1° Workshop

La Scuola Medica Salernitana, le Infezioni Epatitiche e l'HIV

16-17Marzo 2016

Lloyd's Baia Hotel, Vietri sul mare (SA)

Vantaggi e svantaggi delle singole classi PI, NNRTI e INI in prima linea

Antonella Castagna

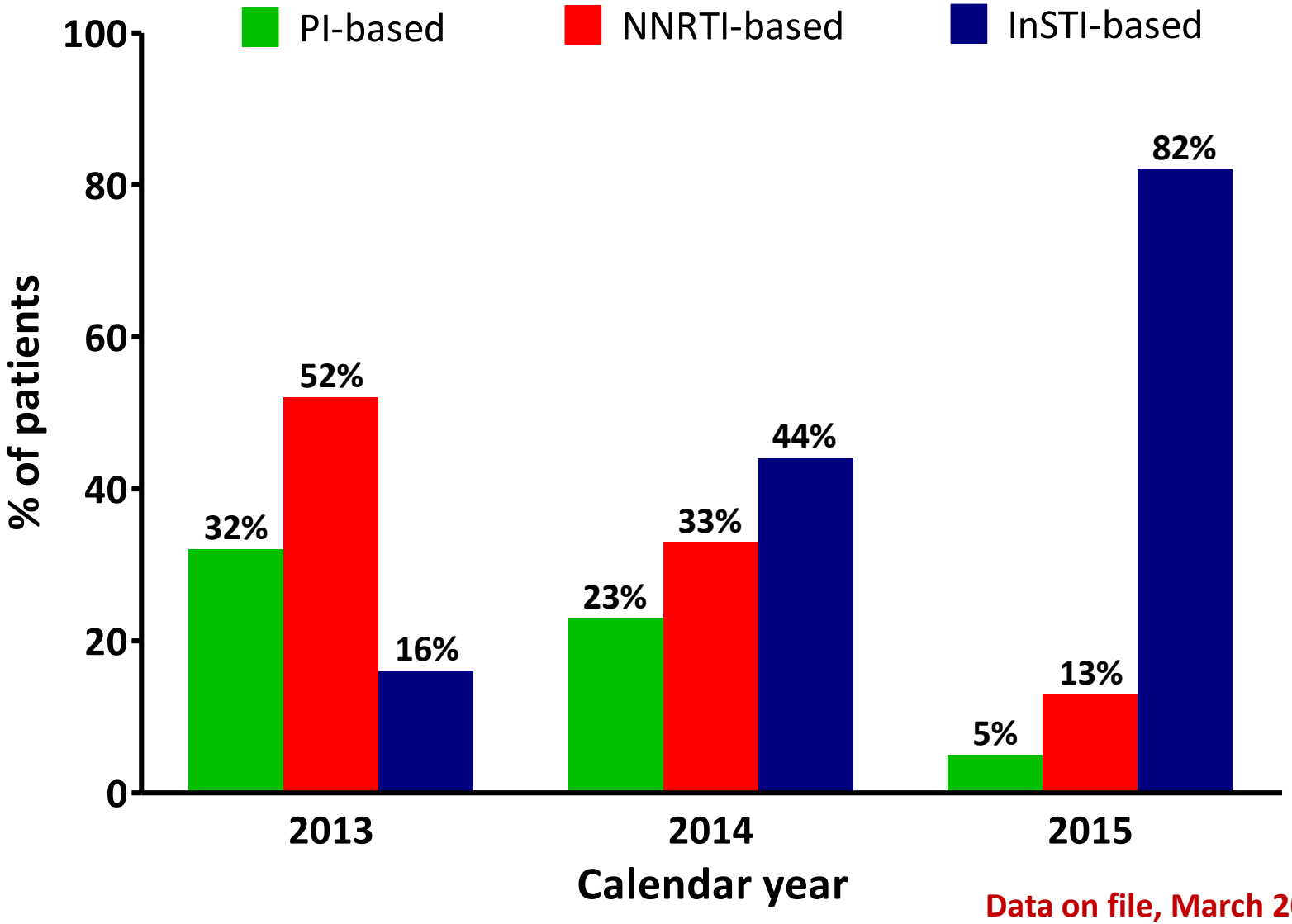
Linee Guida Italiane sull'utilizzo dei farmaci antiretrovirali e sulla gestione diagnostico-clinica delle persone con infezione da HIV-1

17 Dicembre 2015

Tabella 2a - Regimi raccomandati per l'inizio della cART.

REGIME	RACCOMANDAZIONE (FORZA/EVIDENZA)	RIFERIMENTI BIBLIOGRAFICI
Regimi raccomandati		
TDF/FTC+RAL	[AI]	[23-24,26,31-32]
TDF/FTC/EVG/COBI	[AI]	[27-30,66]
TAF/FTC/EVG/COBI	[AI]	[72]
TDF/FTC+DTG	[AI]	[31-32,34]
ABC/3TC+DTG	[AI]	[31-34]
ABC/3TC/DTG	[AI]	[31-35]
TDF/FTC/RPV (in caso di valori di HIV-RNA < 100.000 cp/mL e conta di T CD4+ > 200 cellule/µL)	[AI]	[12,14,18,19]
Regimi raccomandati in particolari condizioni		
TDF/FTC+ATV+r o TDF/FTC+DRV+r (in caso di condizioni non favorenti l'aderenza, di necessità di iniziare il trattamento prima della disponibilità del risultato del test di resistenza, di inizio terapia in gravidanza)	[AII]	[7,11,20-22,26,28-29,34,42,69]
TDF/FTC+ATV/COBI o TDF/FTC+DRV/COBI (in caso di condizioni non favorenti l'aderenza, di necessità di iniziare il trattamento prima della disponibilità del risultato del test di resistenza)	[AII]	[67,68]

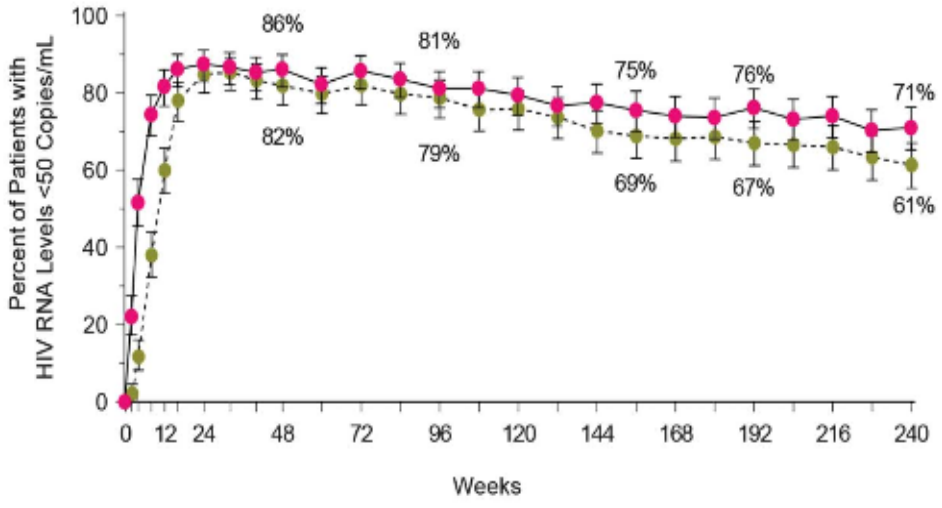
First-line regimens OSR



Data on file, March 2016

STARTMRK

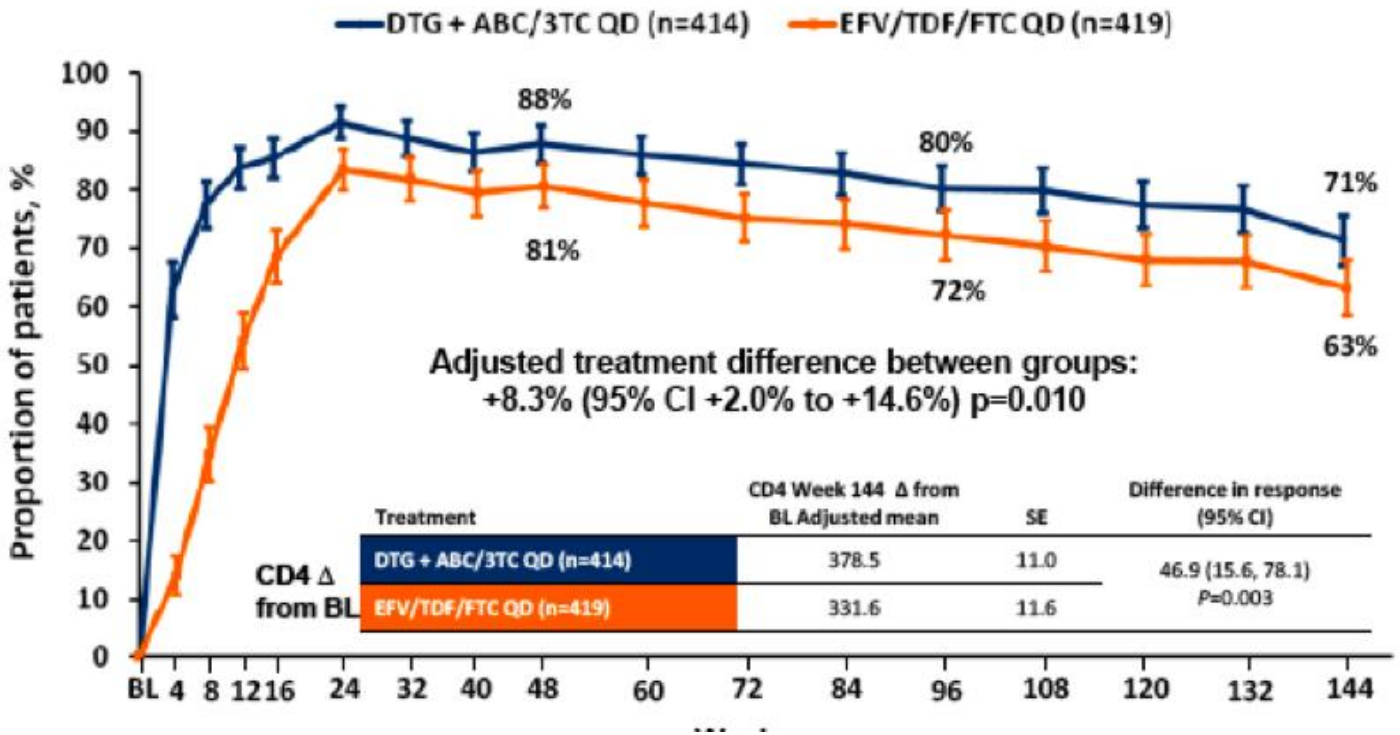
A



Number of Contributing Patients

Raltegravir 400 mg b.i.d.	281	278	279	280	281	281	277	280	281	281	277	279
Efavirenz 600 mg q.h.s.	282	282	282	281	282	282	281	281	282	282	282	279

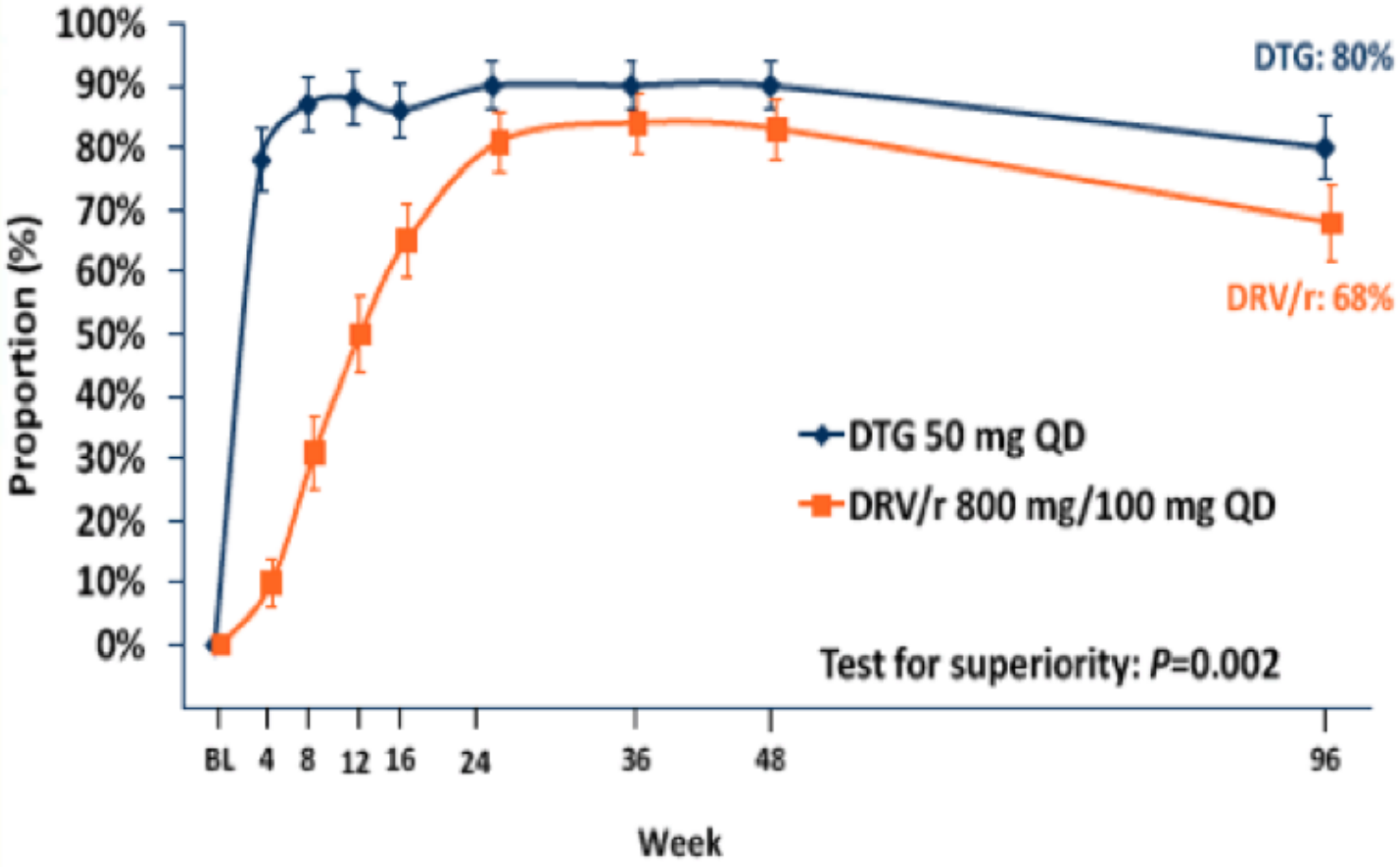
Proportion <50 c/mL (95% CI) and CD4 Change from Baseline



CD4 Δ from BL

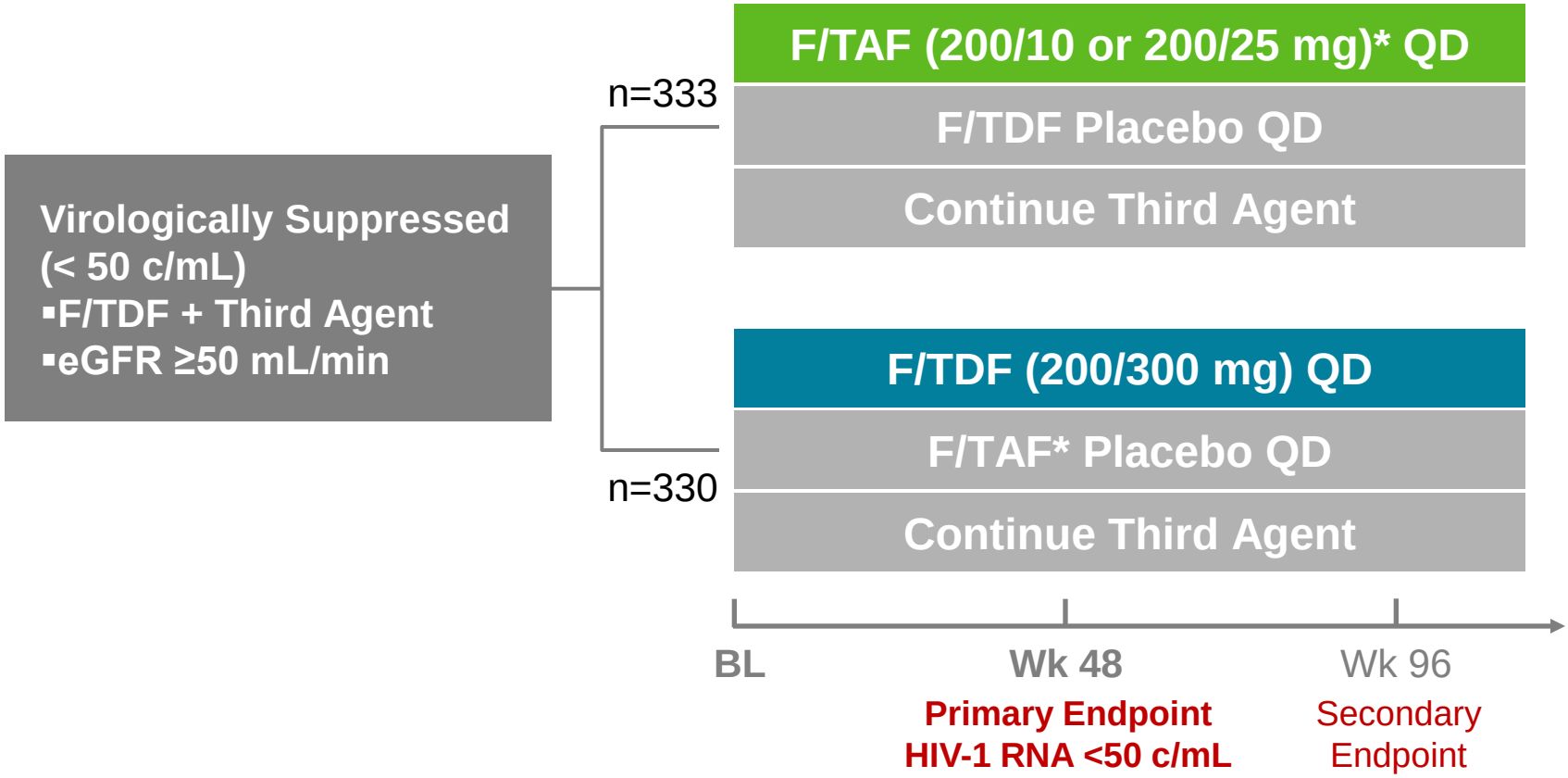
Treatment	CD4 Week 144 Δ from BL Adjusted mean	SE	Difference in response (95% CI)
DTG + ABC/3TC QD (n=414)	378.5	11.0	46.9 (15.6, 78.1) *P*=0.003
EFV/TDF/FTC QD (n=419)	331.6	11.6	

Proportion (95% CI) of Individuals With HIV-1 RNA <50 c/mL Over Time – Snapshot



Switch from F/TDF to F/TAF

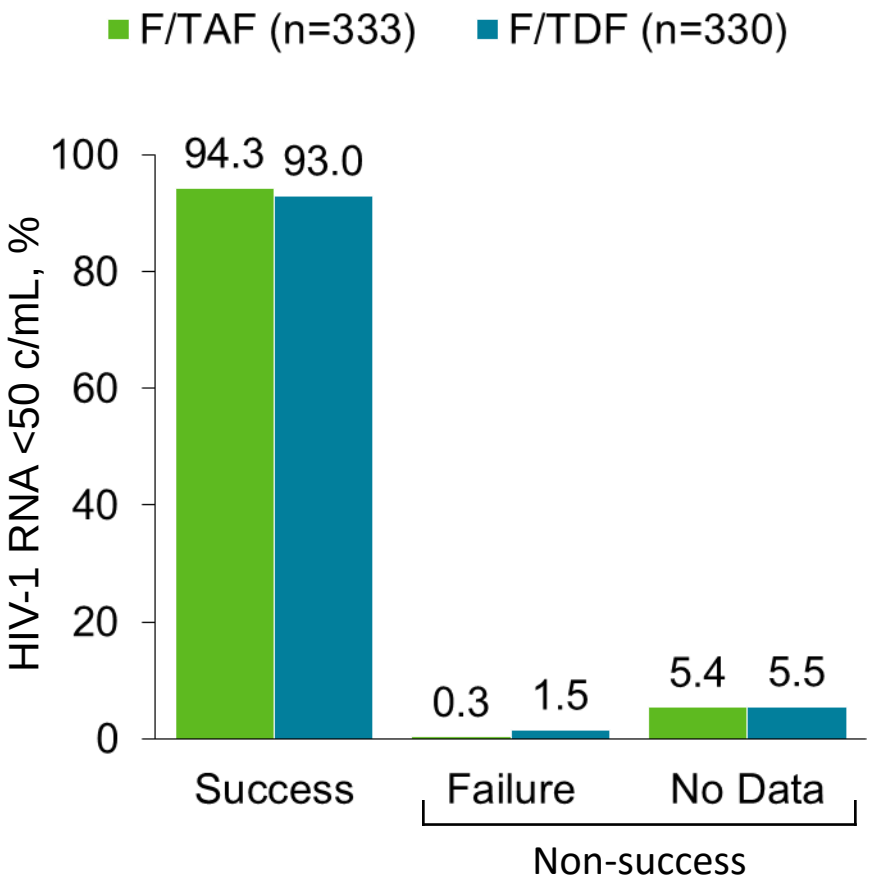
- Randomized, double-blind, double-dummy, active-controlled study



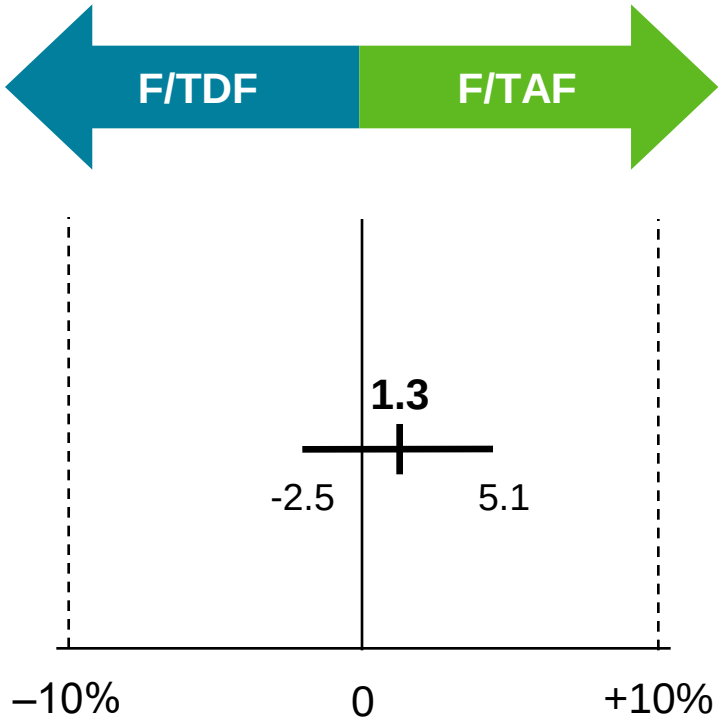
*F/TAF Dose:
- 200/10 mg with boosted PIs
- 200/25 mg with unboosted third agents

Efficacy at Week 48 (Snapshot)

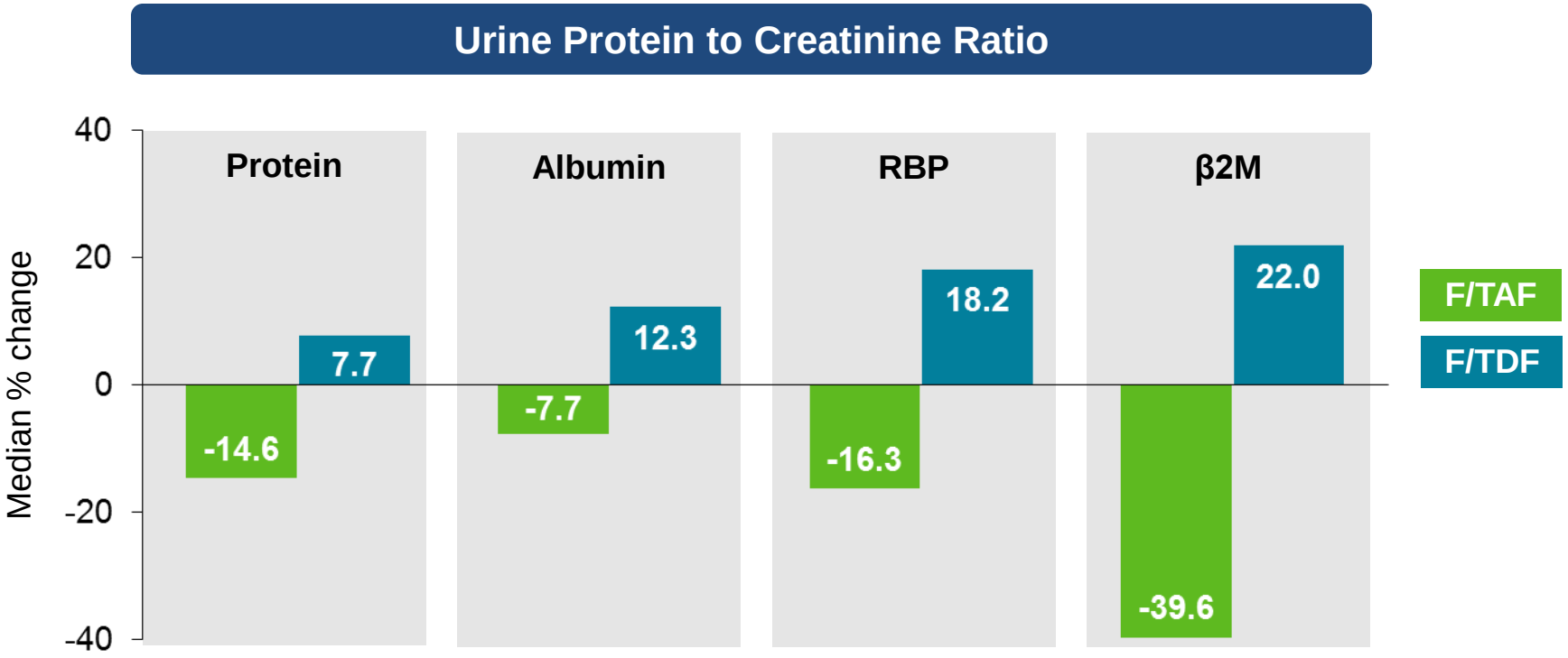
Virologic Outcome



Treatment Difference (95% CI)



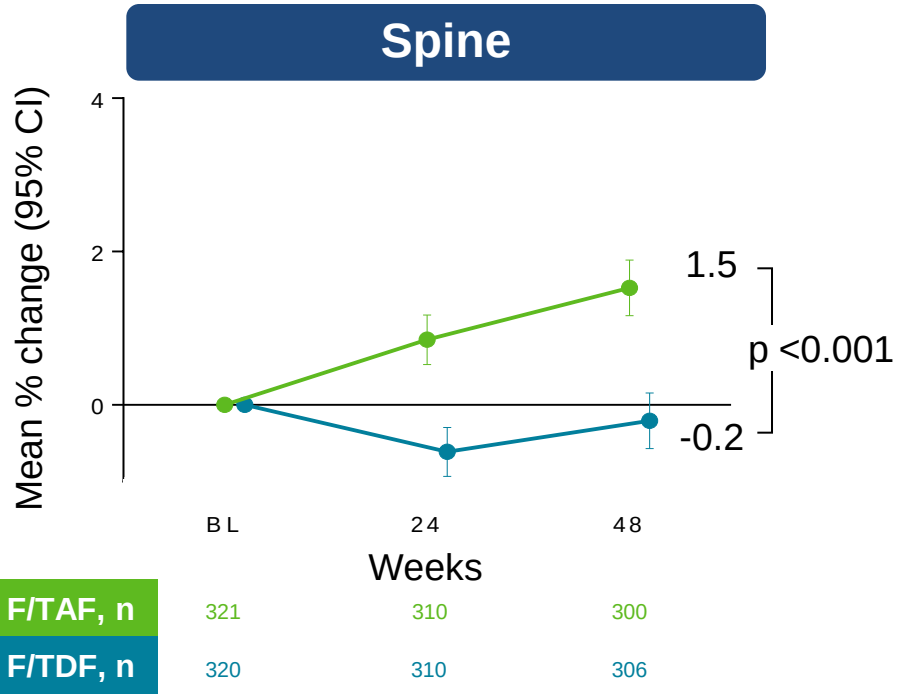
Change in Renal Biomarkers at Week 48

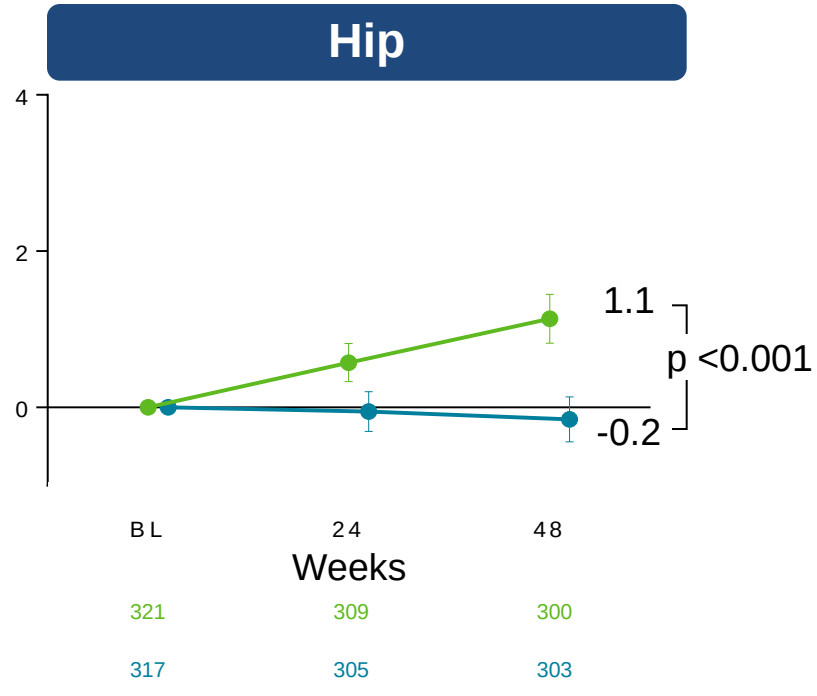


All differences between treatments statistically significant ($p < 0.001$)

RBP, retinol-binding protein; β2M, β2-microglobulin.

Change in Bone Mineral Density through Week 48





F/TAF, n	321	310	300
F/TDF, n	320	310	306

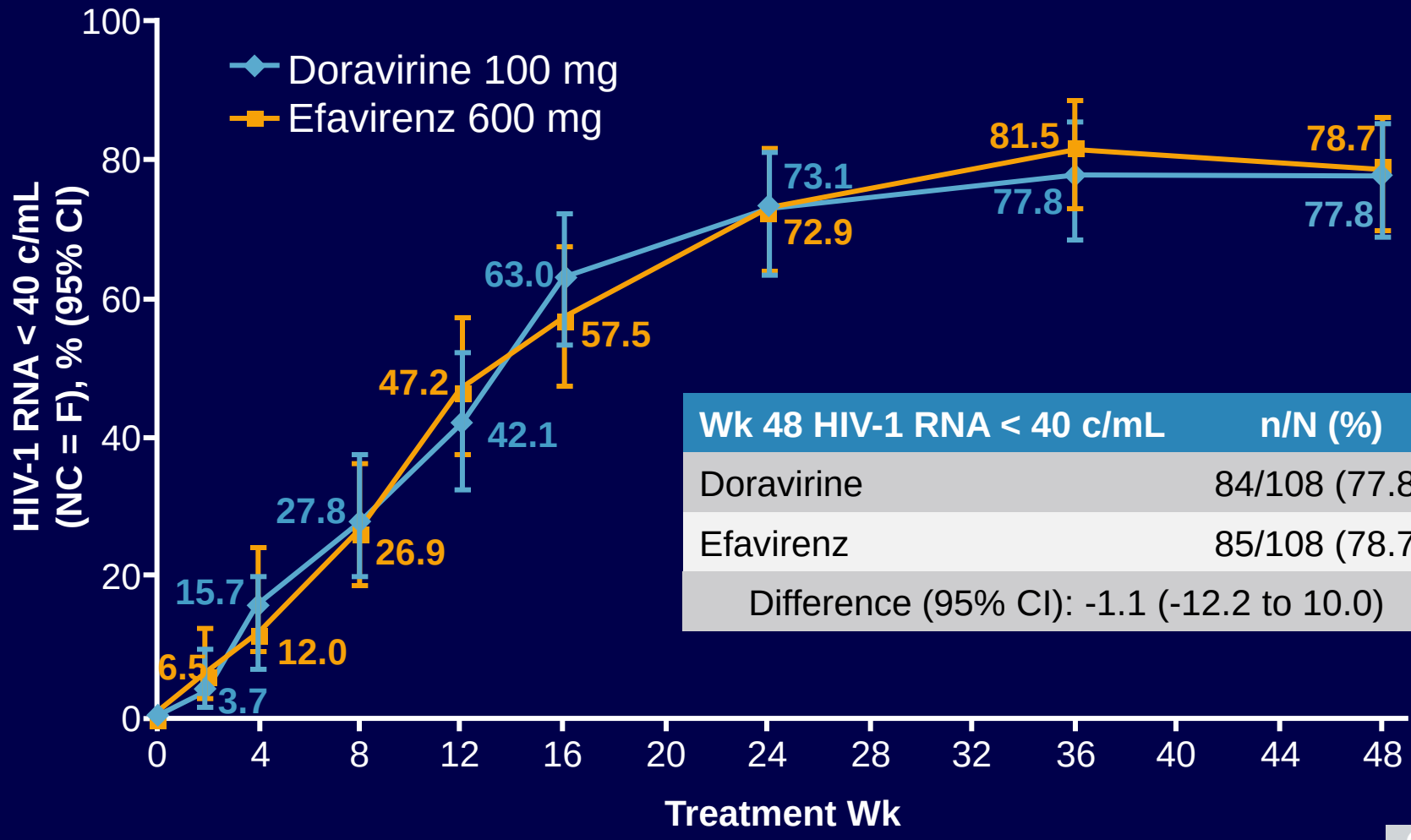
F/TAF, n	321	309	300
F/TDF, n	317	305	303

≥ 3% BMD increase at Week 48

F/TAF	30%	p<0.001
F/TDF	14%	

17%	p=0.003
9%	

MK-1439-007: Primary Endpoint



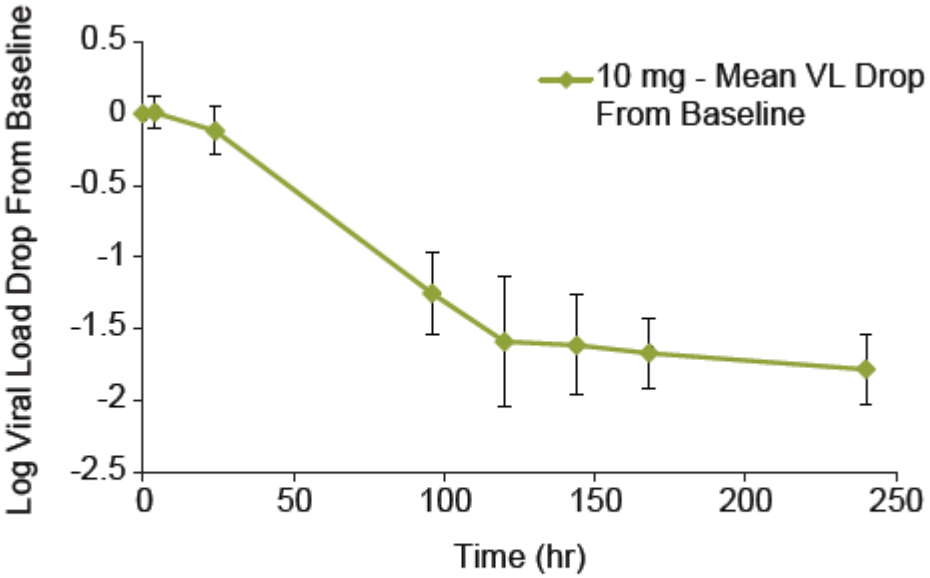
Wk 48 HIV-1 RNA < 40 c/mL	n/N (%)
Doravirine	84/108 (77.8)
Efavirenz	85/108 (78.7)
Difference (95% CI): -1.1 (-12.2 to 10.0)	

Gatell JM, et al. CROI 2016. Abstract 470. Reproduced with permission.

Slide credit: clinicaloptions.com

A Single Monotherapy Dose of MK-8591, a Novel NRTI, Suppresses HIV for Ten Days

MK-8591: Time vs Log_{10} Viral Load Reduction (N=6)



- No NRTI related resistance mutations were identified predose or postdose in any patient

EJ Friedman, CROI 2016

Poster
461LB
2016 Conference on Retroviruses and Opportunistic Infections, February 22-25, 2016, Boston, MA

Early Evidence of Antiviral Activity and Safety of ABX464 in HIV Treatment-Naïve Patients

Didier Scherrer[1], Jean-Marc Steens[1], Supparatpinyo Kuanchai[2], Ratanasuwan Winai[3], Kiat Ruxrungtham[4], Regine Rouzier[5], Jamal Tazi[6], Paul Gineste[1], Hartmut Ehrlich[1], Robert Murphy[7]

[1] ABIVAX, Paris, France; [2] Chiang Mai University Chiang Mai, Thailand; [3] Siriraj Hospital, Bangkok, Thailand; [4] HIV-NAT, Chulalongkorn University Hospital, Bangkok, Thailand; [5] Cap Research, Phoenix, Mauritius; [6] University of Montpellier, Montpellier, France; [7] Northwestern University Feinberg School of Medicine, Chicago, USA

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Effect of ABX464 on Unspliced mRNA Biogenesis in-HIV Infected Cells

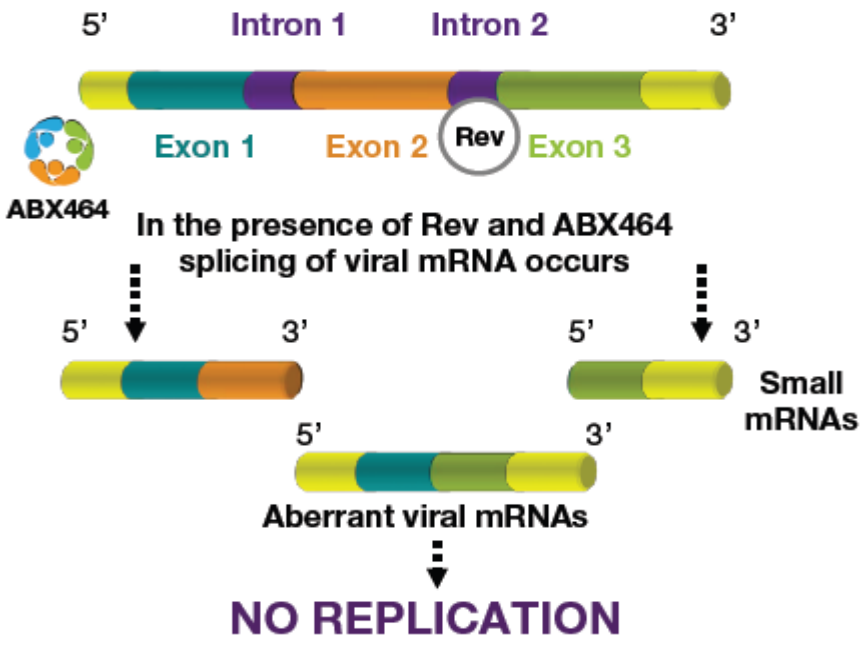
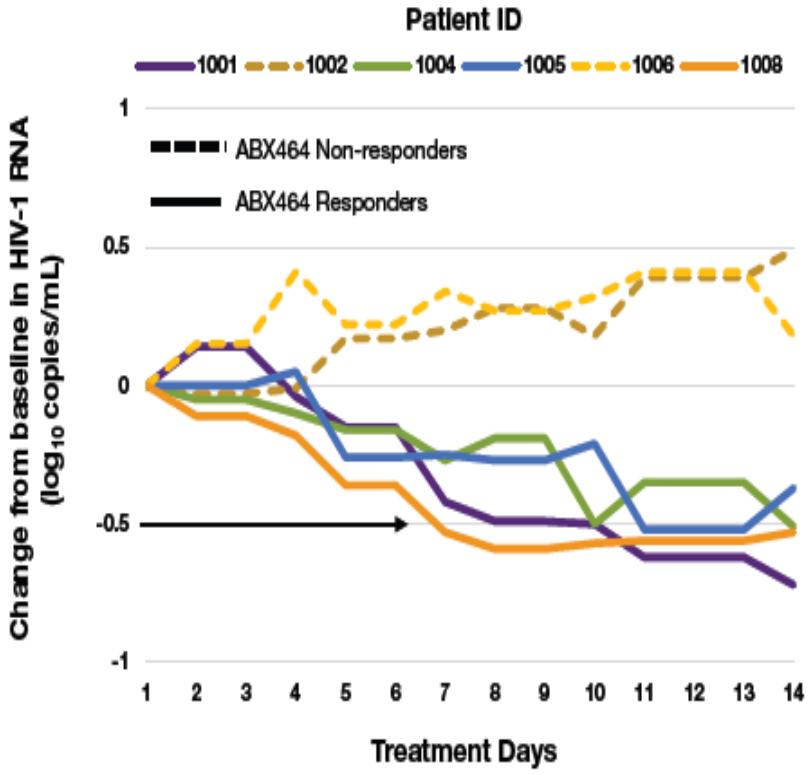


Figure 4. Change in Viral Load from Baseline in the 150 mg ABX464 Treatment Group

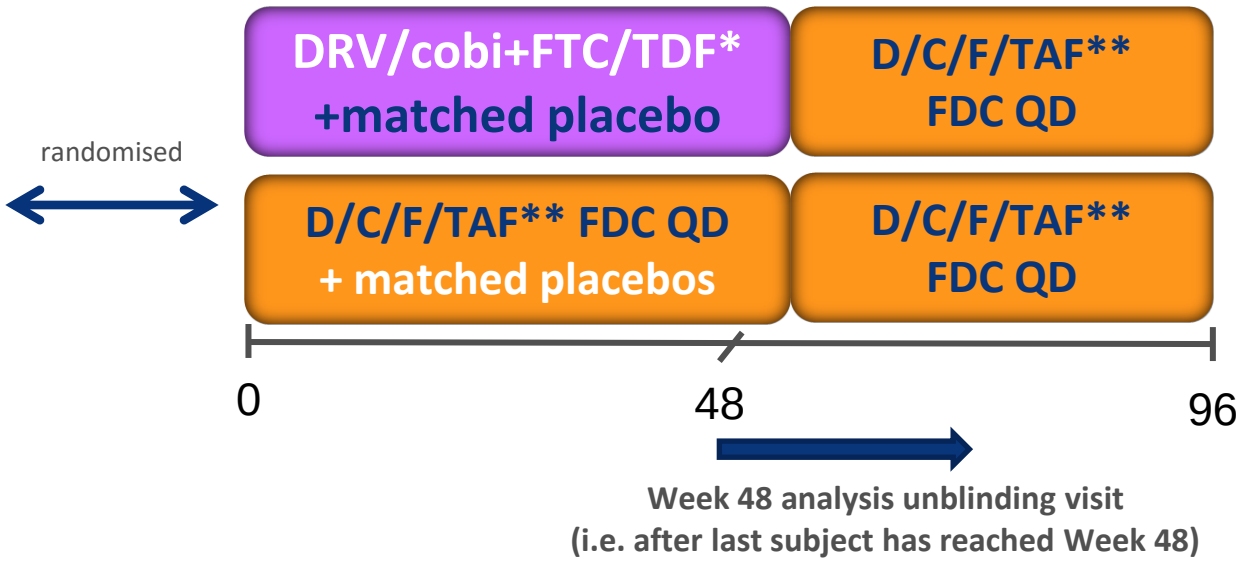


AMBER: D/C/F/TAF FDC in Naïves

Estimated Enrollment:	670 untill March 2016
Study Start Date:	July 2015
Estimated Study Completion Date:	September 2018
Estimated Primary Completion Date:	April 2017 (Final data collection date for primary outcome measure)

- HIV-1 >=18 years
- ART-naïve
- Plasma HIV-1 RNA ≥ 1,000 c/mL at Screening

randomised



- A Phase 3, Randomized, Active-controlled, Double Blind, Non-inferiority Study
- Primary Outcome Measures: Percentage of Participants With HIV-1 RNA< 50 copies/mL defined by FDA Snapshot Approach at Week 48

PI/r Induction Maintenance timeline

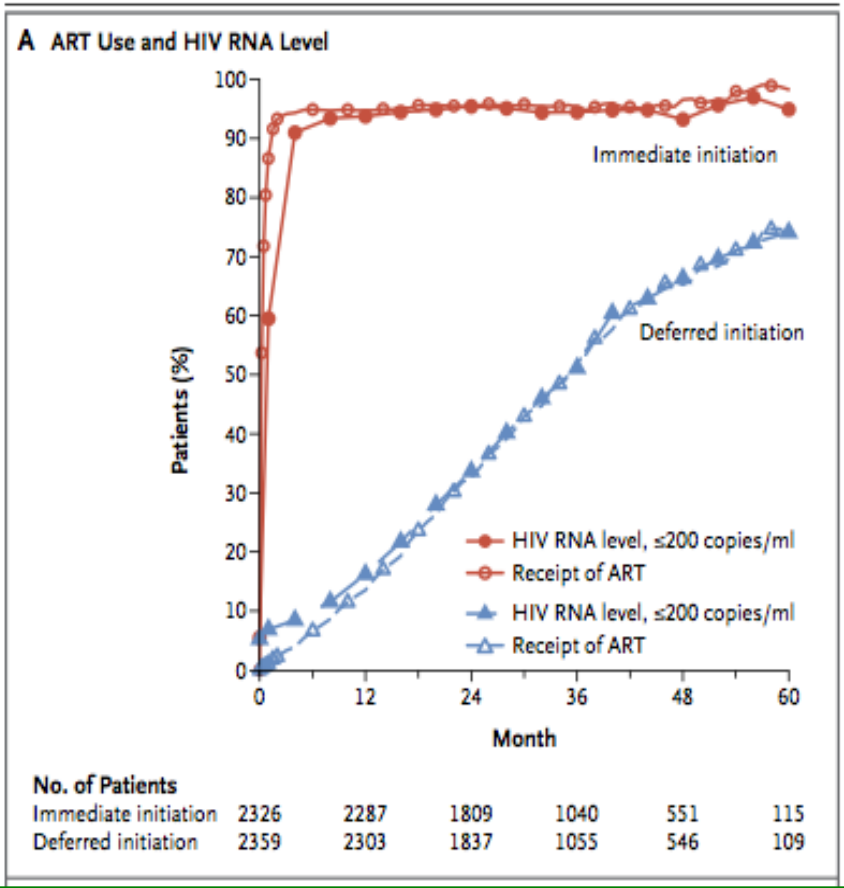
	HIV	ART	< 50 since	PI/r	<50
MONOI	-	8.3 (y)	–	24 (m)	88%
MONET	8.1 (y)	6.5 (y)	-	36 (m)	69%
PIVOT	_	4.2 (y)	38 (m)	36 (m)	65%
PROTEA	8.1 (y)	5.7 (y)	12 (m)	12 (m)	86%
ATLAS-M	4.2 (y)	2.8 (y)	23.5 (m)	12 (m)	86.5%
SALT	5.9 (y)	40.5 (m)	28 (m)	12 (m)	78 %
MODAT	5.1 (y)	25 (m)	19 (m)	24 (m)	63%

START

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Immediate-Initiation Group (N=2326)	Deferred-Initiation Group (N=2359)	All Patients (N=4685)
Median age (IQR) — yr	36 (29–44)	36 (29–44)	36 (29–44)
Female sex — no. (%)	624 (26.8)	633 (26.8)	1,257 (26.8)
Race or ethnic group — no. (%)†			
Asian	198 (8.5)	190 (8.1)	388 (8.3)
Black	702 (30.2)	708 (30.0)	1,410 (30.1)
Latino or Hispanic	320 (13.8)	318 (13.5)	638 (13.6)
White	1,015 (43.6)	1,071 (45.4)	2,086 (44.5)
Other	91 (3.9)	72 (3.1)	163 (3.5)
Geographical region — no. (%)			
Africa	499 (21.5)	501 (21.2)	1,000 (21.3)
Asia	179 (7.7)	177 (7.5)	356 (7.6)
Australia	56 (2.4)	53 (2.2)	109 (2.3)
Europe and Israel	763 (32.8)	776 (32.9)	1,539 (32.8)
North America	248 (10.7)	259 (11.0)	507 (10.8)
South America and Mexico	581 (25.0)	593 (25.1)	1,174 (25.1)
Mode of infection with HIV — no. (%)			
Sexual contact			
Men having sex with men	1,300 (55.9)	1,286 (54.5)	2,586 (55.2)
With person of opposite sex	873 (37.5)	917 (38.9)	1,790 (38.2)
Injection-drug use	37 (1.6)	27 (1.1)	64 (1.4)
Blood products, other, or unknown	116 (5.0)	129 (5.5)	245 (5.2)
Median time since HIV diagnosis (IQR) — yr	1.0 (0.4–3.0)	1.1 (0.4–3.1)	1.0 (0.4–3.1)
Median CD4+ count (IQR) — cells/mm^3‡	651 (585–765)	651 (582–764)	651 (584–765)
Median HIV RNA (IQR) — copies/ml	13,000 (3133–43,808)	12,550 (2963–42,567)	12,759 (3019–43,391)
Current smoker — no. (%)	730 (31.4)	766 (32.5)	1,496 (31.9)
Median CHD risk at 10 yr (IQR) — %§	1.9 (0.5–5.0)	1.9 (0.5–5.3)	1.9 (0.5–5.1)

START


A ART Use and HIV RNA Level
Patients (%)
Month
Immediate initiation
Deferred initiation
HIV RNA level, ≤200 copies/ml
Receipt of ART
HIV RNA level, ≤200 copies/ml
Receipt of ART
No. of Patients
Immediate initiation 2326 2287 1809 1040 551 115
Deferred initiation 2359 2303 1837 1055 546 109

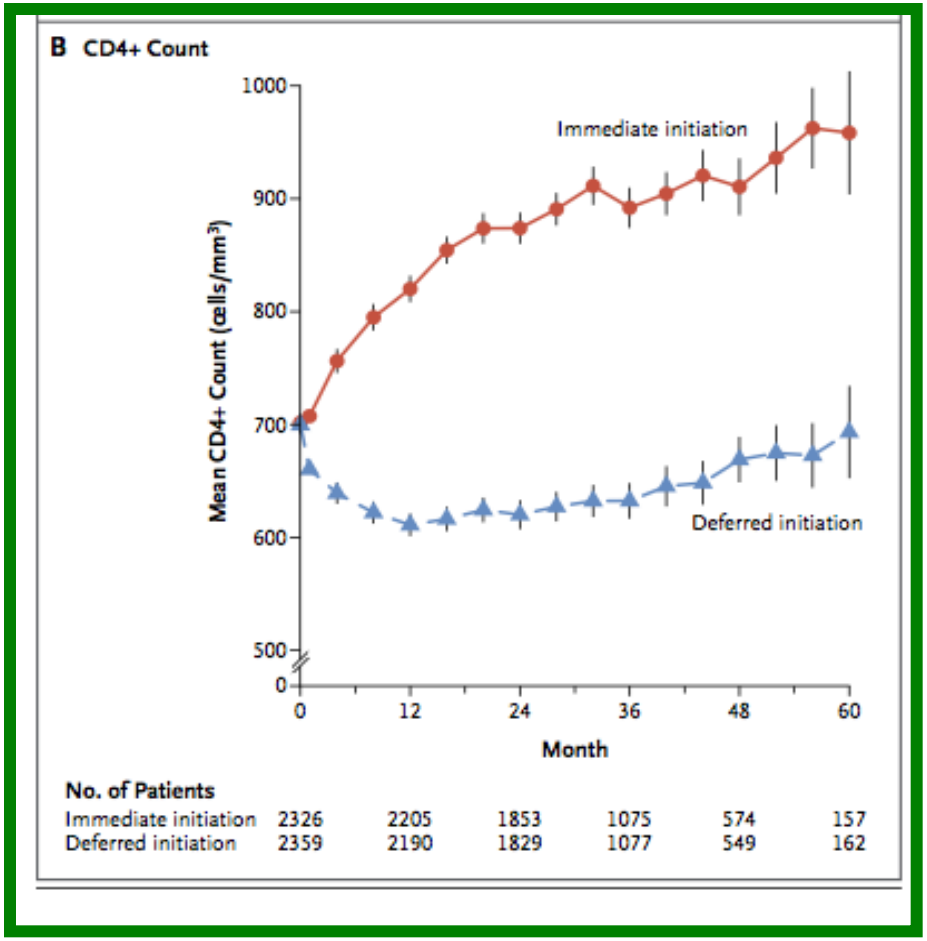

B CD4+ Count
Mean CD4+ Count (cells/mm³)
Month
Immediate initiation
Deferred initiation
No. of Patients
Immediate initiation 2326 2205 1853 1075 574 157
Deferred initiation 2359 2190 1829 1077 549 162

Table 1. Snapshot Responders at Week 96

	SPRING-2		SINGLE		FLAMINGO	
	DTG	RAL	DTG	EFV/FTC/TDF	DTG	DRV/r
OVERALL	332/411 (81%)	314/411 (76%)	332/414 (80%)	303/419 (72%)	194/242 (80%)	164/242 (68%)
INDIVIDUALS WITH HIGH BASELINE VL BY BACKGROUND REGIMEN						
>100,000 c/mL						
ABC/3TC	27/37 (73%)	26/39 (67%)	95/134 (71%)	—	11/13 (85%)	7/12 (58%)
TDF/FTC	62/77 (81%)	47/77 (61%)	—	94/131 (72%)	39/48 (81%)	25/49 (51%)
INDIVIDUALS WITH LOW BASELINE CD4						
<200 c/mm^3	39/55 (71%)	28/50 (56%)	39/57 (68%)	45/62 (73%)	18/23 (78%)	14/24 (58%)
200 to <350 c/mm^3	116/144 (81%)	103/139 (74%)	135/163 (83%)	113/159 (71%)	60/73 (82%)	36/51 (71%)

abstract
948

Unexpectedly High Rate of Intolerance for Dolutegravir in Real Life Setting

Guido van den Berk, Josephine Oryszczyn, Willem Blok, Narda van der Meche, Rosa Regez, Daoud Ait Moha, **Kees Brinkman**

dept internal medicin OLVG, Amsterdam, The Netherlands – k.brinkman@olvg.nl

	total (N=387)		naives(N=65)		non-naives (N=322)		
median age (IQR)	48		46	(22)	48	(13)	ns
female	44	11,4%	8	12,3%	36	11,2%	ns
dutch origin	136	35,1%	28	43,1%	108	33,5%	ns
median CD4/mm3 (IQR)	650		530	(395)	655	(345)	ns
median DGV days (IQR)	220		196	(147)	221	(148)	ns
DGV separate..	156		15		141		
DGV in STR..	231		50		181		

DGV stopped	62	16,0%	13	20,0%	49	15,2%	ns
median DGV days (IQR)	78		81	(71)	75	(99)	ns
female	5	11,4%	3	37,5%	2	5,6%	p=0.01
DGV separate	24	15,4%	1	6,7%	23	16,3%	ns
DGV in STR	38	16,6%	12	24,0%	26	14,4%	ns

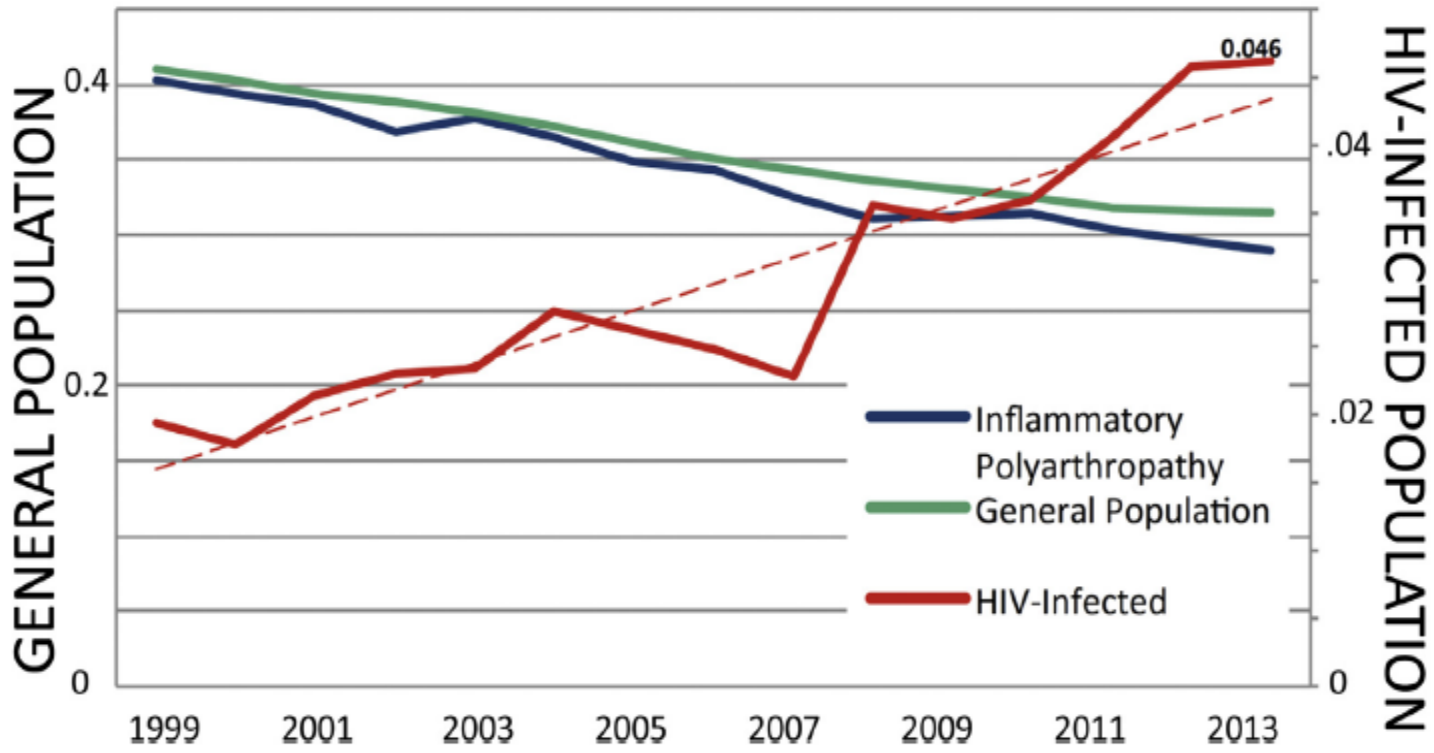
reason for interruption							
other than toxicity*	6	9,7%	1	7,7%	5	10,2%	
toxicity	56	90,3%	12	92,3%	44	89,8%	ns
sleeping..	19	31,3%	5	38,5%	14	28,6%	ns
gastro-intestinal..	18	29,5%	4	30,8%	14	28,6%	ns
neuro-psychiatric..	12	19,7%	3	23,1%	9	18,4%	ns
paresthesia..	6	9,7%	0	0,0%	6	12,2%	ns
headache..	8	12,9%	0	0,0%	8	16,3%	ns
fatigue..	9	14,6%	1	7,7%	8	16,3%	ns
allergy..	1	1,7%	1	7,7%	0	0,0%	ns
other..	5	8,2%	1	7,7%	4	8,2%	ns

*LTFU, HBV protection, Insurance, Induction, patient request, Interaction

Patterns of Cardiovascular Mortality for HIV-Infected Adults in the United States: 1999 to 2013

Matthew J. Feinstein, MD[a,*], Ehete Bahiru, MD[a], Chad Achenbach, MD, MPh[b], Christopher T. Longenecker, MD[c], Priscilla Hsue, MD[d], Kaku So-Armah, PhD[e], Matthew S. Freiberg, MD[f], and Donald M. Lloyd-Jones, MD, ScM[g]

Coronary Artery Disease/CVD Mortality for HIV



Changes in CVD Risk Factors with Immediate and Deferred ART in the START Trial

Jason V. Baker[1,2], Shweta Sharma[3], Amit Achhra[4], Jose Ignacio Bernardino[5], Johannes R Bogner[6], Daniel Duprez[1], Sean Emery[4], Brian Gazzard[7], Jonathan Gordin[8], Greg Grandits[3], Andrew Phillips[9], Siegfried Schwarze[10], Elsayed Z. Soliman[11], Stephen A. Spector[12], Giuseppe Tambussi[13], and Jens Lundgren[14] for the INSIGHT START (Strategic Timing of AntiRetroviral Treatment) Study Group

[1]Department of Medicine, University of Minnesota, USA; [2]Division of Infectious Diseases, Hennepin County Medical Center, USA; [3]Division of Biostatistics, University of Minnesota, USA; [4]Kirby Institute, University of New South Wales, Australia; [5]Department of Medicine. Hospital La Paz. IdiPAZ, Spain; [6]Division of Infectious Diseases, MedIV, University Hospital of Munich, Germany; [7]Chelsea and Westminster Hospital, UK; [8]Division of Cardiology, David Geffen School of Medicine at University of California, USA; [9]HIV Epidemiology & Biostatistics Group, University College London, UK; [10]European AIDS Treatment Group, Germany; [11]Epidemiological Cardiology Research Center, Wake Forest School of Medicine, USA; [12]Division of Pediatric Infectious Diseases, University of California San Diego and Rady Children's Hospital, USA; [13]San Raffaele Scientifi Institute, Italy; [14]CHIP, Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Denmark

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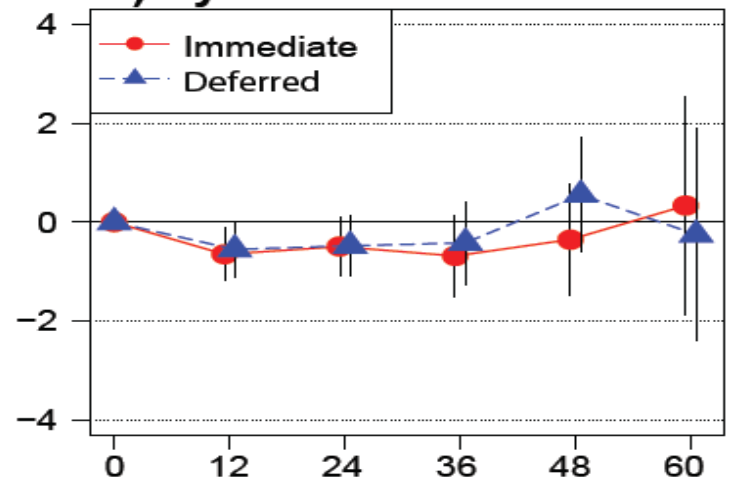
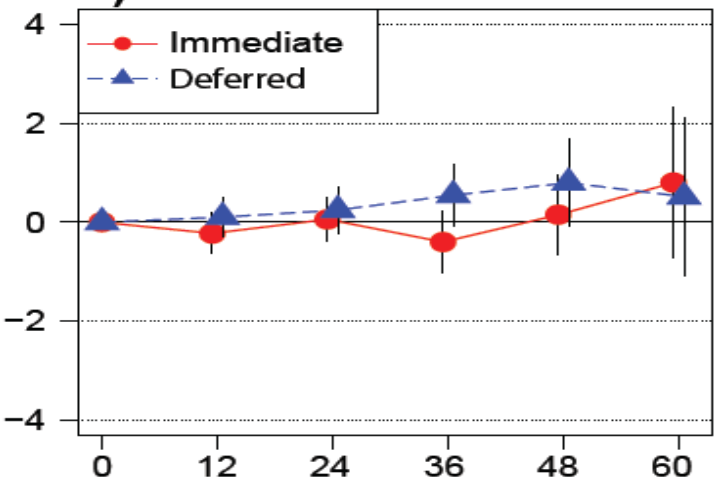
Change from Baseline

A) Systolic BP



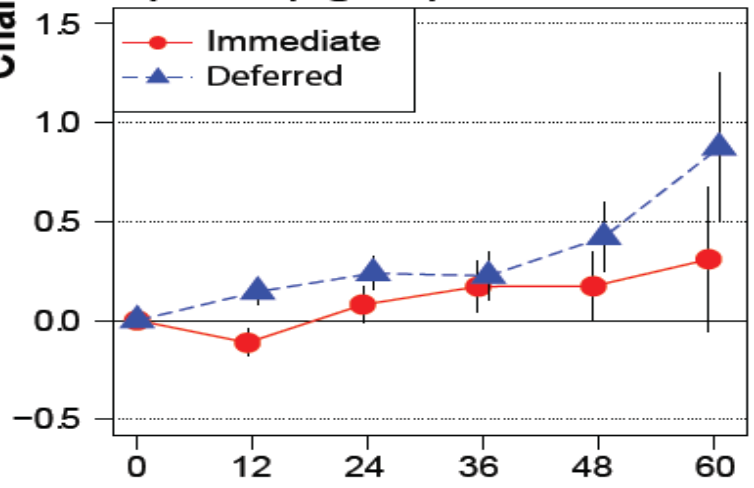
Longitudinal mixed model, adj. for baseline and visit:
Est. diff.: -0.1 95% CI: -0.6 - 0.3 P-value 0.58

B) Diastolic BP

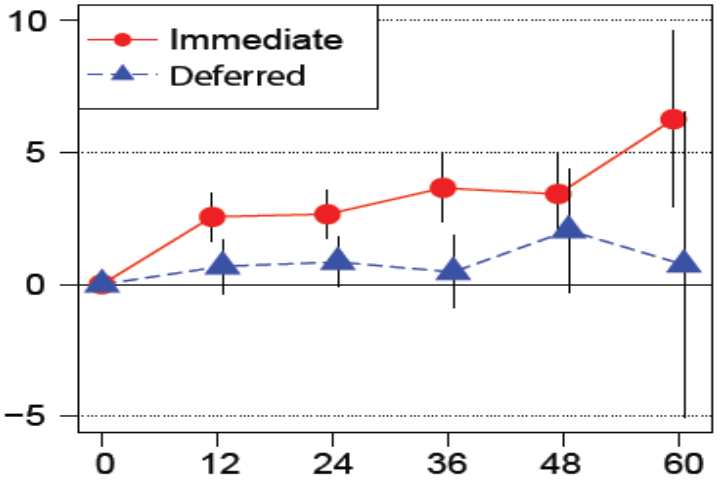


Longitudinal mixed model, adj. for baseline and visit:
Est. diff.: -0.3 95% CI: -0.6 - 0.0 P-value 0.07

C) BMI (kg/m²)



D) Glucose (mg/dL)



Changes in CVD Risk Factors with Immediate and Deferred ART in the START Trial

Jason V. Baker[1,2], Shweta Sharma[3], Amit Achhra[4], Jose Ignacio Bernardino[5], Johannes R Bogner[6], Daniel Duprez[1], Sean Emery[4], Brian Gazzard[7], Jonathan Gordin[8], Greg Grandits[3], Andrew Phillips[9], Siegfried Schwarze[10], Elsayed Z. Soliman[11], Stephen A. Spector[12], Giuseppe Tambussi[13], and Jens Lundgren[14] for the INSIGHT START (Strategic Timing of AntiRetroviral Treatment) Study Group

[1]Department of Medicine, University of Minnesota, USA; [2]Division of Infectious Diseases, Hennepin County Medical Center, USA; [3]Division of Biostatistics, University of Minnesota, USA; [4]Kirby Institute, University of New South Wales, Australia; [5]Department of Medicine. Hospital La Paz. IdiPAZ, Spain; [6]Division of Infectious Diseases, MedIV, University Hospital of Munich, Germany; [7]Chelsea and Westminster Hospital, UK; [8]Division of Cardiology, David Geffen School of Medicine at University of California, USA; [9]HIV Epidemiology & Biostatistics Group, University College London, UK; [10]European AIDS Treatment Group, Germany; [11]Epidemiological Cardiology Research Center, Wake Forest School of Medicine, USA; [12]Division of Pediatric Infectious Diseases, University of California San Diego and Rady Children's Hospital, USA; [13]San Raffaele Scientifi Institute, Italy; [14]CHIP, Department of Infectious Diseases, Rigshospitalet, University of Copenhagen, Denmark

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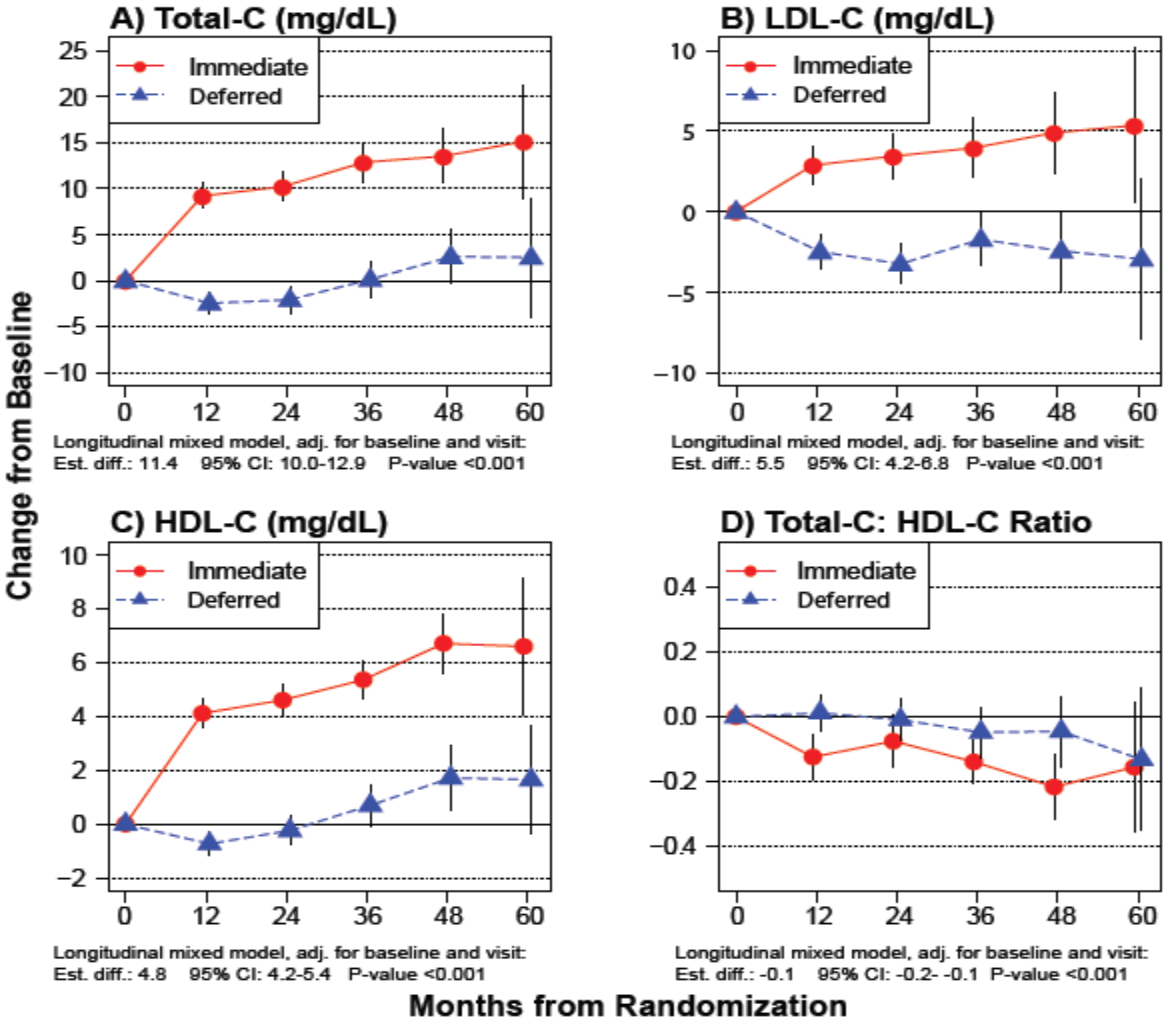
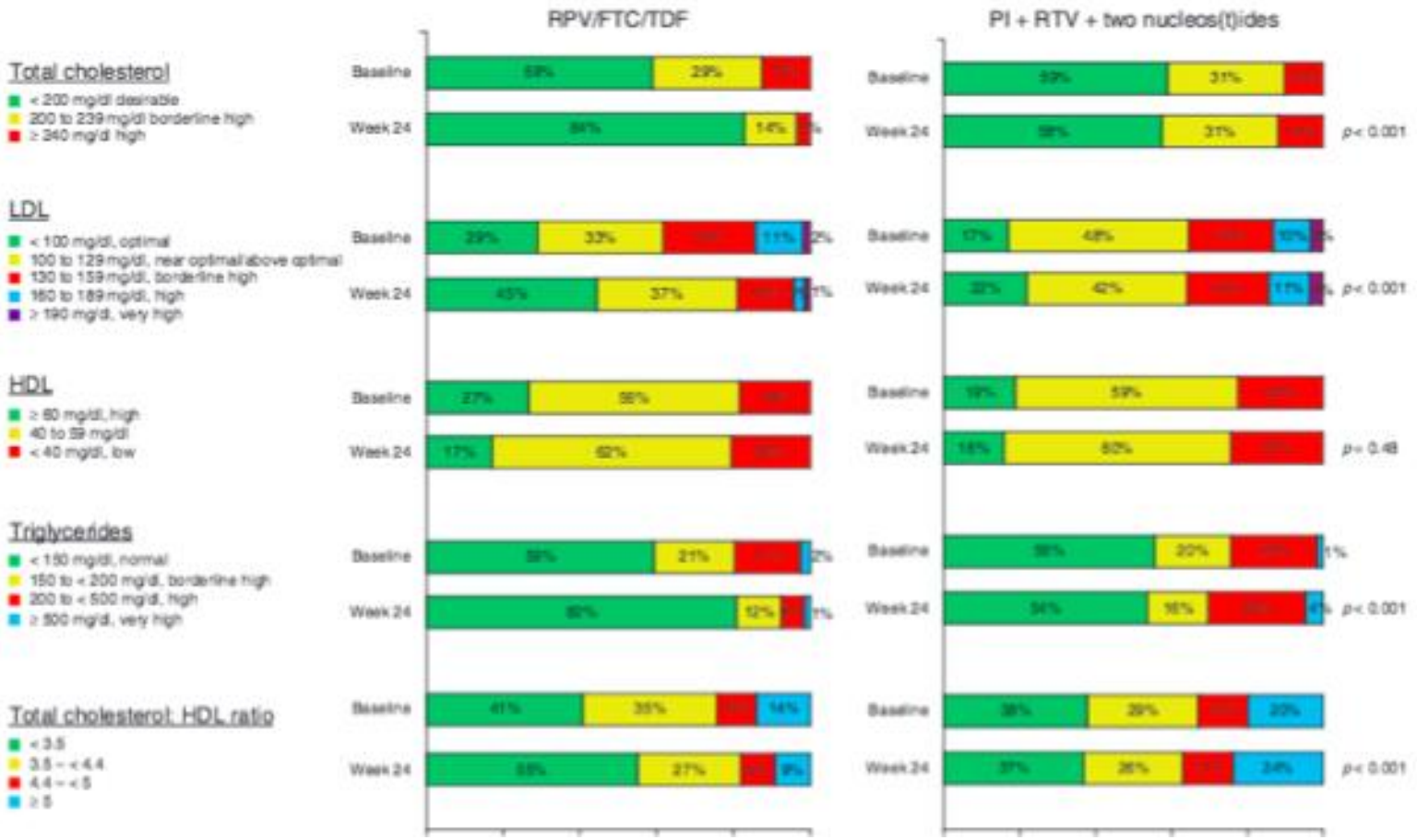
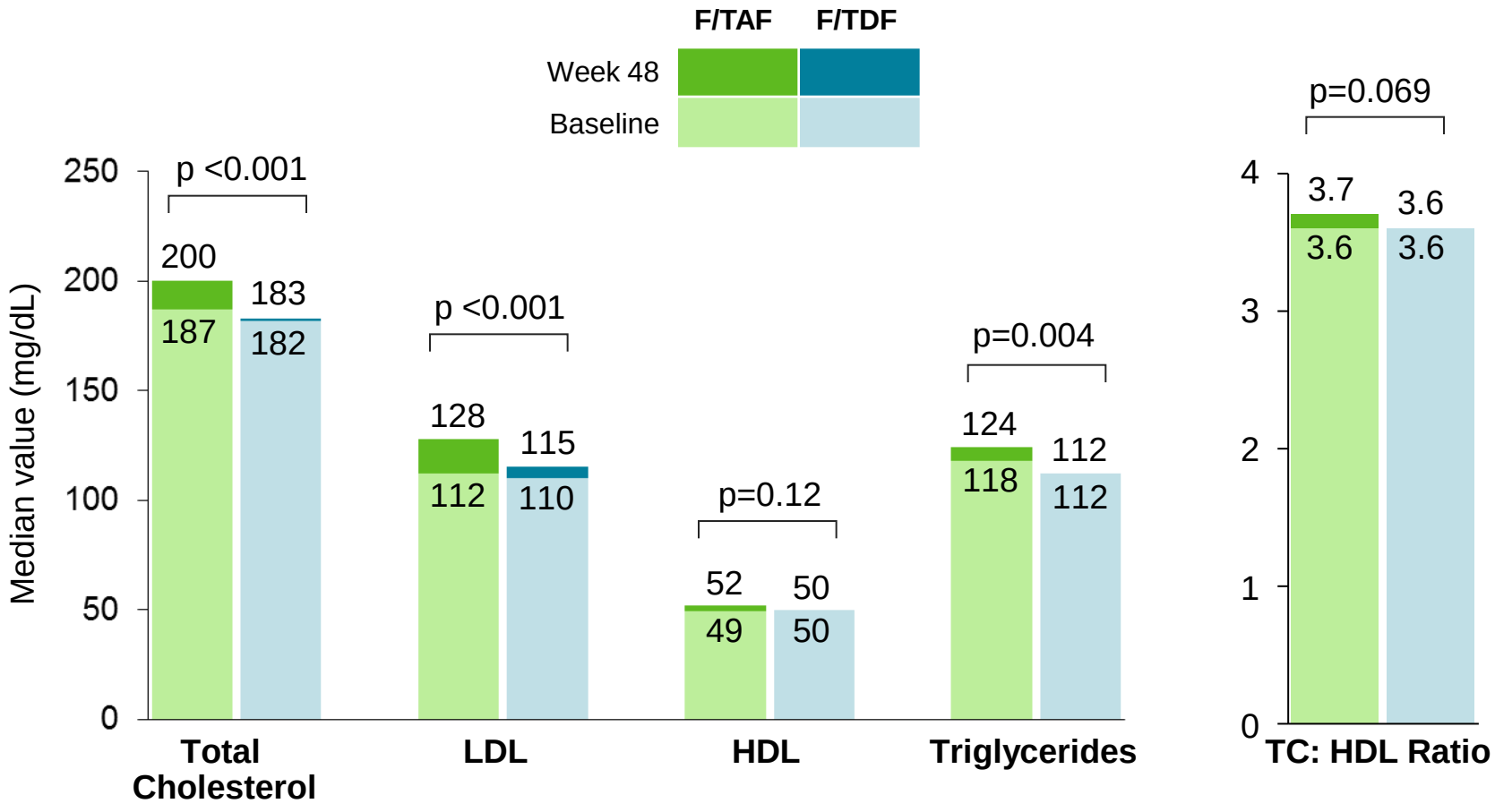
Figure 2: Changes in Blood Cholesterol Levels



SPIRIT

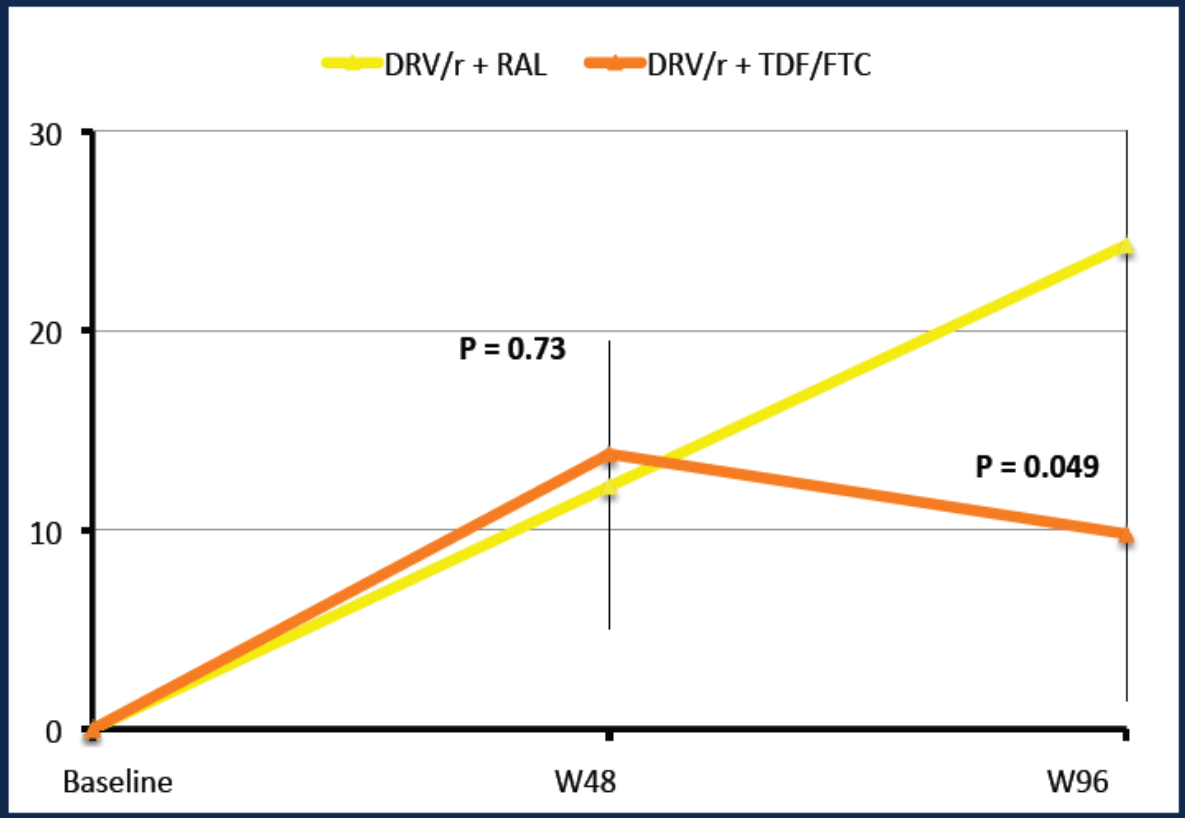

RPV/FTC/TDF
PI + RTV + two nucleos(t)ides
Total cholesterol
< 200 mg/dl desirable
200 to 239 mg/dl borderline high
≥ 240 mg/dl high
LDL
< 100 mg/dl, optimal
100 to 129 mg/dl, near optimal/above optimal
130 to 159 mg/dl, borderline high
160 to 189 mg/dl, high
≥ 190 mg/dl, very high
HDL
≥ 60 mg/dl, high
40 to 59 mg/dl
< 40 mg/dl, low
Triglycerides
< 150 mg/dl, normal
150 to < 200 mg/dl, borderline high
200 to < 500 mg/dl, high
≥ 500 mg/dl, very high
Total cholesterol: HDL ratio
< 3.5
3.5 – < 4.4
4.4 – < 5
≥ 5
Baseline
Week 24
p< 0.001
p< 0.001
p= 0.48
p< 0.001
p< 0.001

Fasting Lipid Results



	F/TAF	F/TDF
Patients initiating lipid-lowering agents	4%	4%

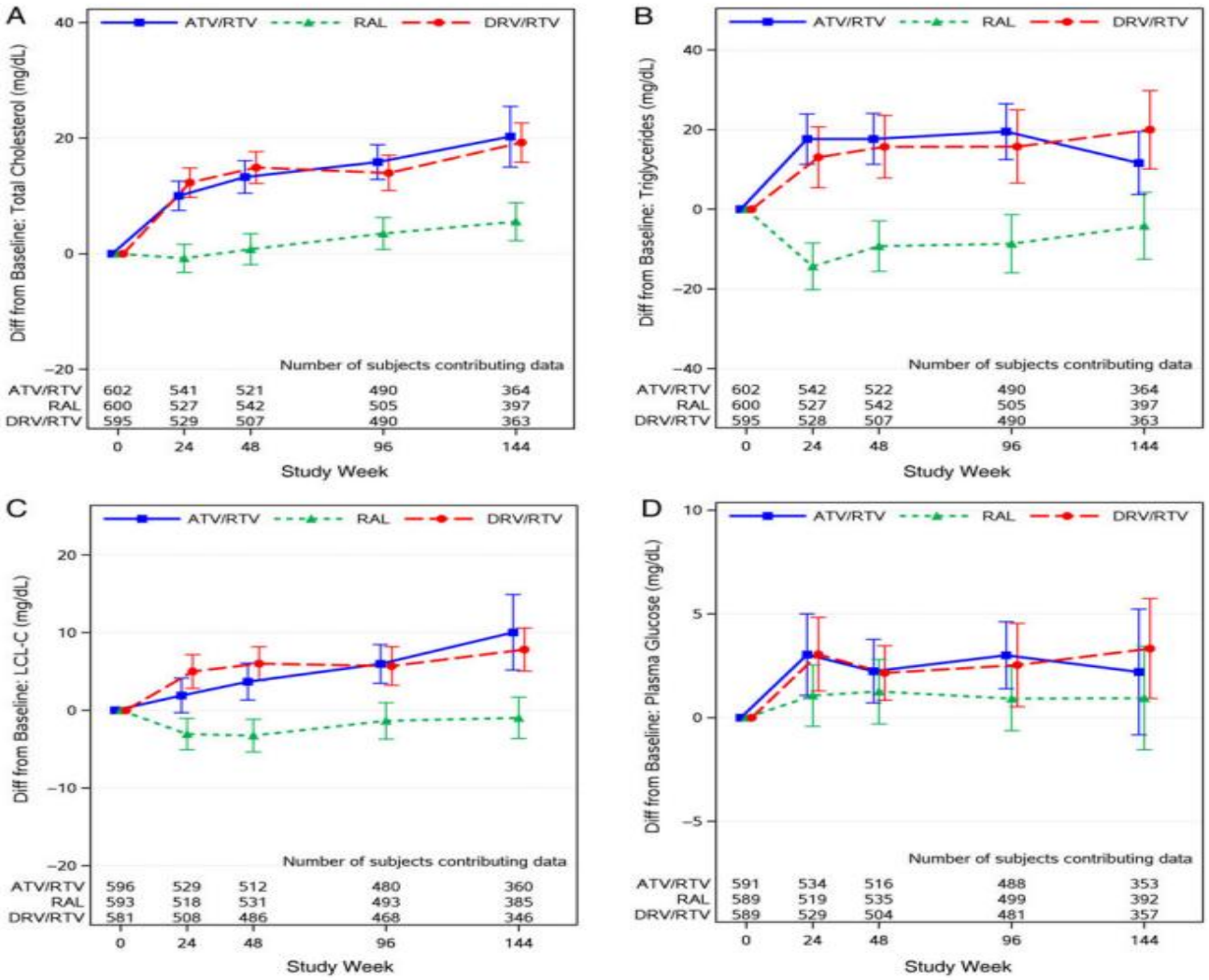
Mean percentage change in trunk fat mass



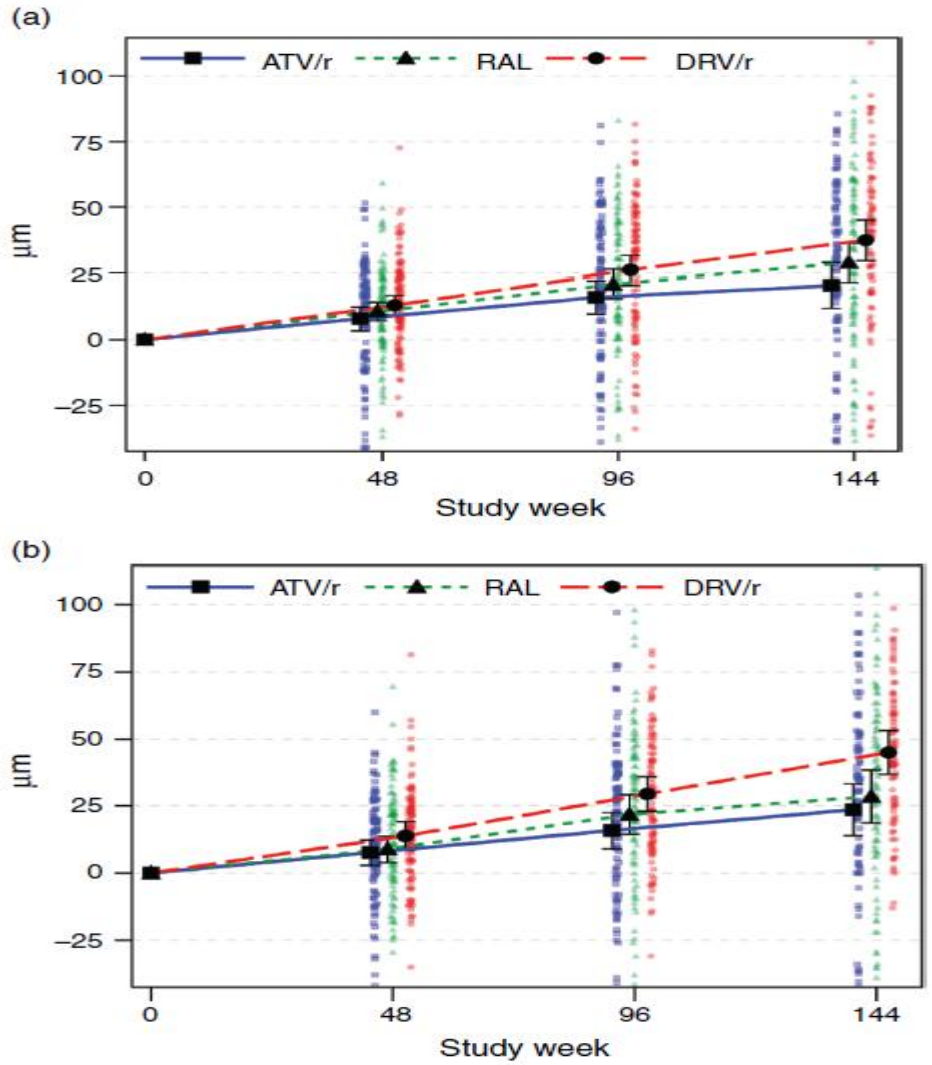
*P values from mean differences between arms (unadjusted)

	W48		W96	
	N	Mean % change (95% CI)	N	Mean % change (95% CI)
DRV/r + RAL n =61	49	12.2 (5.0 to 19.5)	49	24.3 (12.5 to 36.1)
DRV/r + TDF/FTC n = 65	62	13.8 (8.1 to 19.5)	56	9.8 (1.4 to 18.2)
Mean difference (95% CI); p	**1.6 (-7.6 to 10.8); p = 0.73**		**-14.5 (-28.8 to -0.2);p = 0.049**	

ACTG 5257


A
ATV/RTV
RAL
DRV/RTV
Diff from Baseline: Total Cholesterol (mg/dL)
40
20
0
−20
Number of subjects contributing data
ATV/RTV 602 541 521 490 364
RAL 600 527 542 505 397
DRV/RTV 595 529 507 490 363
0 24 48 96 144
Study Week
B
ATV/RTV
RAL
DRV/RTV
Diff from Baseline: Triglycerides (mg/dL)
40
20
0
−20
−40
Number of subjects contributing data
ATV/RTV 602 542 522 490 364
RAL 600 527 542 505 397
DRV/RTV 595 528 507 490 363
0 24 48 96 144
Study Week
C
ATV/RTV
RAL
DRV/RTV
Diff from Baseline: LCL-C (mg/dL)
20
10
0
−10
−20
Number of subjects contributing data
ATV/RTV 596 529 512 480 360
RAL 593 518 531 493 385
DRV/RTV 581 508 486 468 346
0 24 48 96 144
Study Week
D
ATV/RTV
RAL
DRV/RTV
Diff from Baseline: Plasma Glucose (mg/dL)
10
5
0
−5
Number of subjects contributing data
ATV/RTV 591 534 516 488 353
RAL 589 519 535 499 392
DRV/RTV 589 529 504 481 357
0 24 48 96 144
Study Week

A prospective, randomized clinical trial of antiretroviral therapies on carotid wall thickness



JH Stein, AIDS 2015

A prospective, randomized clinical trial of antiretroviral therapies on carotid wall thickness

Table 2. Annualized rates of change in common carotid artery and carotid artery bifurcation intima–media thickness by treatment group and treatment group comparisons.

	CCA IMT (μm/year)[a,c]		CCA IMT (μm/year)[a,d]		CCA IMT (μm/year)[b,d]		Carotid bifurcation IMT (μm/year)[a,c]	
Estimated progression rates by treatment group (95% confidence intervals)[c]								
		P		*P*		*P*		*P*
ATV/r	8.2 (5.6, 10.8)	**<0.001**	7.9 (5.2, 10.6)	**<0.001**	6.6 (3.2, 10.0)	**<0.001**	8.7 (5.6, 11.8)	**<0.001**
DRV/r	12.9 (10.3, 15.5)	**<0.001**	12.6 (9.8, 15.3)	**<0.001**	12.8 (9.7, 15.9)	**<0.001**	14.7 (11.6,17.8)	**<0.001**
RAL	10.7 (9.2, 12.2)	**<0.001**	10.4 (8.7, 12.1)	**<0.001**	10.2 (8.3, 12.2)	**<0.001**	11.5 (9.7, 13.3)	**<0.001**
Estimated difference (first minus second arm) in progression rates (97.5% confidence intervals)[c]								
		P		*P*		*P*		*P*
ATV/r vs. DRV/r	−4.7 (−8.9, −0.4)	**0.013**	−6.0 (−11.0, −1.0)	**0.007**	−4.7 (−9.0, −0.5)	**0.013**	−6.2 (−11.3, −1.1)	**0.007**
ATV/r vs. RAL	−2.8 (−7.0, 1.5)	0.15	−2.3 (−7.4, 2.7)	0.30	−2.7 (−7.0, 1.5)	0.15	−4.6 (−9.7, 0.5)	0.044
DRV/r vs. RAL	1.9 (−2.4, 6.2)	0.31	3.7 (−1.4, 8.7)	0.11	2.0 (−2.3, 6.3)	0.30	1.6 (−3.3, 6.5)	0.46

JH Stein, AIDS 2015

Global epidemiology of drug resistance after failure of WHO recommended first-line regimens for adult HIV-1 infection: a multicentre retrospective cohort study

*The TenoRes Study Group**

Summary

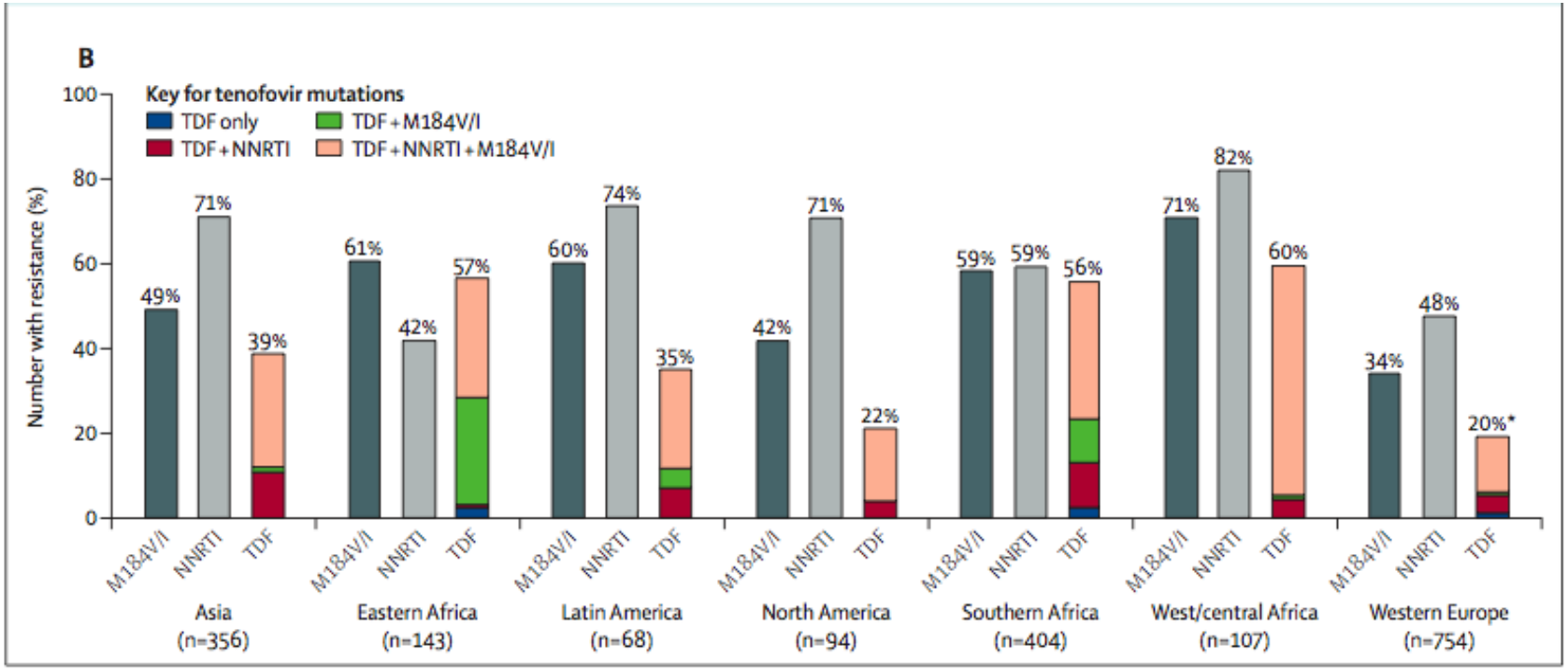
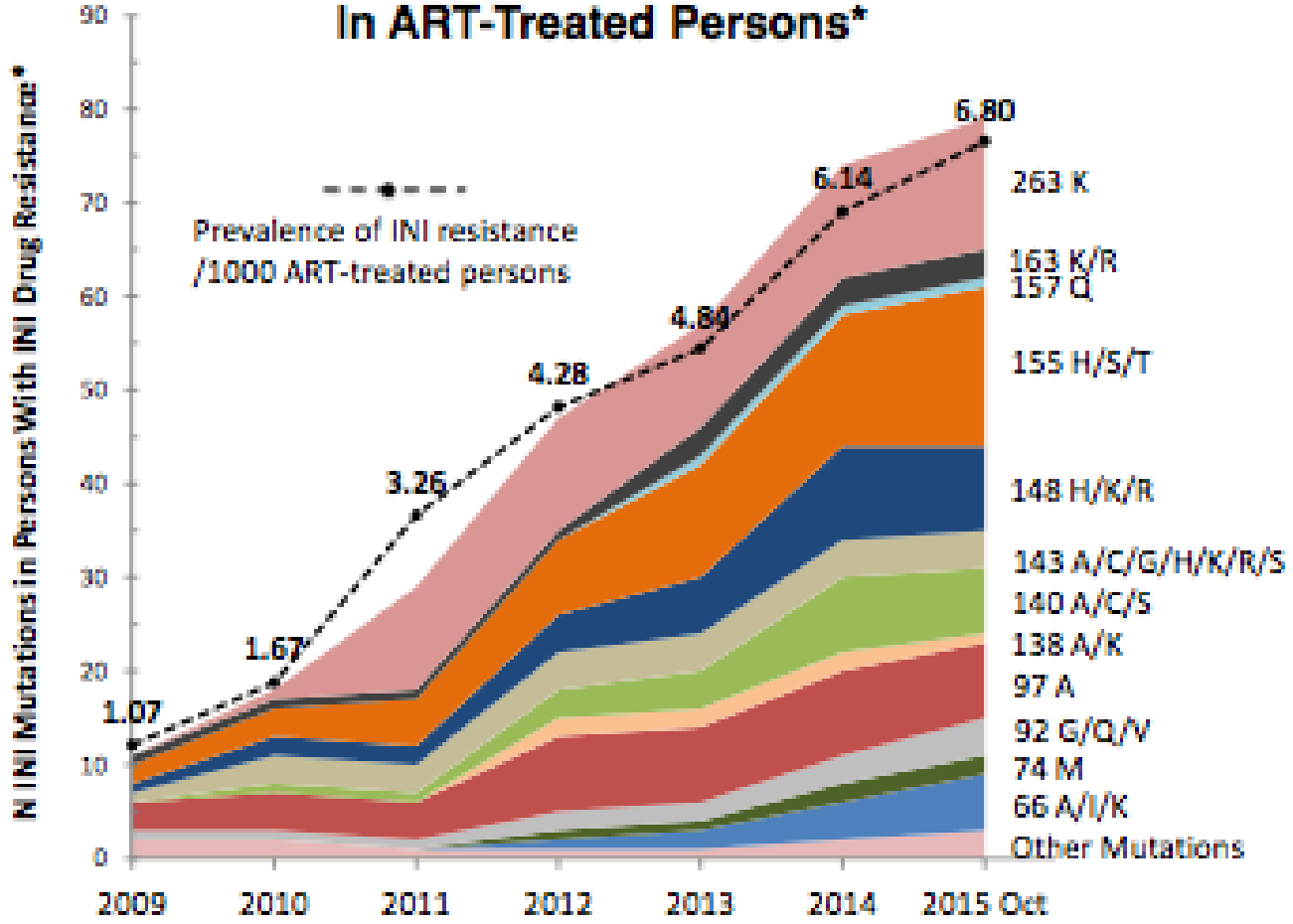


Figure 1: **(A) Countries contributing data to resistance analysis and HIV-1 subtype distribution, (B) prevalence of drug resistance by mutation and by region**
NNRTI=non-nucleotide reverse-transcriptase inhibitor. TDF=tenofovir disoproxil fumarate. *24% (n=462) of participants had tenofovir resistance when genotypes from viral load >1000 copies HIV-1 RNA per mL were considered.

Fig. 2: Prevalence of Integrase Drug Resistance Mutations In ART-Treated Persons*



* Persons with drug resistance mutations conferring a total score ≥30 (Stanford HIV Drug Resistance Algorithm v.7.0.1) for at least one INI. For each person, cumulative INI mutations were reported in the first and each subsequent year following detection of drug resistance.

Lepik et al, CROI 2016

Study	104		111		106
Treatment arm	GEN	STB	GEN	STB	GEN
Cohort	TN	TN	TN	TN	TN
Population	Adults (USA, EU, APAC)		Adults (USA, EU, LATAM)		Adolescents
Study type	Efficacy/safety (double-blind)		Efficacy/safety (double-blind)		Efficacy/safety (open-label)
Full-analysis set, n	435	432	431	435	50
Treatment efficacy at Week 48* 					
Pretreatment resistance analysis, n (%)					
RAMs detected					
PI associated (primary)	13 (3)	13 (3)	16 (4)	15 (3)	0
NRTI associated	39 (9)	22 (5)	34 (8)	34 (8)	4 (8)
NNRTI associated	85 (20)	76 (18)	70 (16)	83 (19)	3 (6)
INSTI associated (primary)	0	0	0	1 (0.2)	0
HIV-1 subtype					
B	340 (78)	345 (80)	403 (94)	404 (93)	11 (22)
Non-B	94 (22)	87 (20)	28 (7)	31 (7)	39 (78)
Week-48 resistance analysis, n (%)					
RAP	5 (1)	7 (2)	11 (3)	12 (3)	2 (4)
HIV-1 RNA <50 copies/mL at Week 48	1 (<1)	2 (<1)	1 (<1)	3 (<1)	1 (2)
Final RAP, n with data (%)†	4 (<1)	5 (1)	10 (2)	8 (2)	1 (2)
No RAMs observed	1 (<1)	2 (<1)	6 (1)	6 (1)	1 (2)
RAMs developed	3 (<1)	3 (<1)	4 (<1)	2 (<1)	0
PI associated (primary)	0	1 (<1)‡	0	0	0
NRTI associated	3 (<1)	3 (<1)	4 (<1)	2 (<1)	0
E44D	—	1	—	—	—
A62V	—	—	—	—	—
K65R	1	1	—	1	—
M184V/I	3	3	4	2	—
NNRTI associated	0	0	0	0	0
INSTI associated (primary)	2 (<1)	2 (<1)	3 (<1)	1 (<1)	0
T66I/A	—	—	2	—	—
E92Q	1	2	1	—	—
S147G	—	—	—	—	—
Q148R	—	1	1	1	—
N155H	1	—	—	—	—

475

Increased Quality of Life with Immediate ART Initiation: Results from the START Trial

Alan R. Lifson[1], Birgit Grund[1], Edward M. Gardner[2], Eileen Denning[1], Nathan Geffen[3], Richard Kaplan[4], Sounkalo Dao[5], Andrew de Burgh-Thomas[6], Fabian Chen[7], Eric Florence[8], Jesus Sanz[9], Catherine L. Carey[10], Sean Emery[10]

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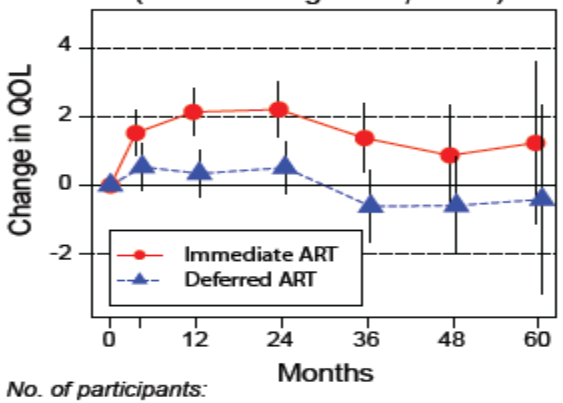
Current Health (Visual Analog Scale, 0-100)



No. of participants:

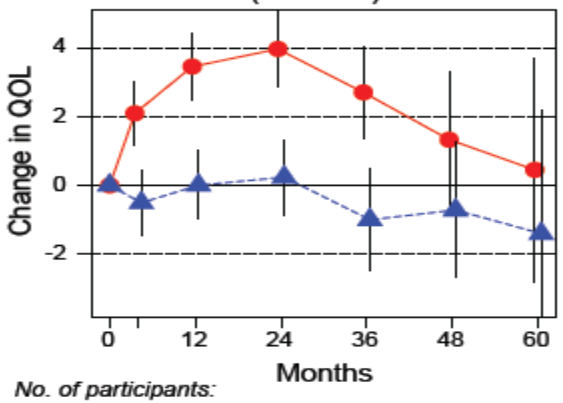
Imm:	2253	2150	1797	1038	559	146
Def:	2287	2121	1173	1026	529	156

P-values, t-tests, unadjusted:

0.03 <0.001 0.002 0.007 0.15 0.37

Longitudinal mixed model, adjusted for visit & baseline QOL:
Est. diff: 1.9 95% CI: 1.2-2.5 P-value: <0.001

General Health (SF-12v2)



No. of participants:

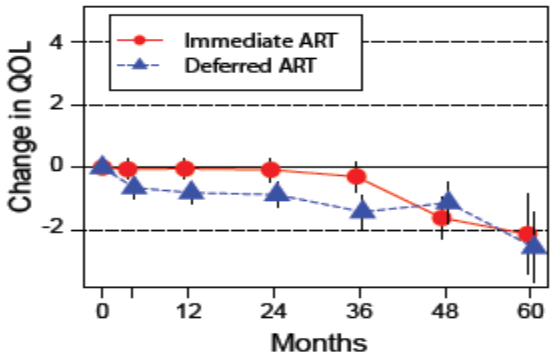
Imm:	2091	1977	1698	1014	555	145
Def:	2119	1949	1677	993	521	153

P-values, t-tests, unadjusted:

<0.001 <0.001 <0.001 <0.001 0.14 0.45

Longitudinal mixed model, adjusted for visit & baseline QOL:
Est. diff: 3.6 95% CI: 2.8-4.5 P-value: <0.001

Physical Component Summary (PCS) (SF-12v2)

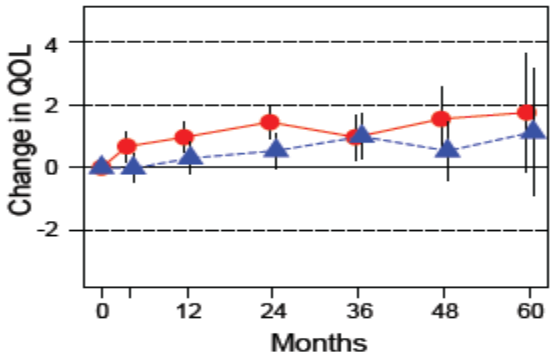


P-values, t-tests, unadjusted:

0.01 0.002 0.003 0.002 0.31 0.62

Longitudinal mixed model, adjusted for visit & baseline QOL:
Est. diff: 0.8 95% CI: 0.5-1.1 P-value: <0.001

Mental Component Summary (MCS) (SF-12v2)

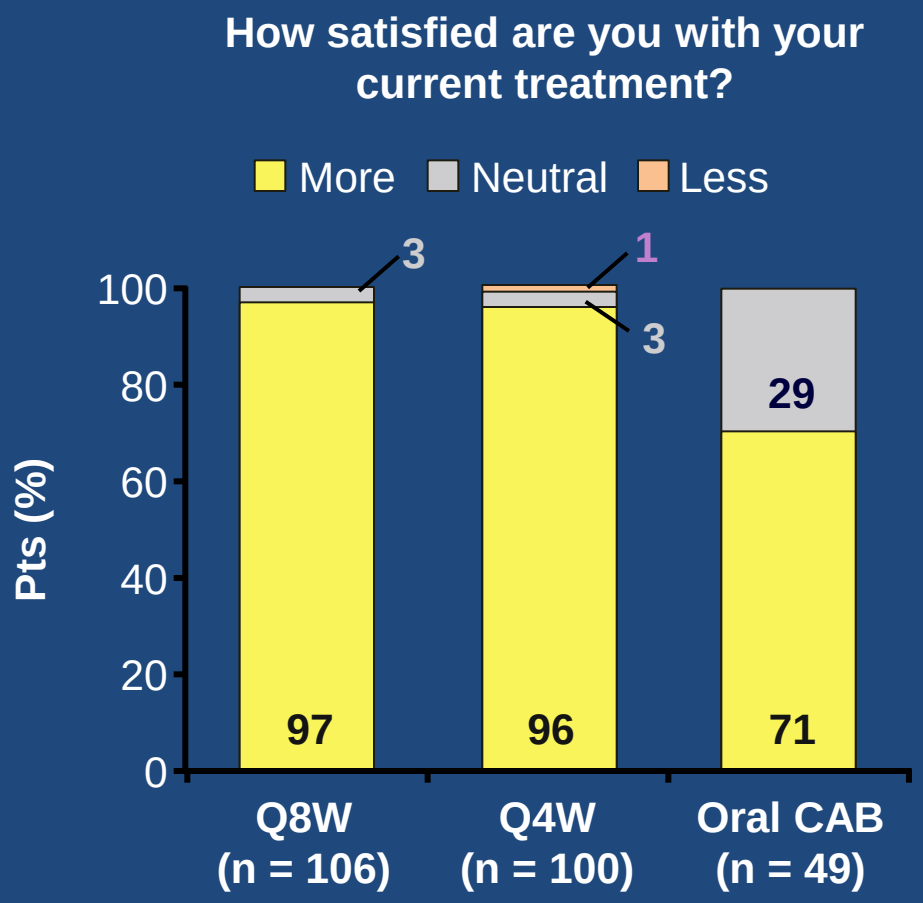


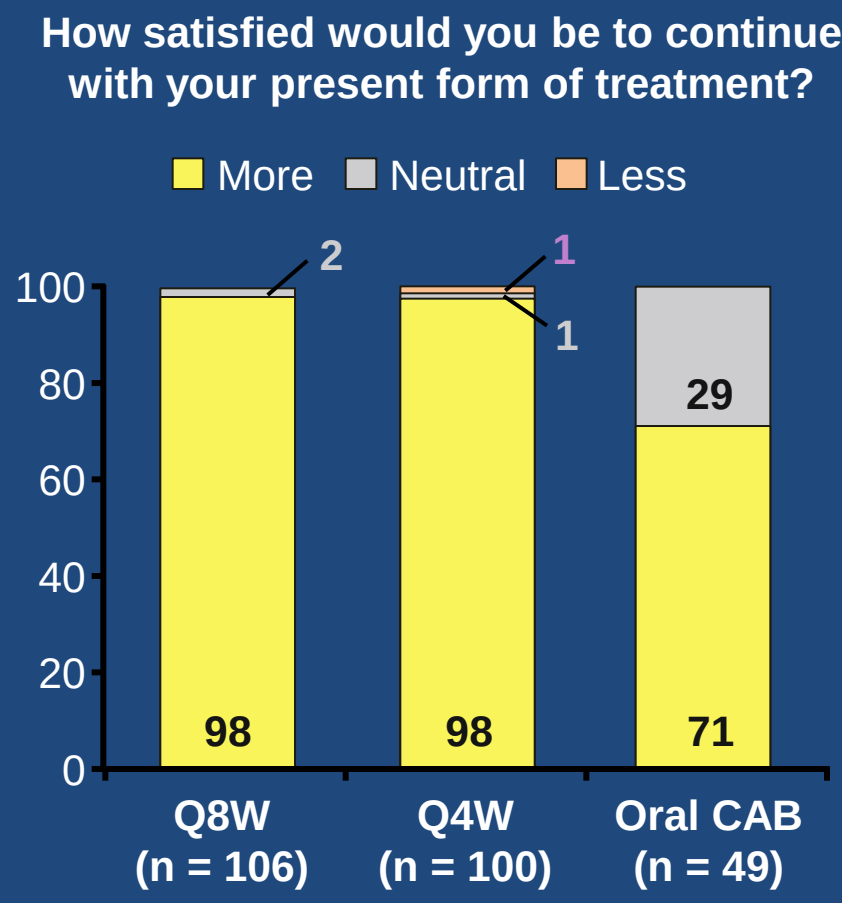
P-values, t-tests, unadjusted:

0.04 0.05 0.02 0.97 0.14 0.65

Longitudinal mixed model, adjusted visit & baseline QOL:
Est. diff: 0.9 95% CI: 0.4-1.3 P-value: <0.001

LATTE-2: Wk 32 Pt Satisfaction With Maintenance Therapy vs Oral Induction





Margolis DA, et al. CROI 2016. Abstract 31LB.
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Low ART Adherence Is Associated With Higher Inflammation Despite HIV Suppression

Jose Castillo-Mancilla[1], Todd Brown[2], Kristine Erlandson[1], Frank J. Palella Jr.[3], Edward M. Gardner[4], Bernard Macatangay[5], Elizabeth C. Breen[6], Lisa P. Jacobson[2], Peter L. Anderson[1], Nikolas Wada[2]

[1]Univ of Colorado, Denver, CO; [2]Johns Hopkins Univ, Baltimore, MD; [3]Northwestern Univ, Chicago, IL; [4]Denver Hlth Med Cntr, Denver, CO; [5]Univ of Pittsburgh Sch of Med, Pittsburgh, PA; [6]Univ of California Los Angeles, Los Angeles, CA.

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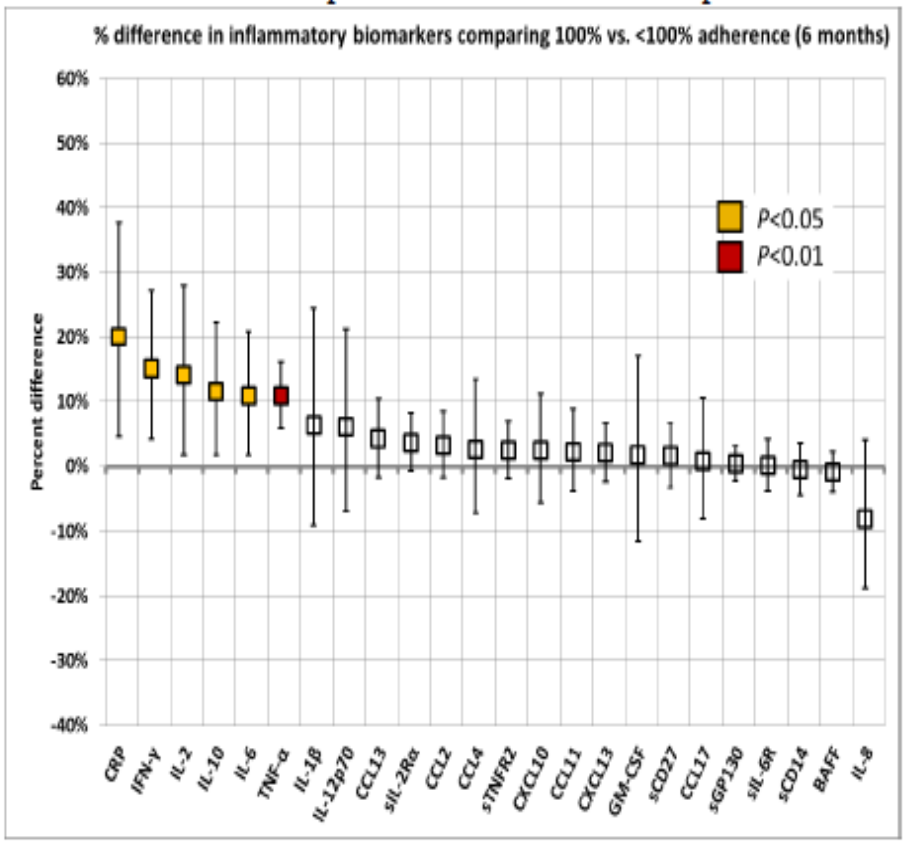
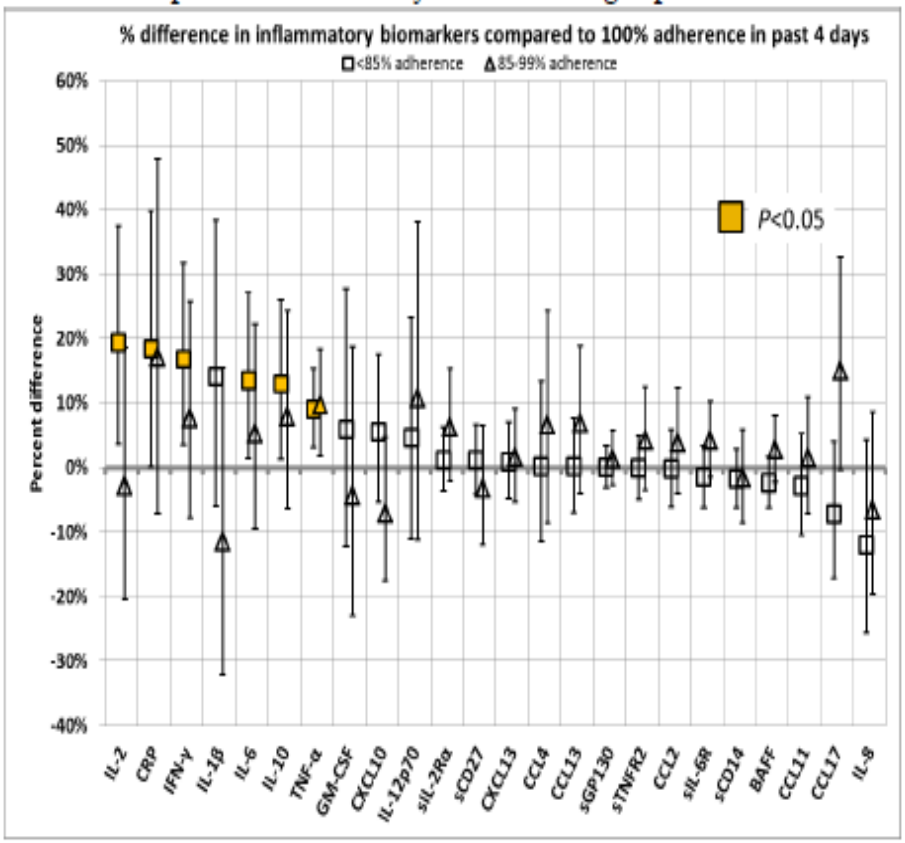
Poster # 283

Figure. Estimates from adjusted models: differences in serum biomarker concentrations at visits with self-reported <100% vs. 100% 6-month adherence (left panel); and visits with self-reported <85% and 85-99% compared to 100% 4-day adherence (right panel).





CROI 2016

Incomplete Adherence to Antiretroviral Therapy is Associated with Higher Levels of Residual HIV-1 Viremia

Jonathan Z. Li[1], Sebastien Gallien[1,2], Heather Ribaudo[3], Andrea Heisey[1], David R. Bangsberg[3,4], Daniel R. Kuritzkes, MD[1]

[1]Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; [2]Hôpital Saint Louis, Paris, France; [3]Harvard School of Public Health, Boston, MA, USA; [4]Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA

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Implications

- Residual HIV-1 viremia may be due to both HIV release from the latent reservoir and active viral replication during incomplete ART adherence.
- ART adherence counseling to counter pill fatigue may have benefits even in the setting of apparently successful virologic suppression.