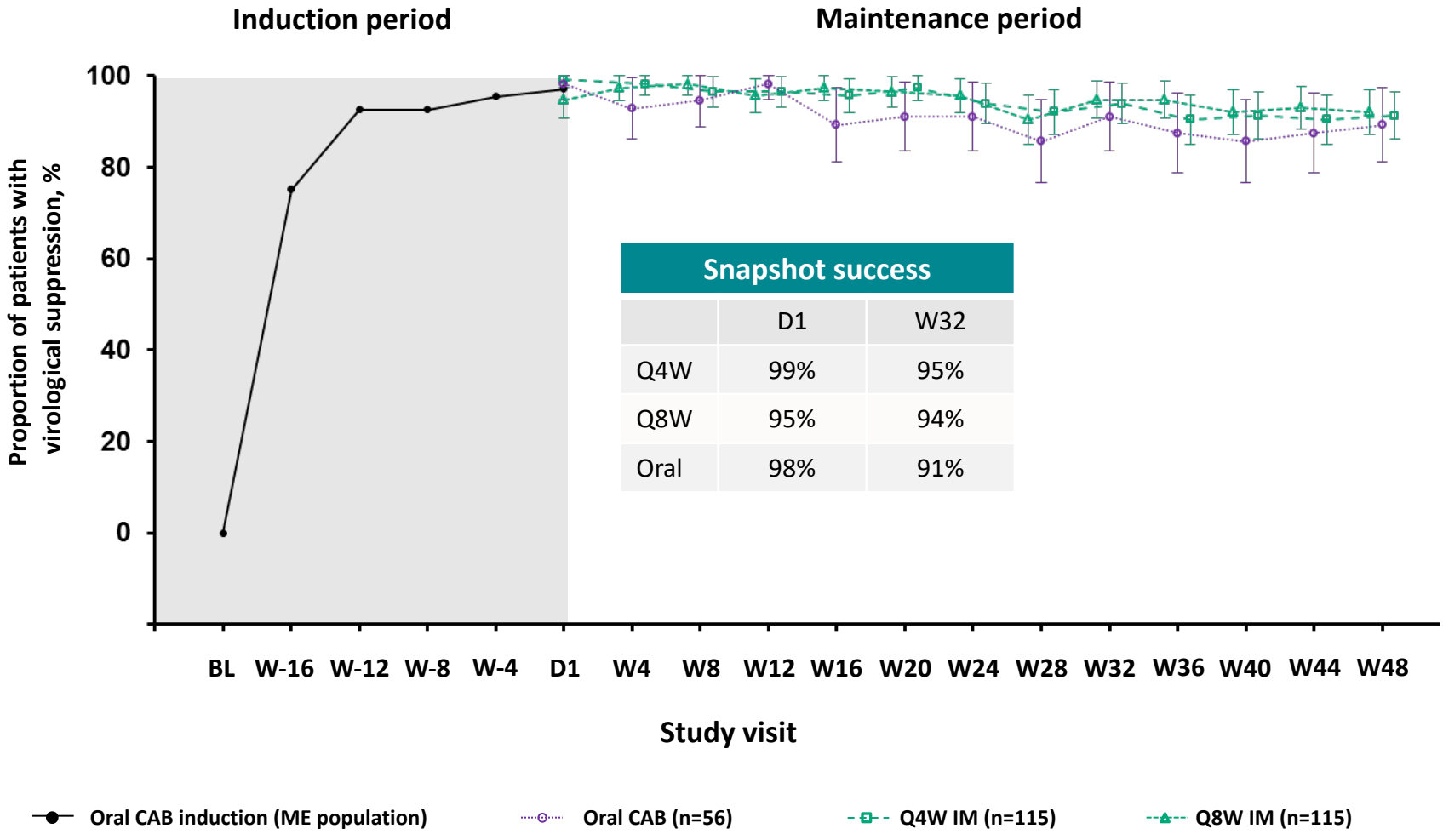


6 pts discontinued for AEs or death in induction analysis. *Pts with HIV-1 RNA < 50 c/mL from Wk 16 to Wk 20 continued to maintenance phase. †Loading dose: Day 1, CAB 800 mg + RPV 600 mg. ‡Loading dose: Day 1, CAB 800 mg + RPV 900 mg; Wk 4, CAB 600 mg.

Margolis DA, et al. CROI 2016. Abstract 31LB.

Slide credit: clinicaloptions.com

LATTE-2 Week 48 Results: HIV-1 RNA <50 c/mL by Snapshot (ITT-ME)



Snapshot success

	D1	W32
Q4W	99%	95%
Q8W	95%	94%
Oral	98%	91%

Margolis et al. AIDS 2016; Durban, South Africa. Abstract THAB0206LB.

Protocol-Defined Virologic Failure (PDVF): Genotype

Maintenance period[a]	Q8W IM (n=115)	Q4W IM (n=115)	Oral CAB (n=56)
Subjects with PDVF	2 (1%)[b]	0	1 (2%)
INI-r mutations	1[c]	0	0
NRTI-r mutations	0	0	0
NNRTI-r mutations	1[c]	0	0

- NNRTI—**K103N, E138G, and K238T** (FC RPV=3.3; Etravirine=1.9); INI—**Q148R** (FC CAB=5.1; Dolutegravir=1.38)[c]
- No additional PDVFs beyond W48 on any arm (all subjects through W72)[d]

PDVF: <1.0 $\log_{10}$ c/mL decrease in plasma HIV-1 RNA by Week 4, OR confirmed HIV-1 RNA ≥200 c/mL after prior suppression to <200 c/mL, OR >0.5 $\log_{10}$ c/mL increase from nadir HIV-1 RNA value ≥200 c/mL. [a]One additional PDVF without treatment-emergent resistance occurred during oral Induction Period due to oral medication non-adherence. [b]One PDVF at Week 4: no detectable RPV at Week 4 and Week 8, suggesting maladministration. [c]One PDVF at Week 48 at HIV-1 RNA 463 c/mL (confirmed at 205 c/mL). [d]Contains data beyond W48.

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Adverse Events and Labs—Maintenance Period

ITT-ME population, n (%)	Q8W IM (n=115)	Q4W IM (n=115)	Oral CAB (n=56)	IM subtotal (N=230)
Drug-related AEs, excluding ISRs (≥3%)				
Pyrexia	3 (3)	5 (4)	0	8 (3)
Fatigue	2 (2)	4 (3)	1 (2)	6 (3)
Influenza-like illness	3 (3)	2 (2)	0	5 (2)
Headache	2 (2)	2 (2)	2 (4)	4 (2)
Rash	0	3 (3)	0	3 (1)
Grade 3 and 4 AEs, excluding ISRs	10 (9%)	13 (11%)	2 (4%)	23 (10%)
Drug-related Grade 3/4 AEs, excluding ISRs[a]	2 (2)	4 (3)	0	6 (3)
Serious AEs (none drug related)	8 (7%)	8 (7%) [b]	3 (5%)	16 (7%)
AEs leading to withdrawal[c]	2 (2%)	7 (6%)	1 (2%)	9 (4%)
Grade 3 and 4 labs[d]	18 (16)	23 (20)	9 (16)	41 (18)

AE, adverse event; ISR, injection-site reaction. [a]Q8W: influenza-like illness, chills and pain; Q4W: influenza-like illness, rash, depression, and psychosis. [b]one death (epilepsy). [c]Q8W: ISR, ISR/chills/body pain; Q4W: Churg-Strauss vasculitis, hepatitis C, depression, epilepsy, psychosis, rash, and mesenteric vein thrombosis; oral CAB: hepatitis C. [d]Maintenance emergent.

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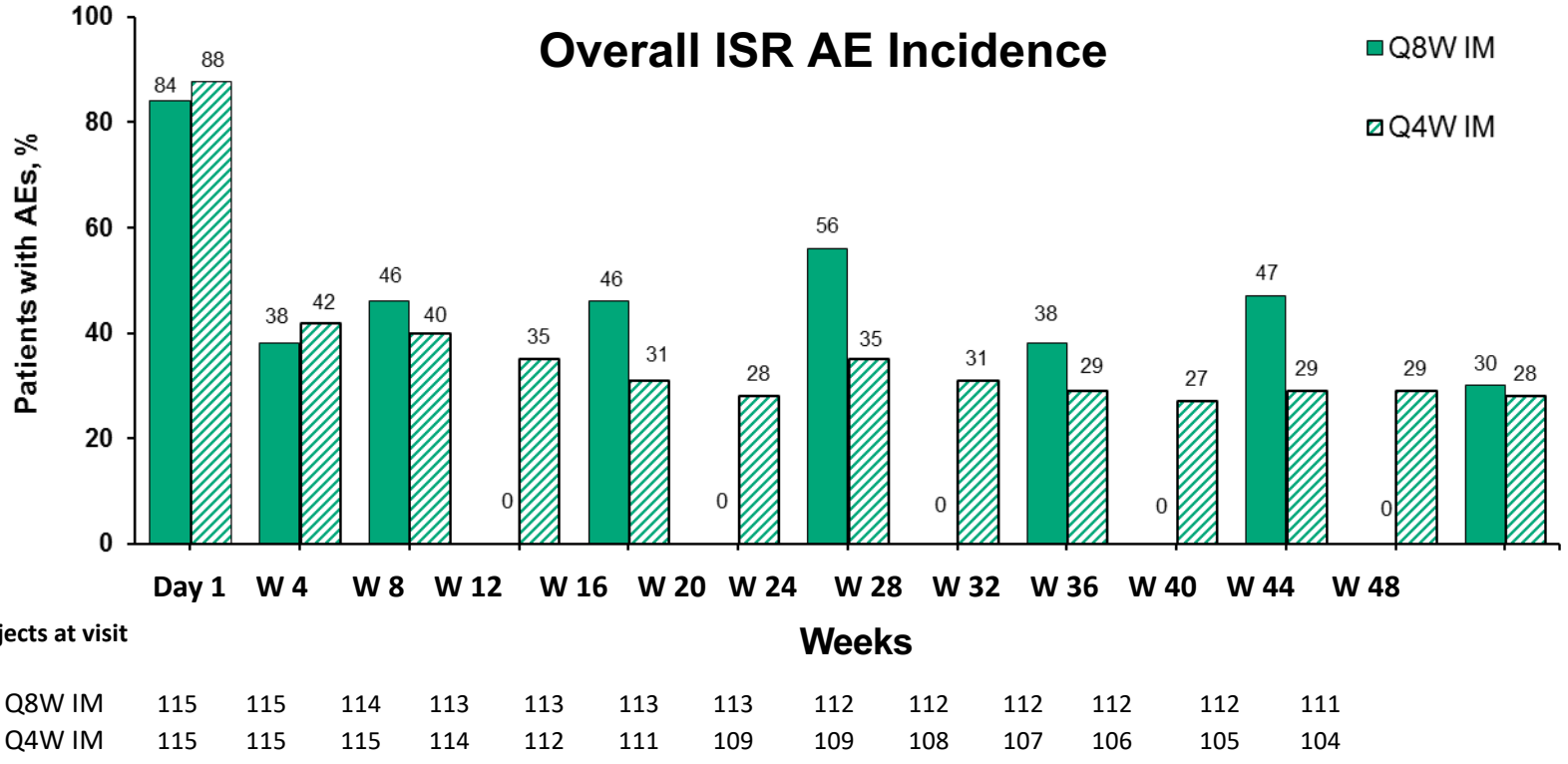
ISRs for CAB LA or RPV LA Over Time



Subjects at visit

Q8W IM	115	115	114	113	113	113	113	112	112	112	112	112	111
Q4W IM	115	115	115	114	112	111	109	109	108	107	106	105	104

- **99% of ISRs were mild (82%) or moderate (17%), and 90% resolved within 7 days**
- **Most common ISR events overall were pain (67%), nodules (7%), and swelling (6%)**
- **2/230 subjects (<1%) withdrew as a result of injection reactions (Q8W)**

Bars represent incidence of onset ISR events relative to the most recent IM injection visit.

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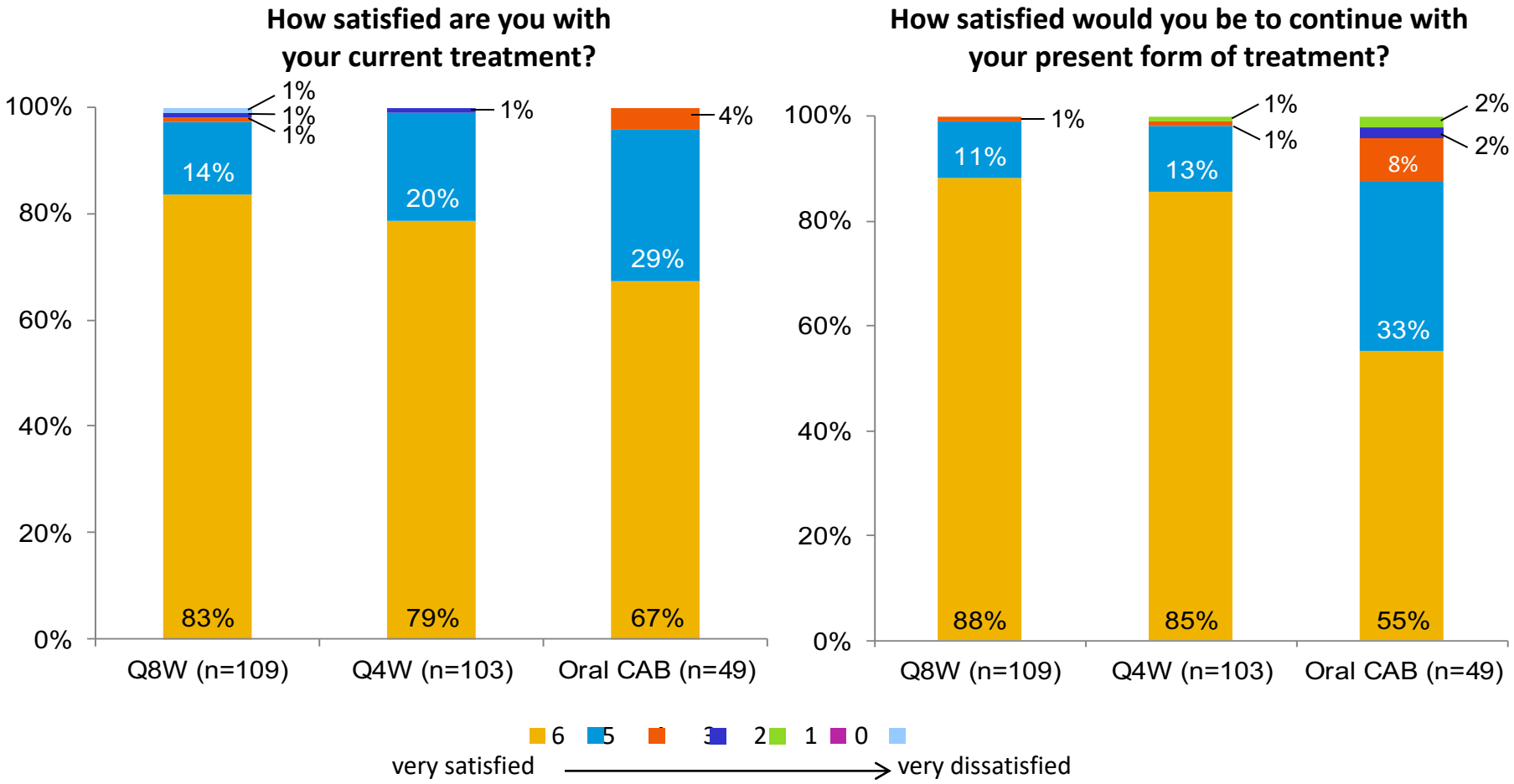
Patient-Reported Outcomes at Week 48: Maintenance Treatment[a]



Note: based on observed case data set of subjects who completed Week 48 questionnaires.
[a]HIV Treatment Satisfaction Questionnaire status version (HIVTSQs).

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Thank you for your attention