

CONFIDENTIAL

Pediatric HIV/AIDS Cohort Study (PHACS)
Adolescent Master Protocol (AMP / PH200) and AMP Up (PH300)
Annual Administrative Report

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1 Enrollment and Demographic Characteristics

1.1 Enrollment

Table 1 and **Table 2** show enrollment by cohort and quarter into AMP and AMP Up, respectively. AMP first enrolled youth living with perinatally-acquired HIV (YPHIV) in the first quarter of 2007 and youth who were perinatally HIV-exposed but without perinatally-acquired (YPHEU) in the second quarter of 2007. Enrollment into AMP ended in 2009 with 451 YPHIV and 227 YPHEU; AMP follow-up ended in February 2020. AMP Up first enrolled young adults with PHIV (YAPHIV) and PHEU (YAPHEU) in the second quarter of 2014 and is ongoing. **Table 3** and **Table 4** show enrollment by cohort and site into AMP and AMP Up, respectively.

Table 5 summarizes prior participation in approved IMPAACT and other network protocols among AMP participants. **Table 6** shows the number of AMP Up participants who were previously enrolled in AMP and other protocols.

1.2 Demographic Characteristics

Demographic characteristics and consent information of the participants in AMP and AMP Up are summarized in **Table 7** and **Table 8**, respectively.

1.3 Entry Visit and Current Status

The number of entry visits in AMP and AMP Up are shown by PHIV status in **Table 9**. Of the participants enrolled in AMP, 448 of 451 (99%) YPHIV and 226 of 227 (99.6%) YPHEU reported an entry study visit. Of the participants enrolled in AMP Up, 614 of 618 (99%) YAPHIV and 126 of 126 (100%) YAPHEU have reported an entry study visit.

Table 10 shows the study status of AMP participants and enrollment into AMP Up for those who have reached 18 years-of-age. Of the AMP participants age 18 and older (N=645), 522 (81%) completed the study, 123 (19%) were lost to follow-up, and no children were still on study. Of those 18+ who completed the study, 390 (75%) have already enrolled in AMP Up. Of the 18+ lost to follow-up, 29 (24%) have already enrolled in AMP Up. In the last row, **Table 10** also shows the study status of AMP Up participants. Ten AMP Up participants (see the row 'Completed protocol V1.0') were taken off study after completing AMP Up V1.0 and will be brought back on for V2.0.

1.4 Select Follow-up Characteristics as of Last Clinic Visit

Selected follow-up characteristics of all enrolled participants with an entry visit as of last clinic visit are summarized by study (AMP vs AMP Up), PHIV status and sex in **Table 11**. Such characteristics include age, pregnancy measures (ever been pregnant and the number of completed pregnancies), HIV seroconversion and death. Completed pregnancies include live births, spontaneous/elective abortions and still births. No AMP YPHEU participants seroconverted to HIV, but one male AMP Up YAPHEU participant seroconverted to HIV. Of 209 male and 239 female AMP YPHIV participants, 3 and 2 have

died, respectively. Of 236 male and 378 female AMP Up YAPHIV participants, 5 and 13 have died, respectively.

2 Characteristics of Participants Still on Study

2.1 Age and HIV Clinical Characteristics

All AMP participants are now off the AMP study and thus only the age (by PHIV status) of AMP Up participants still on study at their last clinic visit is shown in **Table 12**. **Table 13** shows HIV clinical characteristics and ARV regimens at the last visit of YAPHIV AMP Up participants still on study.

2.2 ARV Use in the AMP and AMP Up Studies

Table 14 and **Table 15** show the frequencies of ARV drugs among YAPHIV AMP Up participants still on study used at the entry and last clinical visit, respectively. **Error! Reference source not found.** shows the frequencies of lifetime exposure of AMP participants to ARV classes and individual ARV drugs based on reported regimens. A participant is counted as having taken a drug if any of their reported regimens included the drug.

Figure 1 through **Figure 5** display ARV use among participants with PHIV in AMP/AMP Up (treated as a single study) between 1993 and the first quarter of 2021. For each calendar year, lines indicate the percent exposed among the AMP/AMP Up participants born that year or previously. Participants who were off AMP/AMP Up are included through the year of the date on their final ARV medication form or the date they became off study, whichever was earlier. Participants who were still on study were included through the year of the date on their most recent ARV medication form up to April 1, 2021. Participants may be exposed to more than one regimen during a calendar year and contribute to any line indicating a regimen/drug to which they were exposed. **Figure 1** shows ARV regimen trends for AMP/AMP Up participants with the following hierarchical ARV groupings: cART with INSTI/EI/FI > cART with PI > cART with NNRTI > other ART > 1 or 2 NRTIs > No ART. For instance, if a participant was exposed to any INSTI, disregarding whether or not he was exposed to PI or NNRTI, his ARV exposure would be grouped as cART w/ INSTI/EI/FI. No ART indicates a drug holiday of more than 2 months (greater than 56 days). **Figure 2** through **Figure 5** show the frequencies of exposure to ARV drug classes and individual ARV drugs.

3 Tables and Figures

Table 1: AMP - Study Enrollment by Cohort and Quarter

	Enrollment quarter	Cohort		
		Caregiver (N=588)	PHIV (N=451)	PHEU (N=227)
	2007 Q1	8 (1%)	9 (2%)	0 (0%)
	2007 Q2	51 (9%)	52 (12%)	3 (1%)
	2007 Q3	64 (11%)	61 (14%)	12 (5%)
	2007 Q4	74 (13%)	66 (15%)	14 (6%)
	2008 Q1	46 (8%)	33 (7%)	24 (11%)
	2008 Q2	45 (8%)	38 (8%)	14 (6%)
	2008 Q3	53 (9%)	54 (12%)	17 (7%)
	2008 Q4	21 (4%)	12 (3%)	22 (10%)
	2009 Q1	39 (7%)	18 (4%)	39 (17%)
	2009 Q2	77 (13%)	53 (12%)	38 (17%)
	2009 Q3	66 (11%)	42 (9%)	44 (19%)
	2009 Q4	16 (3%)	13 (3%)	0 (0%)
	2010 or Later	28 (5%)	0 (0%)	0 (0%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV. Participant enrollment ended in 2009, but caregivers continue to change/enroll.

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Table 2: AMP Up - Study Enrollment by Cohort and Quarter

		Cohort	
		PHIV (N=619)	PHEU (N=126)
Enrollment quarter	2014 Q2	22 (4%)	3 (2%)
	2014 Q3	48 (8%)	13 (10%)
	2014 Q4	52 (8%)	11 (9%)
	2015 Q1	20 (3%)	4 (3%)
	2015 Q2	20 (3%)	12 (10%)
	2015 Q3	37 (6%)	5 (4%)
	2015 Q4	32 (5%)	6 (5%)
	2016 Q1	29 (5%)	8 (6%)
	2016 Q2	44 (7%)	4 (3%)
	2016 Q3	24 (4%)	4 (3%)
	2016 Q4	49 (8%)	4 (3%)
	2017 Q1	40 (6%)	1 (1%)
	2017 Q2	23 (4%)	4 (3%)
	2017 Q3	17 (3%)	2 (2%)
	2017 Q4	7 (1%)	4 (3%)
	2018 Q1	22 (4%)	6 (5%)
	2018 Q2	22 (4%)	3 (2%)
	2018 Q3	17 (3%)	5 (4%)
	2018 Q4	11 (2%)	4 (3%)
	2019 Q1	16 (3%)	5 (4%)
	2019 Q2	24 (4%)	2 (2%)
	2019 Q3	10 (2%)	4 (3%)
	2019 Q4	8 (1%)	4 (3%)
	2020 Q1	5 (1%)	1 (1%)
2020 Q2	1 (0%)	3 (2%)	
2020 Q3	9 (1%)	1 (1%)	
2020 Q4	5 (1%)	2 (2%)	
2021 Q1	4 (1%)	1 (1%)	
2021 Q2	1 (0%)	0 (0%)	

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 3: AMP - Study Enrollment by Site

Enrollment site	Cohort		
	Total (N=678)	PHIV (N=451)	PHEU (N=227)
BOSTON CHILDREN'S HOSPITAL	39 (6%)	35 (8%)	4 (2%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	40 (6%)	27 (6%)	13 (6%)
SAN JUAN RESEARCH HOSPITAL	54 (8%)	27 (6%)	27 (12%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	41 (6%)	29 (6%)	12 (5%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	41 (6%)	21 (5%)	20 (9%)
NEW JERSEY MEDICAL CENTER	53 (8%)	46 (10%)	7 (3%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	20 (3%)	14 (3%)	6 (3%)
BRONX/LEBANON HOSPITAL CENTER	37 (5%)	17 (4%)	20 (9%)
UNIVERSITY OF MIAMI	57 (8%)	38 (8%)	19 (8%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	53 (8%)	23 (5%)	30 (13%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	28 (4%)	23 (5%)	5 (2%)
UCSD MEDICAL CENTER	34 (5%)	17 (4%)	17 (7%)
UNIVERSITY OF MARYLAND MED CTR	31 (5%)	23 (5%)	8 (4%)
JACOBI MEDICAL CENTER	53 (8%)	37 (8%)	16 (7%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	97 (14%)	74 (16%)	23 (10%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV.

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Table 4: AMP Up - Study Enrollment by Site

Enrollment site	Cohort		
	Total (N=745)	PHIV (N=619)	PHEU (N=126)
BOSTON CHILDREN'S HOSPITAL	40 (5%)	40 (6%)	0 (0%)
ST. CHRISTOPHER'S HOSPITAL FOR CHILDREN	39 (5%)	29 (5%)	10 (8%)
SAN JUAN RESEARCH HOSPITAL	69 (9%)	54 (9%)	15 (12%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	56 (8%)	48 (8%)	8 (6%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	58 (8%)	47 (8%)	11 (9%)
NEW JERSEY MEDICAL CENTER	75 (10%)	70 (11%)	5 (4%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	33 (4%)	29 (5%)	4 (3%)
BRONX/LEBANON HOSPITAL CENTER	50 (7%)	34 (5%)	16 (13%)
UNIVERSITY OF MIAMI	59 (8%)	52 (8%)	7 (6%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	55 (7%)	34 (5%)	21 (17%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	33 (4%)	29 (5%)	4 (3%)
UCSD MEDICAL CENTER	36 (5%)	28 (5%)	8 (6%)
JACOBI MEDICAL CENTER	69 (9%)	60 (10%)	9 (7%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	73 (10%)	65 (11%)	8 (6%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 5: AMP - Enrollment by Previous Protocol Participation

Protocol group	Studies	PHIV (N=451)	PHEU (N=227)
No Previous Protocol	None	87 (19%)	64 (28%)
219/219C Only	219/219C	292 (65%)	97 (43%)
	219	5 (1%)	5 (2%)
	Total	297 (66%)	102 (45%)
219/219C + Other	219C+ACTG 316	1 (0%)	0 (0%)
	219/219C+WITS	17 (4%)	7 (3%)
	Total	18 (4%)	7 (3%)
WITS Only	WITS	0 (0%)	33 (15%)
Other PACTG/IMPAACT	P1057	1 (0%)	0 (0%)
	ACTG 353	0 (0%)	2 (1%)
	ACTG 326	0 (0%)	1 (0%)
	ACTG 316	0 (0%)	6 (3%)
	ACTG 185	2 (0%)	0 (0%)
	Total	3 (1%)	9 (4%)
Other	PACTS HOPE	0 (0%)	11 (5%)
	LEGACY	46 (10%)	0 (0%)
	257	0 (0%)	1 (0%)
	Total	46 (10%)	12 (5%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV.

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Table 6: AMP Up - Enrollment by Previous Protocol Participation

Protocol group	Studies	PHIV (N=619)	PHEU (N=126)
No Previous Protocol	None	82 (13%)	0 (0%)
AMP Only	PH200	82 (13%)	36 (29%)
AMP + Other	PH200+P219/P219C	183 (30%)	15 (12%)
	PH200+P219/P219C+P1074	5 (1%)	0 (0%)
	PH200+P219/P219C+PH100	19 (3%)	48 (38%)
	PH200+PH100	7 (1%)	24 (19%)
	Total	214 (35%)	87 (69%)
P219/P219C Only	P219/P219C	30 (5%)	0 (0%)
P219/P219C + Other	P219/P219C+P1074	97 (16%)	0 (0%)
	P219/P219C+P1074+PH100	25 (4%)	0 (0%)
	P219/P219C+PH100	28 (5%)	3 (2%)
	Total	150 (24%)	3 (2%)
P1074 Only	P1074	29 (5%)	0 (0%)
P1074 + Other	P1074+PH100	4 (1%)	0 (0%)
PH100 Only	PH100	28 (5%)	0 (0%)

Note: PHIV: perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 7: AMP - Enrollment Demographics and Consent Information

		Cohort		
		Total (N=678)	PHIV (N=451)	PHEU (N=227)
Sex	Male	328 (48%)	210 (47%)	118 (52%)
	Female	350 (52%)	241 (53%)	109 (48%)
Age at enrollment (yrs)	Median (Q1, Q3)	11 (9, 14)	12 (10, 14)	10 (8, 12)
	7-9	229 (34%)	118 (26%)	111 (49%)
	10-12	235 (35%)	154 (34%)	81 (36%)
	13-15	214 (32%)	179 (40%)	35 (15%)
Race	Asian	6 (1%)	2 (0%)	4 (2%)
	Black or African American	454 (67%)	316 (70%)	138 (61%)
	White	173 (26%)	98 (22%)	75 (33%)
	American Indian	3 (0%)	3 (1%)	0 (0%)
	More than One Race	13 (2%)	9 (2%)	4 (2%)
	Participant does not want to report	17 (3%)	15 (3%)	2 (1%)
	Participant does not know	8 (1%)	6 (1%)	2 (1%)
	Race not available to clinic	4 (1%)	2 (0%)	2 (1%)
Ethnicity	Hispanic or Latino	189 (28%)	109 (24%)	80 (35%)
	Not Hispanic or Latino	485 (72%)	341 (76%)	144 (63%)
	Participant does not want to report	4 (1%)	1 (0%)	3 (1%)
Consent to share IMPAACT, WITS, or medical rec data?	No	4 (1%)	4 (1%)	0 (0%)
	Unknown*	12 (2%)	6 (1%)	6 (3%)
	Yes	662 (98%)	441 (98%)	221 (97%)
Permission to store specimen in repository	No	6 (1%)	5 (1%)	1 (0%)
	Yes	672 (99%)	446 (99%)	226 (100%)
Permission includes genetic studies	No	9 (1%)	8 (2%)	1 (0%)
	Yes	669 (99%)	443 (98%)	226 (100%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV

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Table 8: AMP Up - Enrollment Demographics and Consent Information

		Cohort		
		Total (N=745)	PHIV (N=619)	PHEU (N=126)
Sex	Male	297 (40%)	236 (38%)	61 (48%)
	Female	448 (60%)	383 (62%)	65 (52%)
Age at enrollment (yrs)	Median (Q1, Q3)	20 (18, 24)	21 (18, 25)	18 (18, 19)
	Min, Max	18, 39	18, 39	18, 25
	18-19	329 (44%)	225 (36%)	104 (83%)
	20-21	133 (18%)	116 (19%)	17 (13%)
	22-23	74 (10%)	71 (11%)	3 (2%)
	24-25	71 (10%)	69 (11%)	2 (2%)
	26-27	54 (7%)	54 (9%)	0 (0%)
	28-29	20 (3%)	20 (3%)	0 (0%)
	30 or Older	64 (9%)	64 (10%)	0 (0%)
Race	Asian	4 (1%)	1 (0%)	3 (2%)
	Native Hawaiian or other Pacific Islander	2 (0%)	2 (0%)	0 (0%)
	Black or African American	492 (66%)	413 (67%)	79 (63%)
	White	194 (26%)	154 (25%)	40 (32%)
	American Indian	4 (1%)	4 (1%)	0 (0%)
	More than One Race	16 (2%)	14 (2%)	2 (2%)
	Unknown	33 (4%)	31 (5%)	2 (2%)
Ethnicity	Hispanic or Latino	218 (29%)	176 (28%)	42 (33%)
	Not Hispanic or Latino	519 (70%)	438 (71%)	81 (64%)
	Unknown	8 (1%)	5 (1%)	3 (2%)
Permission to store specimen in repository	Yes	736 (99%)	610 (99%)	126 (100%)
	No	4 (1%)	4 (1%)	0 (0%)
	.	5	5	0
Permission includes genetic studies	Yes	733 (99%)	609 (99%)	124 (98%)
	No	7 (1%)	5 (1%)	2 (2%)
	.	5	5	0

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 9: AMP and AMP Up - Entry Visit Status

		Study and HIV Status			
		AMP PHIV (N=451)	AMP PHEU (N=227)	AMP Up PHIV (N=619)	AMP Up PHEU (N=126)
Entry visit status	Visit reported	448 (99%)	226 (100%)	614 (99%)	126 (100%)
	No visit reported	3 (1%)	1 (0%)	5 (1%)	0 (0%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV

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Table 10: AMP and AMP Up - Study Status and AMP Up Enrollment

		Cohort		
		Total	PHIV	PHEU
AMP study status	Completed study	522 (77%)	342 (76%)	180 (79%)
	Enrollment error / eligibility failure	1 (0%)	0 (0%)	1 (0%)
	Death of participant/parent/guardian	5 (1%)	5 (1%)	0 (0%)
	Withdrawal / loss to follow-up	123 (18%)	84 (19%)	39 (17%)
	Site closure	25 (4%)	18 (4%)	7 (3%)
	Other reason	2 (0%)	2 (0%)	0 (0%)
Ever AMP, age 18+	Completed study	522 (81%)	342 (80%)	180 (82%)
	Lost to follow-up	123 (19%)	84 (20%)	39 (18%)
Ever AMP, age 18+, completed study	Enrolled in AMP Up	390 (75%)	268 (78%)	122 (68%)
	Not enrolled	132 (25%)	74 (22%)	58 (32%)
Ever AMP, age 18+, lost to follow-up	Enrolled in AMP Up	29 (24%)	28 (33%)	1 (3%)
	Not enrolled	94 (76%)	56 (67%)	38 (97%)
AMP Up study status	Still on study	678 (91%)	560 (90%)	118 (94%)
	Completed protocol V1.0	10 (1%)	8 (1%)	2 (2%)
	Death of subject	18 (2%)	18 (3%)	0 (0%)
	Subject incarcerated	8 (1%)	6 (1%)	2 (2%)
	Subject withdrew consent	9 (1%)	7 (1%)	2 (2%)
	PT/parent not willing to adhere to reqs	5 (1%)	5 (1%)	0 (0%)
	Site unable to contact participant/parent	14 (2%)	12 (2%)	2 (2%)
	Other reason	3 (0%)	3 (0%)	0 (0%)

Note: PHIV, perinatally-acquired HIV; PHEU, perinatal HIV-exposure without perinatally-acquired HIV

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Table 11: AMP/AMP Up Select Follow-up Characteristics of All Enrolled Participants with an Entry Visit as of Last Clinic Visit

Characteristic		AMP PHIV (N=448)		AMP PHEU (N=226)		AMP Up PHIV (N=614)		AMP Up PHEU (N=126)	
		Male (N=209)	Female (N=239)	Male (N=118)	Female (N=108)	Male (N=236)	Female (N=378)	Male (N=61)	Female (N=65)
Age at last visit (years)	Median	17	18	17	17	25.50	26	21	23
	Q1, Q3	16, 19	17, 18	16, 18	17, 18	23, 28	23, 29	20, 24	21, 25
	7-14	30 (14%)	36 (15%)	18 (15%)	17 (16%)				
	15-17	81 (39%)	75 (31%)	66 (56%)	55 (51%)				
	18-21	96 (46%)	123 (51%)	34 (29%)	36 (33%)	43 (18%)	49 (13%)	31 (51%)	19 (29%)
	22-25	2 (1%)	5 (2%)			75 (32%)	120 (32%)	22 (36%)	35 (54%)
	26-30					89 (38%)	132 (35%)	8 (13%)	11 (17%)
	31-35					27 (11%)	66 (17%)		
	36-40					2 (1%)	10 (3%)		
	41 or older					0 (0%)	1 (0%)		
Ever been pregnant as of last visit*	Yes	.	15 (6%)	.	15 (14%)	.	174 (46%)	.	30 (46%)
	No	.	185 (77%)	.	80 (74%)	.	203 (54%)	.	35 (54%)
	Unknown	.	39 (16%)	.	13 (12%)	.	1 (0%)	.	0 (0%)
Number of completed pregnancies as of last visit	0	.	225 (94%)	.	94 (87%)	.	207 (55%)	.	33 (51%)
	1	.	9 (4%)	.	9 (8%)	.	89 (24%)	.	15 (23%)
	2	.	5 (2%)	.	4 (4%)	.	48 (13%)	.	12 (18%)
	3	.		.	1 (1%)	.	18 (5%)	.	3 (5%)
	4	.		.		.	8 (2%)	.	1 (2%)
	5	.		.		.	6 (2%)	.	1 (2%)
	6	.		.		.	2 (1%)	.	
Seroconverted to HIV as of last visit	No	209 (100%)	239 (100%)	118 (100%)	108 (100%)	236 (100%)	378 (100%)	60 (98%)	65 (100%)
	Yes							1 (2%)	0 (0%)
Death	No	206 (99%)	237 (99%)	118 (100%)	108 (100%)	231 (98%)	365 (97%)	61 (100%)	65 (100%)
	Yes	3 (1%)	2 (1%)			5 (2%)	13 (3%)		

*Based on chart abstraction. Completed pregnancies include live births, spontaneous/elective abortions, and stillbirths.
 Note: PHIV, perinatally-acquired HIV; PHEU: perinatal HIV exposure but without perinatally-acquired HIV

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Table 12: AMP Up - Age as of Last Visit of Participants Still on Study

		Study and HIV Status	
		AMP Up PHIV (N=560)	AMP Up PHEU (N=118)
Age (years)	Median	26.08	22.53
	Q1, Q3	23.21, 29.20	20.64, 24.27
	18-21	93 (17%)	49 (42%)
	22-25	181 (33%)	53 (45%)
	26-30	196 (35%)	16 (14%)
	31-35	74 (13%)	0 (0%)
	36-40	11 (2%)	0 (0%)
	41 or older	1 (0%)	0 (0%)

Note: PHIV: perinatally-acquired HIV; PHEU, perinatal HIV exposure but without perinatally-acquired HIV. Age is based on the date of last scheduled visit or last contact.

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Table 13: AMP Up - Clinical Characteristics as of Last Visit of Participants Living with Perinatal HIV Still on Study

		Study AMP Up (N=560)
CDC Category	N/A/B	410 (73%)
	C	150 (27%)
CD4 (cells/mm ³)	Median	571
	0-250	103 (19%)
	251-500	130 (24%)
	501-750	150 (27%)
	751-1000	103 (19%)
	1001+	61 (11%)
CD4 Percent	Median	30.45
	< 15%	90 (17%)
	15-25%	109 (20%)
	25% or more	343 (63%)
HIV-1 RNA (copies/mL)	Median	400
	0-400	408 (74%)
	401-5000	48 (9%)
	5001-50000	65 (12%)
	50001+	30 (5%)
ARV regimen	cART with INSTI/EI/FI	387 (70%)
	cART with PI	48 (9%)
	cART with NNRTI	53 (10%)
	Other ARV	28 (5%)
	No ARV	31 (6%)
	Missing ARV information	7 (1%)

Note: HIV-1 RNA viral load measurements less than 400 copies/mL are treated as equal to 400 copies/mL when calculating the median. Clinical characteristics are based on last recorded measurement.

Note: ARV data for some AMP Up participants who were not enrolled in AMP are not yet included. ARV regimen categories are hierarchical.

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Table 14: AMP Up - Individual ARV Drugs at Entry

Class Drug	Label	N	Percent
NRTI ftc	FTC/Coviracil	356	58.8
NRTI tdf	Tenofovir/TDF	252	41.7
NRTI taf	Tenofovir Alafenamide (TAF)	119	19.7
NRTI _3tc	3tc/Epivir/Lamivudine	117	19.3
NRTI abc	Abacavir	93	15.4
NRTI zdv	ZDV/AZT	37	6.1
NRTI ddi	Didanosine/Videx/DDI	13	2.1
NRTI d4t	Stavudine/d4T	9	1.5
NNRTI rpv	Rilpivirine/TMC-278	98	16.2
NNRTI etr	Etravirine/TMC-125	38	6.3
NNRTI efv	Efavirenz/Sustiva/DMP-266	33	5.5
NNRTI nvp	Nevirapine/Viramune/NVP	5	0.8
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	200	33.1
PI drv	Prezista/Darunavir/TMC-114	169	27.9
PI atv	Atazanavir/ATV	63	10.4
PI kal	Kaletra	32	5.3
PI nfv	Nelfinavir/Viracept/NFV	9	1.5
PI sqv	Saquinavir/Invirase/Fortovase/SQV	3	0.5
PI tpv	Tipranavir	2	0.3
PI fpv	Fosamprenavir	1	0.2
FI/EI mvc	Maraviroc	11	1.8
FI/EI enf	T-20/Pentafuside/Enfuvirtide/ENF	3	0.5
INSTI dtg	Dolutegravir/GSK-1349572	133	22.0
INSTI evg	Elvitegravir/GS-9137	77	12.7
INSTI ral	Raltegravir/Isentress	68	11.2
INSTI bic	Bictegravir	17	2.8
BOOSTER cob1	Cobicistat	121	20.0

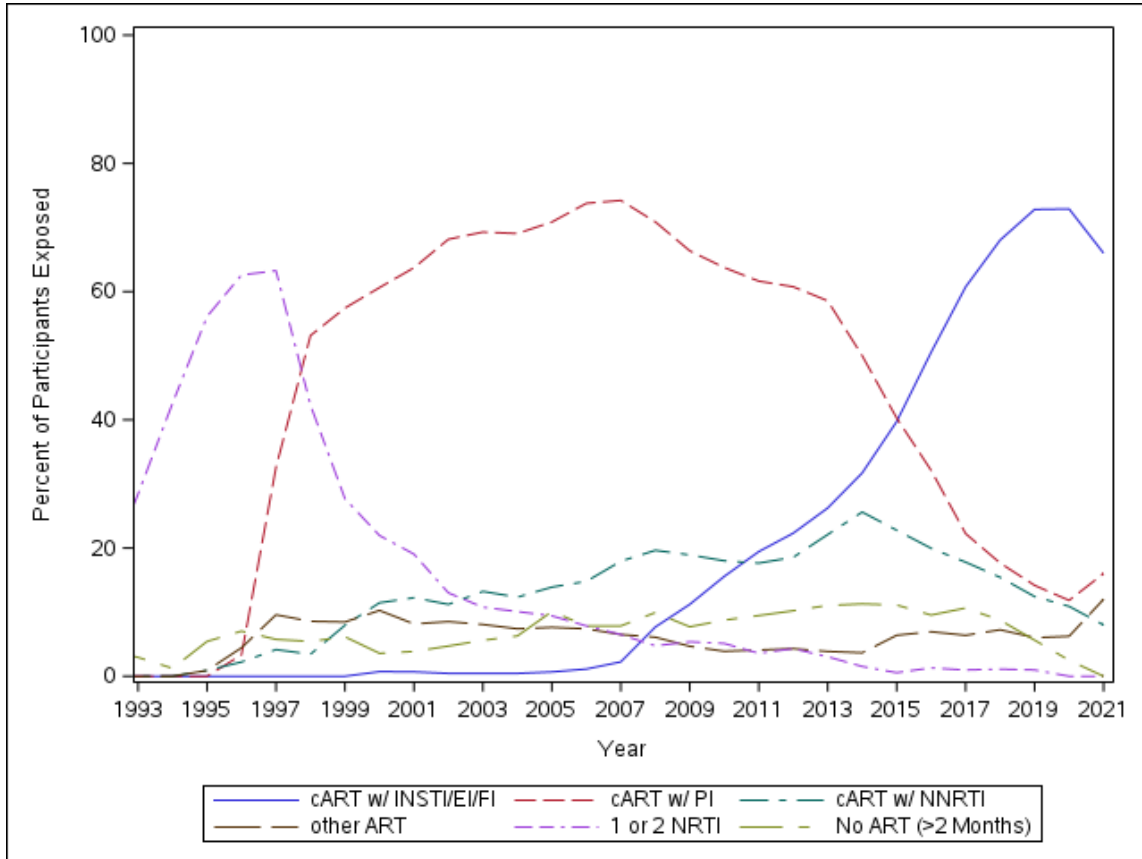
Created by: /home/phacs/actgPH300/monitoring/detlprogs/entry_visit_arv.sas on April 22, 2021

Table 15: AMP Up - Individual ARV Drugs at Last Clinical Visit for Participants Still On Study

Class Drug	Label	N	Percent
NRTI ftc	FTC/Coviracil	389	69.6
NRTI taf	Tenofovir Alafenamide (TAF)	328	58.7
NRTI _3tc	3tc/Efavir/Lamivudine	78	14.0
NRTI abc	Abacavir	72	12.9
NRTI tdf	Tenofovir/TDF	72	12.9
NRTI zdv	ZDV/AZT	10	1.8
NRTI d4t	Stavudine/d4T	1	0.2
NRTI ddi	Didanosine/Videx/DDI	1	0.2
NNRTI rpv	Rilpivirine/TMC-278	87	15.6
NNRTI etr	Etravirine/TMC-125	20	3.6
NNRTI efv	Efavirenz/Sustiva/DMP-266	7	1.3
PI drv	Prezista/Darunavir/TMC-114	142	25.4
PI rtvboost	Ritonavir/Norvir/RTV (Boost)	68	12.2
PI atv	Atazanavir/ATV	27	4.8
PI kal	Kaletra	5	0.9
PI nfv	Nelfinavir/Viracept/NFV	1	0.2
PI sqv	Saquinavir/Invirase/Fortovase/SQV	1	0.2
FI/EI mvc	Maraviroc	8	1.4
INSTI dtg	Dolutegravir/GSK-1349572	159	28.4
INSTI bic	Bictegravir	111	19.9
INSTI evg	Elvitegravir/GS-9137	107	19.1
INSTI ral	Raltegravir/Isentress	36	6.4
BOOSTER cob1	Cobicistat	188	33.6

Created by: /home/phacs/actgPH300/monitoring/det/progs/current_arv.sas on April 22, 2021

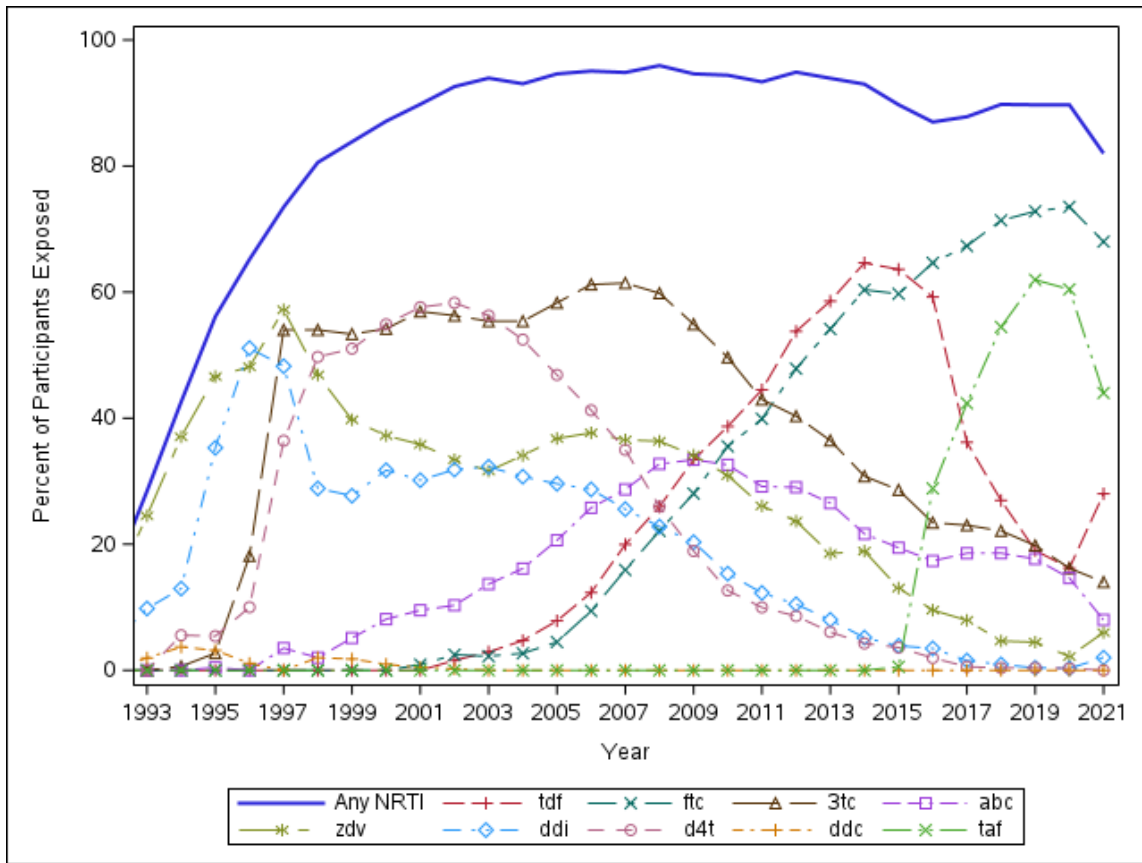
Figure 1: AMP/AMP Up - ARV Trends Over Time



Note: No ART indicates a drug holiday of >56 days.

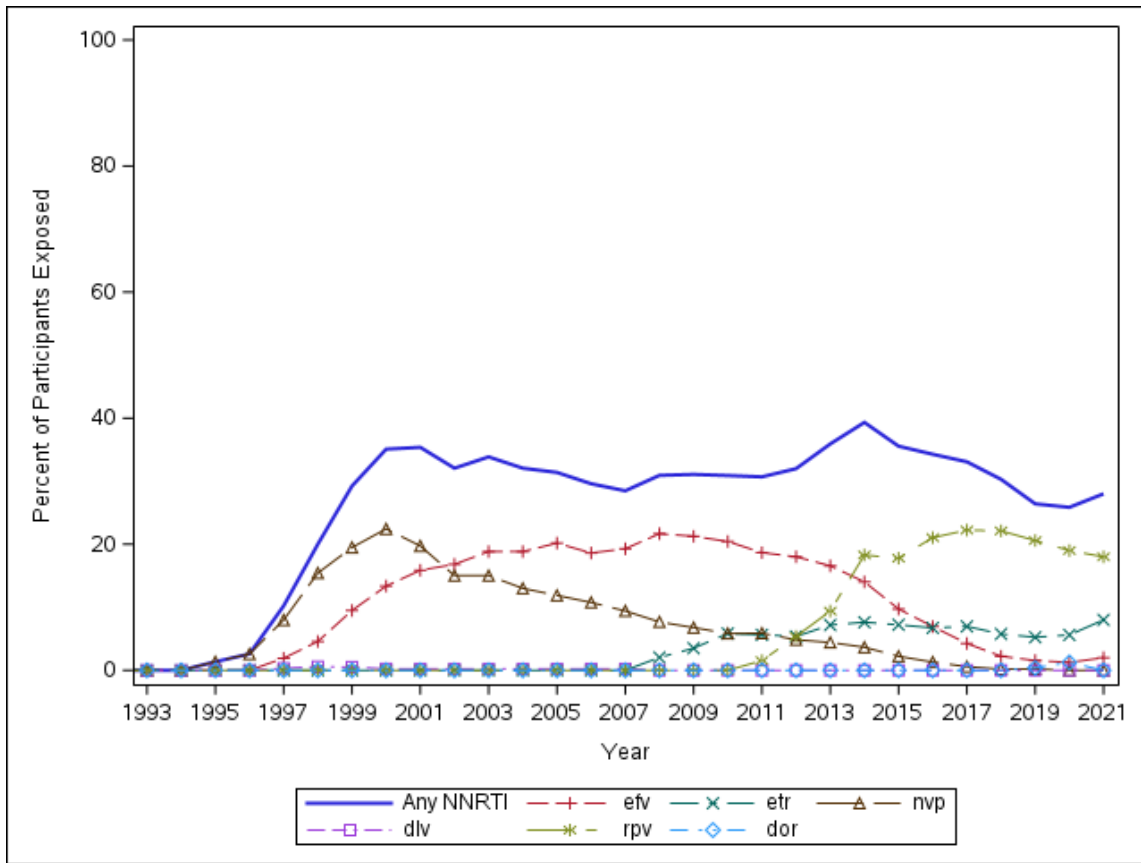
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Figure 2: AMP/AMP Up - NRTI Use, 1993 - 2021



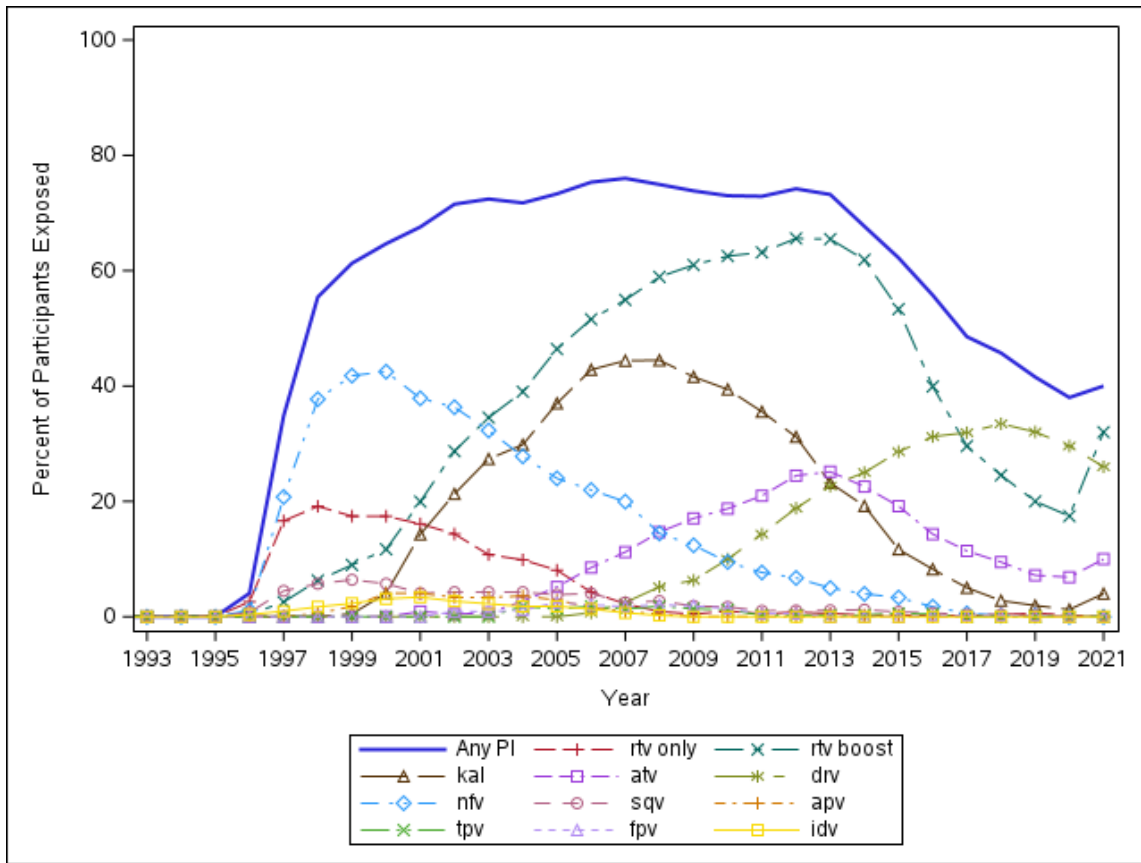
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Figure 3: AMP/AMP Up - NNRTI Use, 1993 - 2021



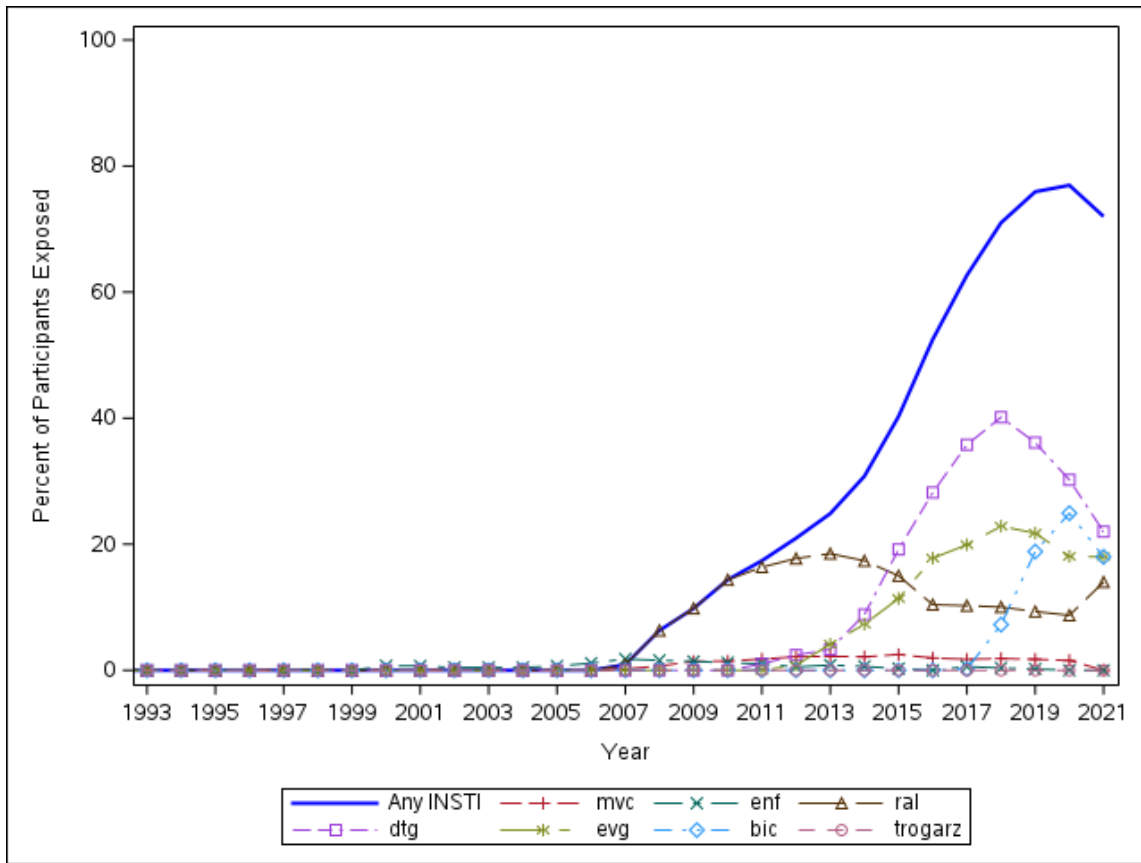
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Figure 4: AMP/AMP Up - PI Use, 1993 - 2021



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Figure 5: AMP/AMP Up - FI/EI and INSTI Use, 1993 - 2021



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