

**Pediatric HIV/AIDS Cohort Study (PHACS)
Surveillance Monitoring of ART Toxicities (SMARTT) Study
Annual Administrative Report**

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Use: *This report is intended primarily for generating data analysis concept sheets and substudy proposals for PHACS. Information contained in the report also may be used in presentations and published manuscripts with acknowledgement or citation.*

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Summary

As of April 1, 2021, 4783 children and 3628 caregivers enrolled in SMARTT ([Table 1](#)). As shown in the table, there were 3304 children in the dynamic cohort and 1240 in the static cohort (enrollment for the static cohort was closed on July 31, 2009). Starting in March 2010, a cohort of HIV-unexposed, uninfected children was enrolled to serve as a reference group; the enrollment target was 50 each from four specific age groups (1, 3, 5, and 9 years old). After enrollment into the reference cohort began, echocardiograms were added to the schedule of evaluations for 3- and 5-year olds. In order to ensure a sufficient number of echocardiograms, 35 additional children from the 3- and 5-year old groups were enrolled into a modified reference cohort. A total of 239 children were enrolled in the reference cohort and evaluations are now complete. These children completed a limited set of evaluations including echocardiograms.

Enrollment by site is summarized in [Table 2](#). For the static cohort, most children (79%) previously participated in a PACTG/IMPAACT protocol: 24% in P1025 only; 23% in 219/219C; 13% in WITS only; 7% in 219/219C and WITS; 6% in 219C and P1025; 2% in 219C, P1025 and WITS ([Table 3](#)). Approximately half of the children enrolled were male ([Table 4](#)). Most children were Black or African American (66%), and 30% were of Hispanic ethnicity. The median age at enrollment of children in the static cohort was 4.1 years. The numbers of children enrolled in the different age groups of the reference cohort are: 52 one-year olds; 67 three-year olds; 71 five-year olds and 49 nine-year olds.

As shown in [Table 5](#), 78% of infants were born full-term (≥ 37 weeks gestation) and the majority weighed more than 2500 g (79%). Forty-three percent of infants delivered by spontaneous vaginal delivery, 38% delivered by C-section before labor/membrane rupture and 13% delivered by C-section after labor/membrane rupture. [Note that the dynamic cohort allows study entry during gestation; thus birth characteristics may not yet be available]. Of the children enrolled in the dynamic and static cohorts, 78% and 26% children are still on study as of the last data retrieval date, respectively; 611 (18%) dynamic and 287 (23%) static children were withdrawn / lost to follow-up; and 56 (2%) dynamic and 52 (4%) static children were off study because of site closure ([Table 6](#)). A total of 43 children were off study because of death (n=24), fetal demise (n=18) or the death of parent (n=1). Twelve dynamic children have gone off study due to HIV infection. Among dynamic and static children who were still on study, the median age at the last scheduled clinic visit were 5.3 and 15.2 years, respectively ([Table 7](#)). Overall, 97% of the children enrolled completed the entry visit and 88% of visits were done on time or early ([Table 8](#)). Eleven children missed the entry visit and 105 (2%) children dropped out of the study before any study visit.

Table 9-Table 13 contain some initial summaries of key measures across domains of interest for SMARTT, including cognitive assessments (Table 9-Table 10), hearing and language assessments (Table 11-Table 12), and growth data (Table 13).

[Table 9](#) summarizes the results of the Bayley Screen for three-year olds. Of the participants assessed, 34-56% of the dynamic cohort, 30-53% of the static cohort and 16-49% of the reference cohort were at risk or some risk of developmental delay across the different sub-domains, with the highest percentage for cognitive delay and lowest percentage for gross motor delay. Overall, at least 63 participants were identified to require further evaluation for delay in at least one of the assessed skills categories.

Neurodevelopment assessments for other ages are summarized in [Table 10](#), including the Full Bayley-III (1-year olds), WPPSI (5-year olds), WASI, WIAT and BRIEF-PR (Parent-Report). Ages at administering WASI, WIAT and BRIEF-PR have been changed across the different versions of protocol; they were administered at odd years of age starting at 7 years old before version 4 protocol, then have been changed thereafter to be administered only at 9 years of age. The normative scores for the Bayley -III, WPPSI, WASI and WIAT have a mean of 100 and a standard deviation of 15, with a higher score indicating a better performance. The normative scores for the BRIEF have a mean of 50 and a standard deviation of 10, with a higher score indicating a worse performance. As shown in the table, the mean scores across different neurodevelopment batteries were mostly within 5 – 10 points of the general population norms.

Information related to caregiver-reported hearing information is summarized in [Table 11](#). Among participants who submitted a demographic form at entry visit, 28% of children (27% of dynamic cohort, 29% of static cohort and 21% of reference cohort) had an audiologic exam before enrolling in the study, of whom 9 (2 from dynamic and 7 from the static cohort) were identified with permanent hearing loss in 1 or 2 ears. Summary measures for the age-specific language assessments are provided in [Table 12](#), including the MacArthur CDI (1-year olds), Ages and Stages Questionnaire (ASQ: 2-year olds), TELD (3-year olds), and TOLD (5-year olds). The normative scores are 50th percentile for the CDI, and 100 (standard deviation: 15) for TELD and TOLD. The general population means are age specific for the ASQ. As shown in the table, the mean scores of MacArthur CDI, TELD and TOLD were mostly within 5 – 10 points of the general population; the means of ASQ were 44 for dynamic and 45 for static children.

The growth measurements in [Table 13](#) suggest that infants enrolled in the dynamic cohort were below average length and weight at birth, while those in the static cohort and reference cohort were above average height/length and weight for their ages at the time of study entry. The mean BMI (≥ 2 years old) for the static cohort and reference cohort were also higher than average.

[Table 14](#) and [Table 15](#) summarize self-reported maternal substance use during pregnancy by trimester of pregnancy, for the dynamic and static cohort, respectively. Calculations are based on the number of children with maternal substance use data available. Overall, 917 (29%) mothers in the dynamic cohort and 275 (27%) mothers in the static cohort reported some substance use (licit or illicit) at some point during their pregnancy. Substance use was highest during the first trimester and then decreased; cigarette smoking (17% of dynamic cohort; 19% of static cohort) was the most frequently reported

substance, followed by alcohol (9% of dynamic cohort; 7% of static cohort) and marijuana (9% dynamic cohort; 6% of static cohort).

In utero ARV exposure by birth year for the static and dynamic cohorts combined is summarized in [Table 16](#). Overall, of the 4379 children who completed a scheduled study visit, 4207 (96%) were exposed *in utero* to an ARV; 51 (1%) were exposed to ARV during labor and delivery only; while 36 (1%) were not exposed to any ARV during pregnancy, labor, or delivery. For 38% of the children, their mother received ARVs at conception.

[Figure 1 - Figure 4](#) show the trends of *in utero* ARV exposure by year of birth, for each ARV class and the individual agents within each class. Calculations are based on the number of children with *in utero* ARV exposure data available. Prenatal exposure to NRTI-containing regimens remained very high (nearly 100%) across all birth years ([Figure 1](#)). There was a decreasing trend in zidovudine (ZDV) exposure over time (from 100% in 1995 to about 6% in 2020); lamivudine (3TC) exposure increased dramatically from about 5% in 1996 to more than 90% in 2000 and fluctuated around this percentage until 2005, then decreased thereafter with a similar trend as ZDV; abacavir (ABC) became a common NRTI agent received during pregnancy after 2001, with use decreasing after 2007 and fluctuating around 10% since 2012; tenofovir disoproxil fumarate (TDF) use increased from about 3% in 2002 to about 79% in 2015, then decreased thereafter with a simultaneously increased use of tenofovir alafenamide fumarate (TAF) (from 6% in 2016 to 63% in 2020); emtricitabine (FTC) use increased steadily from about 1% in 2004 to above 90% in 2020; in addition, TDF and FTC surpassed ZDV and 3TC as the most commonly used NRTI agents in 2012. The use of NNRTI-containing regimens increased from about 5% in 1996 to more than 30% in 2003, then decreased to about 10% between 2008 and 2011 and then increased again to about 34% in 2015 and decreased since then ([Figure 2](#)). Nevirapine (NPV) was the most commonly used NNRTI agent before 2009, with use increasing between 1996 and 2003, and decreasing since then (0% exposure in 2020); the use of efavirenz (EFV) was consistently low (less than 10%); the use of rilpivirine (RPV) increased since 2012 and became the most commonly used NNRTI agent (increased from 4% in 2012 to about 30% in 2015, and decreased a little since then). Starting in 1997, the use of PI-containing regimens increased to more than 85% in 2010, and has decreased since then ([Figure 3](#)). Nelfinavir (NFV) was initially the most commonly-used PI, but in 2007 it was surpassed by use of ritonavir-boosted other PIs, and that trend continues. Lopinavir/r exposure increased between 2001 and 2009 and has decreased since then. There was also an increasing trend in the use of atazanavir between 2004 and 2013; use has decreased since then. The use of darunavir (DRV) increased from below 1% in 2007 to about 21% in 2019. The first reported use of a fusion inhibitor (FI) was in 2006 and of an integrase inhibitor (INSTI) was in 2008. Use of an INSTI agent increased consistently from about 1% in 2008 to more than 75% in 2020 ([Figure 4](#)). Use of the FIs enfuvirtide (ENF) and maraviroc (MVC) have remained low; use of the INSTI raltegravir (RAL) increased from about 1% in 2008 to about 15% in 2013, decreased to less than 10% in 2016 and then increased to about 19% in 2020. Use of elvitegravir (EVG)

paired with cobicistat (a non-ARV booster for EVG), and in combination with FTC and TDF (as Stribild) emerged in 2013 (or in combination with FTC and TAF as Genvoya since 2016) and increased from 1% to more than 25% in 2020, although the use was decreased in 2018. Dolutegravir (DTG) use was first reported in 2014 at about 2% and increased to about 30% in 2018, decreasing to 26% in 2020. Use of bictegravir (BIC) in combination with FTC and TAF as Biktarvy emerged in 2018 and increased to 25% in 2020. The most commonly-used regimen has changed over time; ZDV monotherapy was the most commonly-used regimen before 1999, then ZDV+3TC in 1999, ZDV+3TC+NFV between 2000 and 2007, and ZDV+3TC+lopinavir/r after 2007 until 2014 when TDF+FTC+boosted ATV became the most frequently used regimen in 2014 and after 2018, and TDF+FTC+RPV from 2015 to 2017, FTC+TAF+EVG/c became the most frequently used regimen in 2020 ([Figure 5](#)).

The median duration of follow-up in SMARTT was 142 months among the static and 76 months among the dynamic participants. The follow-up time is based on the assumption that a participant is still on study as of the last data retrieval date unless known to have discontinued. It is not based on their last study visit.

Tables and Figures

Table 1: SMARTT - Enrollment by Cohort and Year

		Caregiver (N=3628)	Dynamic (N=3304)	Static (N=1240)	Reference (N=239)
Enrollment Year	2007	520 (14%)	130 (4%)	544 (44%)	0 (0%)
	2008	581 (16%)	315 (10%)	434 (35%)	0 (0%)
	2009	433 (12%)	327 (10%)	262 (21%)	0 (0%)
	2010	293 (8%)	267 (8%)	0 (0%)	78 (33%)
	2011	298 (8%)	263 (8%)	0 (0%)	123 (51%)
	2012	214 (6%)	236 (7%)	0 (0%)	35 (15%)
	2013	222 (6%)	279 (8%)	0 (0%)	3 (1%)
	2014	187 (5%)	244 (7%)	0 (0%)	0 (0%)
	2015	193 (5%)	271 (8%)	0 (0%)	0 (0%)
	2016	153 (4%)	210 (6%)	0 (0%)	0 (0%)
	2017	146 (4%)	214 (6%)	0 (0%)	0 (0%)
	2018	156 (4%)	218 (7%)	0 (0%)	0 (0%)
	2019	156 (4%)	204 (6%)	0 (0%)	0 (0%)
	2020 Q1	32 (1%)	47 (1%)	0 (0%)	0 (0%)
	2020 Q2	4 (0%)	9 (0%)	0 (0%)	0 (0%)
	2020 Q3	9 (0%)	19 (1%)	0 (0%)	0 (0%)
	2020 Q4	15 (0%)	23 (1%)	0 (0%)	0 (0%)
	2021 Q1	16 (0%)	28 (1%)	0 (0%)	0 (0%)

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Table 2: SMARTT - Study Enrollment by Site

Enrollment site	Cohort			
	Total (N=4783)	Dynamic (N=3304)	Static (N=1240)	Reference (N=239)
NYU MEDICAL CTR/BELLEVUE	149 (3%)	91 (3%)	58 (5%)	0 (0%)
UNIVERSITY OF ALABAMA AT BIRMINGHAM *	238 (5%)	185 (6%)	29 (2%)	24 (10%)
UNIVERSITY OF SOUTHERN CALIFORNIA	406 (8%)	322 (10%)	84 (7%)	0 (0%)
SAN JUAN RESEARCH HOSPITAL	141 (3%)	80 (2%)	61 (5%)	0 (0%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL *	360 (8%)	292 (9%)	44 (4%)	24 (10%)
SUNY DOWNSTATE MEDICAL CENTER *	286 (6%)	145 (4%)	119 (10%)	22 (9%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	258 (5%)	194 (6%)	64 (5%)	0 (0%)
NEW JERSEY MEDICAL CENTER	128 (3%)	120 (4%)	8 (1%)	0 (0%)
SUNY STONY BROOK MEDICAL CENTER	25 (1%)	8 (0%)	17 (1%)	0 (0%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR) *	167 (3%)	119 (4%)	22 (2%)	26 (11%)
BRONX/LEBANON HOSPITAL CENTER *	484 (10%)	306 (9%)	137 (11%)	41 (17%)
UNIVERSITY OF FLORIDA HEALTH SCIENCE CTR	330 (7%)	232 (7%)	98 (8%)	0 (0%)
UNIVERSITY OF ILLINOIS (CHICAGO) *	246 (5%)	137 (4%)	88 (7%)	21 (9%)
UNIVERSITY OF PUERTO RICO MEDICAL CENTER	239 (5%)	149 (5%)	90 (7%)	0 (0%)
CHILDREN'S HOSPITAL OF PHILADELPHIA	27 (1%)	20 (1%)	7 (1%)	0 (0%)
UNIVERSITY OF MIAMI *	438 (9%)	359 (11%)	40 (3%)	39 (16%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR) *	277 (6%)	171 (5%)	82 (7%)	24 (10%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE) *	131 (3%)	102 (3%)	11 (1%)	18 (8%)
UCSD MEDICAL CENTER	121 (3%)	83 (3%)	38 (3%)	0 (0%)
UNIVERSITY OF MARYLAND MED CTR	42 (1%)	24 (1%)	18 (1%)	0 (0%)
JACOBI MEDICAL CENTER	35 (1%)	12 (0%)	23 (2%)	0 (0%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	255 (5%)	153 (5%)	102 (8%)	0 (0%)

*Sites with * enroll reference cohort*

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Table 3: SMARTT - Enrollment by Previous Protocol Participation (Static cohort only)

Protocol group	Studies	Static (N=1240)
No Previous Protocol	None	264 (21%)
219/219C/P1025	P1025+NATURAL HISTORY	1 (0%)
	P1025	293 (24%)
	219C+P1025	75 (6%)
	219/219C	291 (23%)
	219	2 (0%)
	Total	662 (53%)
	WITS Only	WITS
219/219C/P1025+WITS	P1025+WITS	5 (0%)
	219C+P1025+WITS	20 (2%)
	219/219C+WITS	90 (7%)
	Total	115 (9%)
Other PACTG/IMPAACT	PACTG 1039	3 (0%)
	PACTG 1025	1 (0%)
	PACTG 1022	1 (0%)
	ACTG A5084	2 (0%)
	ACTG 394	1 (0%)
	ACTG 367	1 (0%)
	ACTG 354	1 (0%)
	ACTG 353	2 (0%)
	ACTG 326	2 (0%)
	ACTG 316/247	1 (0%)
	ACTG 316	7 (1%)
	ACTG 247	1 (0%)
	Total	23 (2%)
	Other	PACTG 386
NATURAL HISTORY		15 (1%)
CHS		1 (0%)
Total		17 (1%)

Above table summarizes enrollment in previous studies based on the information provided at PHACS enrollment. 219/219C, P1025, and WITS enrollment information was captured for all static participants. However, enrollment information for other studies was only captured at PHACS enrollment for participants who did not participate in 219/219C, P1025, or WITS. Children in the dynamic cohort may also be enrolled in other studies (e.g. P1025).

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Table 4: SMARTT - Enrollment Demographics

		Total (N=4783)	Dynamic (N=3304)	Static (N=1240)	Reference (N=239)
Sex	Male	2,439 (51%)	1,677 (51%)	643 (52%)	119 (50%)
	Female	2,255 (47%)	1,538 (47%)	597 (48%)	120 (50%)
	Missing - Form not submitted	89 (2%)	89 (3%)	0 (0%)	0 (0%)
Age* at enrollment (yrs)	Median (Q1, Q3)	4.1 (2.0, 7.0)	. (. .)	4.1 (2.0, 7.0)	4.7 (2.8, 5.2)
	Birth, <1**	3,333 (70%)	3,304 (100%)	29 (2%)	0 (0%)
	1-2	404 (8%)	0 (0%)	352 (28%)	52 (22%)
	3-4	358 (7%)	0 (0%)	291 (23%)	67 (28%)
	5-6	277 (6%)	0 (0%)	206 (17%)	71 (30%)
	7-12	411 (9%)	0 (0%)	362 (29%)	49 (21%)
Race	Asian	24 (1%)	13 (0%)	7 (1%)	4 (2%)
	Native Hawaiian or other Pacific Islander	4 (0%)	3 (0%)	1 (0%)	0 (0%)
	Black or African American	3,162 (66%)	2,227 (67%)	765 (62%)	170 (71%)
	White	1,221 (26%)	812 (25%)	350 (28%)	59 (25%)
	American Indian	7 (0%)	6 (0%)	1 (0%)	0 (0%)
	More than One Race	136 (3%)	113 (3%)	23 (2%)	0 (0%)
	Participant does not want to report	9 (0%)	4 (0%)	4 (0%)	1 (0%)
	Participant does not know	95 (2%)	59 (2%)	32 (3%)	4 (2%)
	Race not available to clinic	125 (3%)	67 (2%)	57 (5%)	1 (0%)
Ethnicity	Hispanic or Latino	1,420 (30%)	934 (28%)	432 (35%)	54 (23%)
	Not Hispanic or Latino	3,353 (70%)	2,364 (72%)	806 (65%)	183 (77%)
	More than one ethnicity	3 (0%)	3 (0%)	0 (0%)	0 (0%)
	Participant does not want to report	1 (0%)	0 (0%)	1 (0%)	0 (0%)
	Participant does not know	4 (0%)	2 (0%)	1 (0%)	1 (0%)
	Ethnicity not available to clinic	2 (0%)	1 (0%)	0 (0%)	1 (0%)

*Age is rounded to the nearest year. So a child who enrolled at 4 years 11 months is in the 5-6 year group.

Age at enrollment for reference cohort is 1, 3, 5 or 9 years old

** Birth is for dynamic, <1 for static participants

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Table 5: SMARTT - Baseline Maternal Pregnancy and Delivery History Characteristics

Characteristic	Total (N=4783)	Cohort			
		dynamic (N=3304)	static (N=1240)	reference (N=239)	
Gestational age (weeks) at birth	< 32	111 (2%)	68 (2%)	37 (3%)	6 (3%)
	32 - < 37	731 (15%)	499 (15%)	207 (17%)	25 (10%)
	≥ 37	3,720 (78%)	2,602 (79%)	927 (75%)	191 (80%)
	Unknown	221 (5%)	135 (4%)	69 (6%)	17 (7%)
Weight at birth	> 2500 grams	3,794 (79%)	2,633 (80%)	969 (78%)	192 (80%)
	between 2500 and 1500 grams	705 (15%)	477 (14%)	195 (16%)	33 (14%)
	< 1500 grams	92 (2%)	59 (2%)	30 (2%)	3 (1%)
	Unknown	192 (4%)	135 (4%)	46 (4%)	11 (5%)
Mode of delivery	Spontaneous Vaginal	2,048 (43%)	1,331 (40%)	569 (46%)	148 (62%)
	Assisted vaginal (forceps, vacuum)	79 (2%)	39 (1%)	25 (2%)	15 (6%)
	C-section before labor/membrane rupture	1,823 (38%)	1,337 (40%)	449 (36%)	37 (15%)
	C-section after labor/membrane rupture	623 (13%)	455 (14%)	140 (11%)	28 (12%)
	Unknown	210 (4%)	142 (4%)	57 (5%)	11 (5%)
Apgar score at one minute	< 7	421 (9%)	329 (10%)	92 (7%)	0 (0%)
	≥ 7	3,747 (78%)	2,792 (85%)	955 (77%)	0 (0%)
	Unknown	615 (13%)	183 (6%)	193 (16%)	239 (100%)
Apgar score at minute five	< 7	94 (2%)	77 (2%)	17 (1%)	0 (0%)
	≥ 7	4,079 (85%)	3,048 (92%)	1,031 (83%)	0 (0%)
	Unknown	610 (13%)	179 (5%)	192 (15%)	239 (100%)

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Table 6: SMARTT - Study Status

	Total (N=4783)	Dynamic (N=3304)	Static (N=1240)	Reference (N=239)
Study status Still on study	2,890 (60%)	2,565 (78%)	325 (26%)	0 (0%)
Completed study	799 (17%)	9 (0%) **	559 (45%)	231 (97%)
Enrollment error / eligibility failure*	15 (0%)	13 (0%)	2 (0%)	0 (0%)
Death of participant/parent/guardian	43 (1%)	40 (1%)	3 (0%)	0 (0%)
Withdrawal / loss to follow-up	905 (19%)	611 (18%)	287 (23%)	7 (3%)
Site closure	108 (2%)	56 (2%)	52 (4%)	0 (0%)
Other reason	23 (0%)	10 (0%)	12 (1%)	1 (0%)

* 12 Dynamic children in the Enrollment error/eligibility failure category are HIV-infected

** The 9 dynamic children reported as having completed study were queried for data accuracy

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Table 7: SMARTT - Age at Last Scheduled Clinic Visit Among Participants Still on Study

Characteristic		Cohort		
		Total (N=2890)	Dynamic (N=2565)	Static (N=325)
Age (years) at Last Scheduled Clinical Visit	Median (Min, Max)	7 (0, 22)	5.3 (0.0, 13.4)	15.2 (10.9, 22.0)
	0	176 (6%)	176 (7%)	0 (0%)
	1-2	394 (14%)	394 (15%)	0 (0%)
	3-4	394 (14%)	394 (15%)	0 (0%)
	5-6	432 (15%)	432 (17%)	0 (0%)
	7-12	1,145 (40%)	1,118 (44%)	27 (8%)
	13-15	227 (8%)	51 (2%)	176 (54%)
	>15	122 (4%)	0 (0%)	122 (38%)

* For participants who did not attend the scheduled study visits, the scheduled clinical visit date was used to calculate the age.

For dynamic participants not yet born or just born and study visit form not submitted by the time of data retrieval, the age was set as 0 in above table.

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Table 8: SMARTT - Entry Visit Status

Visit status	Total	Cohort		
		Dynamic	Static	Reference
Visit reported	4630 (97%)	3194 (97%)	1200 (97%)	236 (99%)
Early	27 (1%)	2 (0%)	21 (2%)	4 (2%)
In window	4157 (87%)	2955 (89%)	999 (81%)	203 (85%)
Late	446 (9%)	237 (7%)	180 (15%)	29 (12%)
No visit reported	153 (3%)	110 (3%)	40 (3%)	3 (1%)
Delinquent	10 (0%)	10 (0%)	0 (0%)	0 (0%)
In window	27 (1%)	27 (1%)	0 (0%)	0 (0%)
Missed visit	11 (0%)	11 (0%)	0 (0%)	0 (0%)
Off study *	105 (2%)	62 (2%)	40 (3%)	3 (1%)

* Includes participants who were off study before the entry visit and participants who missed the entry visit and all follow-up visits until were taken off study.

Table (above) reports on the status and timeliness of the entry visit for all enrolled participants. This is based on the Visit Report form (PH5801) and the participant's birthday. For the static cohort and reference cohort, the allowed visit window is the birthday +/- 90 days.

For the dynamic cohort, the permitted visit window is from after birth up to two weeks. A visit is Delinquent if no visit has been reported, the visit window has passed, and an additional 2 weeks have passed (to allow time for submission of PH5801). This is a total of 4 weeks from an infant's birthdate. For those infants with no recorded birthdate, an estimated delivery date has been generated based on 43 weeks of gestation (or the visit date on PH5801).

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Table 9: Bayley Screen for Three Year-Olds

ND Assessment		Cohort			
		Total (N=1579)	Dynamic (N=1261)	Static (N=275)	Reference (N=43)
Cognitive	At Risk for Devl Delay/Further Eval Needed	61 (4%)	50 (4%)	11 (4%)	0 (0%)
	Some Risk for Devl Delay	809 (51%)	653 (52%)	135 (49%)	21 (49%)
	Low Risk for Devl Delay	709 (45%)	558 (44%)	129 (47%)	22 (51%)
Receptive Communication	At Risk for Devl Delay/Further Eval Needed	47 (3%)	36 (3%)	11 (4%)	0 (0%)
	Some Risk for Devl Delay	596 (38%)	485 (38%)	97 (35%)	14 (33%)
	Low Risk for Devl Delay	933 (59%)	737 (58%)	167 (61%)	29 (67%)
	Not Done	3 (0%)	3 (0%)	0 (0%)	0 (0%)
Expressive Communication	At Risk for Devl Delay/Further Eval Needed	63 (4%)	54 (4%)	9 (3%)	0 (0%)
	Some Risk for Devl Delay	659 (42%)	541 (43%)	108 (39%)	10 (23%)
	Low Risk for Devl Delay	852 (54%)	661 (52%)	158 (57%)	33 (77%)
	Not Done	5 (0%)	5 (0%)	0 (0%)	0 (0%)
Fine Motor	At Risk for Devl Delay/Further Eval Needed	37 (2%)	29 (2%)	8 (3%)	0 (0%)
	Some Risk for Devl Delay	618 (39%)	515 (41%)	91 (33%)	12 (28%)
	Low Risk for Devl Delay	921 (58%)	714 (57%)	176 (64%)	31 (72%)
	Not Done	3 (0%)	3 (0%)	0 (0%)	0 (0%)
Gross Motor	At Risk for Devl Delay/Further Eval Needed	34 (2%)	28 (2%)	6 (2%)	0 (0%)
	Some Risk for Devl Delay	492 (31%)	407 (32%)	78 (28%)	7 (16%)
	Low Risk for Devl Delay	1,049 (66%)	822 (65%)	191 (69%)	36 (84%)
	Not Done	4 (0%)	4 (0%)	0 (0%)	0 (0%)

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Table 10: Age-specific ND Assessments

ND Assessment	Score	Cohort					
		Dynamic		Static		Reference	
		N	Mean (S.D)	N	Mean (S.D)	N	Mean (S.D)
Bayley-III (1 year old)	Cognitive, Composite	1720	102.6 (14.1)	146	102.9 (15.2)	49	102.2 (14.0)
	Language, Composite	1718	94.8 (13.6)	145	93.2 (14.7)	49	95.1 (12.5)
	Motor, Composite	1709	97.2 (12.7)	145	96.9 (15.9)	49	100.9 (14.7)
	Social-Emotional, Composite	1675	101.7 (17.7)	142	101.6 (18.5)	49	100.5 (16.4)
	General Adaptive, Composite	1671	94.7 (14.3)	142	93.4 (15.0)	49	92.3 (11.3)
WPPSI (5 years old)	Full Scale IQ	945	94.1 (15.3)	445	94.6 (14.5)	47	93.6 (15.6)
	Performance IQ	964	96.3 (15.7)	447	97.3 (15.2)	47	95.6 (15.3)
	Verbal IQ	961	92.3 (14.3)	447	92.1 (12.9)	47	91.6 (13.9)
	Processing Speed IQ	922	94.8 (15.5)	442	96.3 (15.9)	47	95.0 (15.4)
	General Language IQ	581	92.5 (13.7)	210	91.0 (14.1)	19	91.1 (11.4)
WASI (7+ odd years old)*	Full Scale IQ	383	101.0 (15.7)	781	97.9 (14.0)	48	100.8 (12.6)
	Performance IQ	383	97.0 (13.5)	781	95.2 (13.1)	49	95.3 (13.0)
	Verbal IQ	383	104.8 (18.8)	781	101.0 (16.0)	48	105.8 (14.2)
WIAT (7+ odd years old)*	Word Reading, Standard Score	376	97.9 (17.3)	779	97.3 (16.1)	49	97.1 (15.0)
	Spelling, Standard Score	375	97.0 (18.9)	776	97.8 (16.5)	48	98.8 (15.8)
	Numerical Operations, Standard Score	375	93.5 (17.5)	779	94.0 (16.6)	49	94.5 (15.5)
BRIEF Parent-Report (7+ odd years old)*	Behavioral Regulation Index, T-Score	450	51.6 (11.8)	731	53.6 (12.2)	46	53.3 (12.2)
	Metacognition Index, T-Score	449	51.3 (12.0)	730	52.8 (11.8)	46	52.6 (11.8)
	Global Executive Composite, T-Score	449	51.5 (12.1)	730	53.3 (12.1)	46	52.9 (11.7)

* WASI, WIAT AND BRIEF-PR: For participants completing an assessment at more than one time point, the earliest assessment is used.

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Table 11: SMARTT Caregiver-Reported Hearing Information at Entry

Characteristic		Cohort			
		Total (N=4628)	Dynamic (N=3197)	Static (N=1195)	Reference (N=236)
Concerns about hearing?	Yes	141 (3%)	55 (2%)	77 (6%)	9 (4%)
	No	4,427 (96%)	3,090 (97%)	1,111 (93%)	226 (96%)
	Unknown	60 (1%)	52 (2%)	7 (1%)	1 (0%)
Child has repeated ear infections?	Yes	124 (3%)	0 (0%)	102 (9%)	22 (9%)
	No	4,444 (96%)	3,145 (98%)	1,086 (91%)	213 (90%)
	Unknown	60 (1%)	52 (2%)	7 (1%)	1 (0%)
Child failed hearing screening?	Yes	160 (3%)	84 (3%)	65 (5%)	11 (5%)
	No	4,408 (95%)	3,061 (96%)	1,123 (94%)	224 (95%)
	Unknown	60 (1%)	52 (2%)	7 (1%)	1 (0%)
Child tested by audiologist?	Yes	1,275 (28%)	876 (27%)	349 (29%)	50 (21%)
	No	3,293 (71%)	2,269 (71%)	839 (70%)	185 (78%)
	Unknown	60 (1%)	52 (2%)	7 (1%)	1 (0%)
Perm hearing loss in 1-2 ears?	Yes	9 (0%)	2 (0%)	7 (1%)	0 (0%)
	No	1,265 (27%)	873 (27%)	342 (29%)	50 (21%)
	Test not done	3,293 (71%)	2,269 (71%)	839 (70%)	185 (78%)
	Unknown	61 (1%)	53 (2%)	7 (1%)	1 (0%)

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Table 12: SMARTT Age-Specific Language Assessments

Language Assessment		Dynamic		Static		Reference	
		Total N	Mean (S.D.)	Total N	Mean (S.D.)	Total N	Mean (S.D.)
CDI (1 year old)	Phrases Understood	1932	56.9 (27.5)	169	50.4 (27.8)	47	52.6 (27.8)
	Vocabulary Comprehension	1932	47.5 (30.0)	169	43.6 (29.7)	47	44.7 (31.1)
	Words Production	1932	49.2 (21.9)	169	45.0 (21.2)	47	56.3 (20.0)
	A-E Total Gestures	1933	49.6 (28.4)	169	40.6 (28.8)	47	55.9 (30.9)
ASQ (2 years old)	Total Score	1884	43.9 (15.6)	269	45.1 (15.7)		. (.)
TELD (3 years old)	Receptive Language	37	98.9 (16.0)	286	98.8 (14.4)	37	97.8 (11.1)
	Expressive Language	37	98.9 (13.3)	286	99.6 (14.7)	37	102.6 (10.9)
	Spoken Language Quotient	37	95.6 (22.6)	286	99.5 (17.4)	37	98.1 (19.8)
TOLD (5 years old)	Spoken Language	865	91.8 (14.8)	424	90.1 (14.1)	45	87.9 (14.3)
	Listening	867	97.2 (14.7)	424	94.6 (13.6)	45	92.0 (13.4)
	Speaking	866	91.9 (15.2)	424	91.6 (13.9)	45	90.2 (13.6)
	Syntax	865	89.0 (14.7)	424	89.4 (14.5)	45	89.0 (13.7)

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Table 13: SMARTT Growth Data at Entry

Score	Dynamic			Static			Reference		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Height or Length Z-score	3159	-0.11	1.04	1191	0.31	1.13	235	0.34	1.15
Weight Z-score	3164	-0.55	0.87	1193	0.51	1.25	235	0.20	1.21
BMI Z-score (≥ 2 years old)	.	.	.	844	0.63	1.30	172	0.08	1.56

BMI is not calculated for children < 2 years.

Z-scores for premature participants are adjusted for newborn and 1-year olds.

Extreme growth Z-scores (> 6 in absolute values) were excluded from calculations and will be queried.

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Table 14: Maternal Substance Use During Pregnancy in SMARTT Dynamic Cohort

		Trimester			
		Any Trimester (N=3131)	First (N=3131)	Second (N=3131)	Third (N=3131)
Any Substance Use	Yes	917 (29%)	793 (25%)	518 (17%)	473 (15%)
	No	2,212 (71%)	2,336 (75%)	2,611 (83%)	2,656 (85%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Tobacco	Yes	547 (17%)	515 (16%)	342 (11%)	292 (9%)
	No	2,582 (82%)	2,602 (83%)	2,775 (89%)	2,825 (90%)
	Unknown	2 (0%)	14 (0%)	14 (0%)	14 (0%)
Alcohol	Yes	284 (9%)	256 (8%)	74 (2%)	53 (2%)
	No	2,845 (91%)	2,871 (92%)	3,053 (98%)	3,074 (98%)
	Unknown	2 (0%)	4 (0%)	4 (0%)	4 (0%)
Marijuana	Yes	292 (9%)	257 (8%)	135 (4%)	100 (3%)
	No	2,837 (91%)	2,868 (92%)	2,990 (95%)	3,025 (97%)
	Unknown	2 (0%)	6 (0%)	6 (0%)	6 (0%)
Cocaine	Yes	69 (2%)	57 (2%)	38 (1%)	28 (1%)
	No	3,060 (98%)	3,072 (98%)	3,091 (99%)	3,101 (99%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Antidepressants	Yes	133 (4%)	88 (3%)	70 (2%)	74 (2%)
	No	2,994 (96%)	3,039 (97%)	3,057 (98%)	3,053 (98%)
	Unknown	4 (0%)	4 (0%)	4 (0%)	4 (0%)
Pain Medications	Yes	137 (4%)	58 (2%)	68 (2%)	64 (2%)
	No	2,990 (95%)	3,069 (98%)	3,059 (98%)	3,063 (98%)
	Unknown	4 (0%)	4 (0%)	4 (0%)	4 (0%)
Methadone	Yes	21 (1%)	18 (1%)	20 (1%)	21 (1%)
	No	3,105 (99%)	3,110 (99%)	3,108 (99%)	3,107 (99%)
	Unknown	5 (0%)	3 (0%)	3 (0%)	3 (0%)
Heroin	Yes	15 (0%)	12 (0%)	7 (0%)	6 (0%)
	No	3,113 (99%)	3,116 (100%)	3,121 (100%)	3,122 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
Sedative	Yes	15 (0%)	9 (0%)	7 (0%)	6 (0%)
	No	3,113 (99%)	3,119 (100%)	3,121 (100%)	3,122 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
Methamphetamines	Yes	19 (1%)	17 (1%)	7 (0%)	4 (0%)
	No	3,110 (99%)	3,112 (99%)	3,122 (100%)	3,125 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Ecstasy	Yes	3 (0%)	3 (0%)	0 (0%)	0 (0%)

		Trimester			
		Any Trimester (N=3131)	First (N=3131)	Second (N=3131)	Third (N=3131)
PCP	No	3,126 (100%)	3,126 (100%)	3,129 (100%)	3,129 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	2 (0%)	2 (0%)	1 (0%)	1 (0%)
Opium	No	3,126 (100%)	3,126 (100%)	3,127 (100%)	3,127 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
	Yes	5 (0%)	2 (0%)	3 (0%)	2 (0%)
Other Drug	No	3,124 (100%)	3,127 (100%)	3,126 (100%)	3,127 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	17 (1%)	11 (0%)	8 (0%)	7 (0%)
Stimulants	No	3,111 (99%)	3,117 (100%)	3,120 (100%)	3,121 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
	Yes	7 (0%)	5 (0%)	0 (0%)	0 (0%)
Barbiturates	No	3,122 (100%)	3,124 (100%)	3,129 (100%)	3,129 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
Amphetamines	No	3,128 (100%)	3,128 (100%)	3,129 (100%)	3,129 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	2 (0%)	1 (0%)	0 (0%)	0 (0%)
Inhalants	No	3,127 (100%)	3,128 (100%)	3,129 (100%)	3,129 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	1 (0%)	1 (0%)	1 (0%)	0 (0%)
LSD	No	3,128 (100%)	3,128 (100%)	3,128 (100%)	3,129 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
Other Hallucinogens	No	3,125 (100%)	3,127 (100%)	3,128 (100%)	3,128 (100%)
	Unknown	5 (0%)	3 (0%)	3 (0%)	3 (0%)
	Yes	2 (0%)	2 (0%)	1 (0%)	0 (0%)
Ketamine	No	3,124 (100%)	3,125 (100%)	3,126 (100%)	3,127 (100%)
	Unknown	5 (0%)	4 (0%)	4 (0%)	4 (0%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,128 (100%)	3,128 (100%)	3,129 (100%)	3,129 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)

All Dynamic children including those from multiple gestations (twins/triplets, etc) are included in above table.

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Table 15: Maternal Substance Use During Pregnancy in SMARTT Static Cohort

		Trimester			
		Any Trimester (N=1035)	First (N=1035)	Second (N=1035)	Third (N=1035)
Any Substance Use	Yes	275 (27%)	243 (23%)	172 (17%)	138 (13%)
	No	760 (73%)	792 (77%)	863 (83%)	897 (87%)
Tobacco	Yes	197 (19%)	185 (18%)	132 (13%)	108 (10%)
	No	838 (81%)	845 (82%)	898 (87%)	922 (89%)
	Unknown	0 (0%)	5 (0%)	5 (0%)	5 (0%)
Alcohol	Yes	72 (7%)	63 (6%)	27 (3%)	15 (1%)
	No	963 (93%)	970 (94%)	1,006 (97%)	1,018 (98%)
	Unknown	0 (0%)	2 (0%)	2 (0%)	2 (0%)
Marijuana	Yes	66 (6%)	60 (6%)	40 (4%)	26 (3%)
	No	969 (94%)	974 (94%)	994 (96%)	1,008 (97%)
	Unknown	0 (0%)	1 (0%)	1 (0%)	1 (0%)
Cocaine	Yes	26 (3%)	21 (2%)	12 (1%)	5 (0%)
	No	1,009 (97%)	1,013 (98%)	1,022 (99%)	1,029 (99%)
	Unknown	0 (0%)	1 (0%)	1 (0%)	1 (0%)
Antidepressants	Yes	27 (3%)	19 (2%)	17 (2%)	16 (2%)
	No	1,008 (97%)	1,013 (98%)	1,015 (98%)	1,016 (98%)
	Unknown	0 (0%)	3 (0%)	3 (0%)	3 (0%)
Pain Medications	Yes	33 (3%)	18 (2%)	14 (1%)	13 (1%)
	No	1,002 (97%)	1,015 (98%)	1,019 (98%)	1,020 (99%)
	Unknown	0 (0%)	2 (0%)	2 (0%)	2 (0%)
Methadone	Yes	14 (1%)	14 (1%)	14 (1%)	13 (1%)
	No	1,020 (99%)	1,020 (99%)	1,020 (99%)	1,021 (99%)
	Unknown	1 (0%)	1 (0%)	1 (0%)	1 (0%)
Heroin	Yes	7 (1%)	5 (0%)	4 (0%)	4 (0%)
	No	1,027 (99%)	1,028 (99%)	1,029 (99%)	1,029 (99%)
	Unknown	1 (0%)	2 (0%)	2 (0%)	2 (0%)
Sedative	Yes	7 (1%)	5 (0%)	4 (0%)	2 (0%)
	No	1,028 (99%)	1,030 (100%)	1,031 (100%)	1,033 (100%)
Methamphetamines	Yes	4 (0%)	4 (0%)	0 (0%)	0 (0%)
	No	1,031 (100%)	1,031 (100%)	1,035 (100%)	1,035 (100%)
Ecstasy	Yes	2 (0%)	1 (0%)	1 (0%)	0 (0%)

		Trimester			
		Any Trimester (N=1035)	First (N=1035)	Second (N=1035)	Third (N=1035)
PCP	No	1,033 (100%)	1,034 (100%)	1,034 (100%)	1,035 (100%)
	Yes	1 (0%)	1 (0%)	1 (0%)	1 (0%)
Opium	No	1,032 (100%)	1,032 (100%)	1,032 (100%)	1,032 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Other Drug	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	1,034 (100%)	1,034 (100%)	1,035 (100%)	1,035 (100%)
Stimulants	Yes	5 (0%)	3 (0%)	2 (0%)	2 (0%)
	No	1,030 (100%)	1,032 (100%)	1,033 (100%)	1,033 (100%)
Barbiturates	No	1,034 (100%)	1,034 (100%)	1,034 (100%)	1,034 (100%)
	Unknown	1 (0%)	1 (0%)	1 (0%)	1 (0%)
Amphetamines	Yes	5 (0%)	3 (0%)	2 (0%)	2 (0%)
	No	1,030 (100%)	1,032 (100%)	1,033 (100%)	1,033 (100%)
Inhalants	No	1,035 (100%)	1,035 (100%)	1,035 (100%)	1,035 (100%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	Unknown	1 (0%)	1 (0%)	1 (0%)	1 (0%)
LSD	No	1,033 (100%)	1,033 (100%)	1,034 (100%)	1,034 (100%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	Unknown	1 (0%)	1 (0%)	1 (0%)	1 (0%)
Other Hallucinogens	No	1,035 (100%)	1,035 (100%)	1,035 (100%)	1,035 (100%)
Ketamine	No	1,034 (100%)	1,034 (100%)	1,034 (100%)	1,034 (100%)
	Unknown	1 (0%)	1 (0%)	1 (0%)	1 (0%)

All Static children including those from multiple gestations (twins/triplets, etc) are included in above table.

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Table 16: Maternal ARV Exposure by Birth Year, Static and Dynamic Cohorts Combined

Year of birth	At conception	During pregnancy	At labor and delivery only	No ARV during pregnancy, labor or delivery	Unknown ARV use during pregnancy	Total *
1995	0 (0%)	6 (100%)	0 (0%)	0 (0%)	0 (0%)	6
1996	2 (5%)	33 (89%)	2 (5%)	2 (5%)	0 (0%)	37
1997	3 (10%)	27 (90%)	1 (3%)	2 (7%)	0 (0%)	30
1998	10 (19%)	48 (92%)	2 (4%)	0 (0%)	2 (4%)	52
1999	15 (21%)	66 (93%)	2 (3%)	2 (3%)	1 (1%)	71
2000	21 (23%)	87 (94%)	1 (1%)	3 (3%)	2 (2%)	93
2001	24 (24%)	91 (89%)	5 (5%)	4 (4%)	2 (2%)	102
2002	35 (34%)	98 (94%)	0 (0%)	2 (2%)	4 (4%)	104
2003	35 (28%)	117 (95%)	0 (0%)	2 (2%)	4 (3%)	123
2004	43 (37%)	108 (93%)	4 (3%)	3 (3%)	1 (1%)	116
2005	45 (35%)	123 (97%)	0 (0%)	2 (2%)	2 (2%)	127
2006	48 (30%)	153 (95%)	3 (2%)	3 (2%)	2 (1%)	161
2007	70 (30%)	223 (94%)	6 (3%)	1 (0%)	6 (3%)	236
2008	97 (27%)	337 (95%)	8 (2%)	2 (1%)	7 (2%)	354
2009	102 (32%)	314 (98%)	1 (0%)	2 (1%)	5 (2%)	322
2010	84 (32%)	258 (98%)	2 (1%)	0 (0%)	3 (1%)	263
2011	96 (37%)	259 (99%)	1 (0%)	0 (0%)	2 (1%)	262
2012	98 (42%)	228 (97%)	1 (0%)	1 (0%)	5 (2%)	235
2013	107 (41%)	255 (97%)	0 (0%)	2 (1%)	7 (3%)	264
2014	112 (44%)	238 (93%)	1 (0%)	3 (1%)	13 (5%)	255
2015	121 (48%)	249 (99%)	1 (0%)	0 (0%)	1 (0%)	251
2016	122 (54%)	223 (99%)	2 (1%)	0 (0%)	0 (0%)	225
2017	96 (51%)	184 (97%)	4 (2%)	0 (0%)	1 (1%)	189
2018	105 (51%)	201 (99%)	1 (0%)	0 (0%)	2 (1%)	204
2019	104 (54%)	184 (95%)	2 (1%)	0 (0%)	7 (4%)	193
2020	54 (52%)	97 (93%)	1 (1%)	0 (0%)	6 (6%)	104
Total	1649 (38%)	4207 (96%)	51 (1%)	36 (1%)	85 (2%)	4379

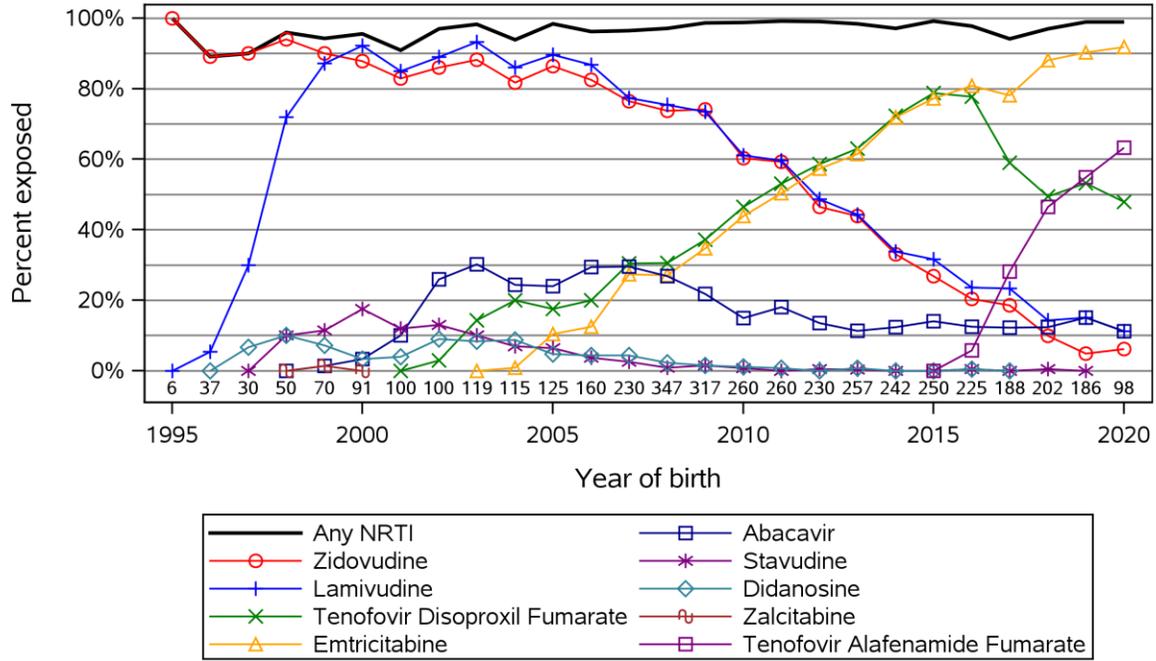
Includes participants who were born at least three months prior to current data download.

Conception time was defined as 14 days after the first date of the last menstrual period.

** Total = Sum of number of participants who received ARVs during pregnancy, at labor and delivery only, never during pregnancy/labor/delivery, and those with unknown ARV use during pregnancy.*

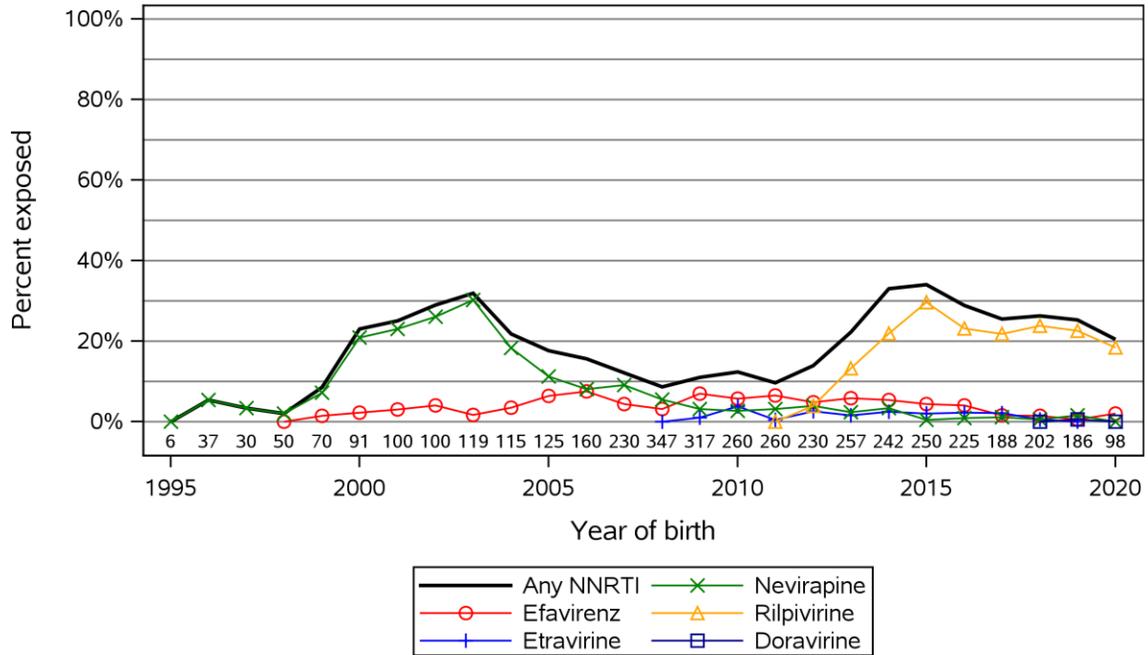
Created by: /home/phacs/actgPH100/monitoring/detlprogs/mat_arv.sas on April 14, 2021

Figure 1: *In Utero* NRTI Exposures by Year of Birth



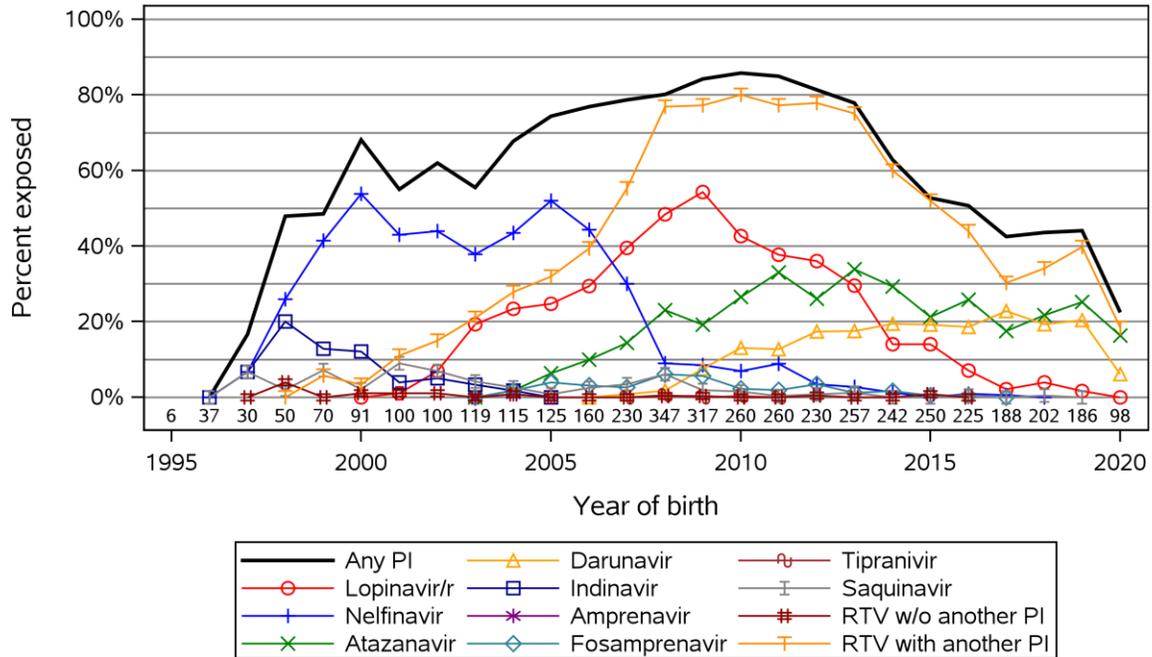
Number above the x-axis represents the number of children with in utero ARV exposure data available

Figure 2: *In Utero* NNRTI Exposures by Year of Birth



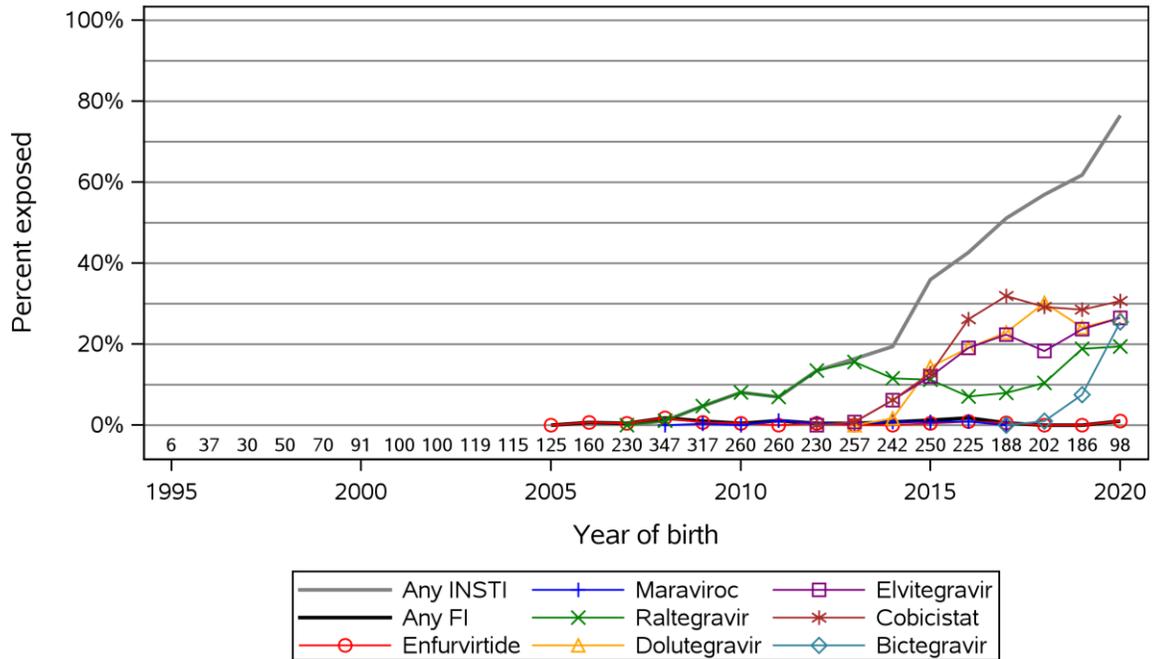
Number above the x-axis represents the number of children with in utero ARV exposure data available

Figure 3: In Utero PI Exposures by Year of Birth



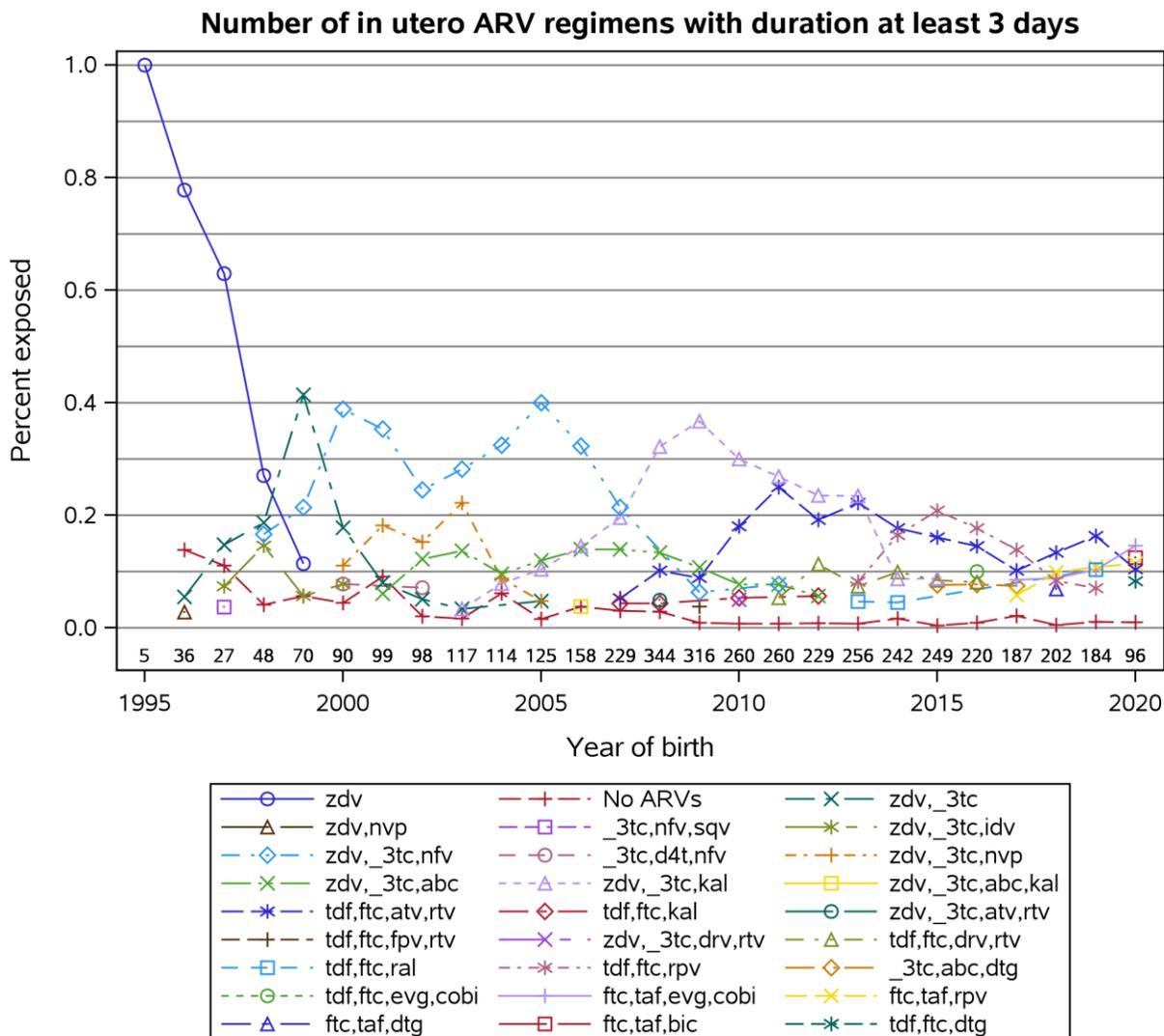
Number above the x-axis represents the number of children with in utero ARV exposure data available

Figure 4: In Utero FI/II Exposures by Year of Birth



Number above the x-axis represents the number of children with in utero ARV exposure data available

Figure 5: Five Most Common *in Utero* ARV Regimens by Year of Birth



Number above the x-axis represents the number of children with detailed timing of in utero ARV exposure available

Figures 1 to 5 were created by: /home/phacs/actgPH100/monitoring/detlprogs/arvfigs.sas