

**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, 2023, 4999 children and 3762 caregivers enrolled in SMARTT ([Table 1](#)). As shown in the table, there were 3520 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](#), 77% 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, 60% and 1% children respectively are still on study as of the last data retrieval date; 795 (23%) dynamic and 288 (23%) static children were withdrawn / lost to follow-up; and 176 (5%) dynamic and 125 (10%) static children were off study because of site closure ([Table 6](#)). A total of 52 children were off study because of death (n=29), fetal demise (n=21) or the death of parent (n=2). Twelve dynamic children have gone off study due to HIV infection. Among dynamic and static children who were still on study, the median ages at the last scheduled clinic visit were 5.5 and 13.6 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](#)). Twelve children missed the entry visit and 114 (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, 36-56% of the dynamic cohort, 30-53% of the static cohort and 16-49% of the reference cohort had elevated risk ('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 76 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 of administration of the WASI, WIAT and BRIEF-PR have changed across the different versions of protocol. They were initially administered at odd ages starting at age 7 years; beginning with version 4, these tests are administered only at age 9. 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 the entry visit, 28% of children (28% 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-Bates 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 for the MacArthur-Bates CDI, TELD and TOLD were mostly within 5 – 10 points of the general population norms; the mean scores for the 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 in the general population.

[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, 962 (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 exposures by birth year for the static and dynamic cohorts combined are summarized in [Table 16](#). Overall, of the 4592 children who completed a scheduled study visit, 4381 (95%) were exposed *in utero* to an ARV; 51 (1%) were exposed to ARV during labor and delivery only; while 42 (1%) were not exposed to any ARV during pregnancy, labor, or delivery. For 38% of the children, their mother received ARVs at conception, although this percentage has increased steadily over time.

[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 1% in 2022); 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 67% in 2022); emtricitabine (FTC) use increased steadily from about 1% in 2004 to above 90% since 2020; in addition, TDF and FTC surpassed ZDV and 3TC in 2012, and then was surpassed by TAF and FTC in 2019 as the most commonly used NRTI agents. 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 since 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 thereafter). 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 20% in 2017, and then decreased to about 8% in 2022. 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 above 90% in 2022 ([Figure 4](#)). 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 increased again since then (about 24% in 2022). Use of elvitegravir (EVG) paired with cobicistat (a non-ARV booster), 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, and decreased to about 17% in 2022.

Dolutegravir (DTG) use was first reported in 2014 at about 2% and increased to more than 45% in 2022. Use of bicitgravir (BIC) in combination with FTC and TAF as Biktarvy emerged in 2018 and increased to about 30% in 2022. Use of the FIs enfurvirtide (ENF) and maraviroc (MVC) have remained low. The most commonly-used regimen has changed over time; ZDV monotherapy was initially 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, 2018 and 2019, and TDF+FTC+RPV from 2015 to 2017, FTC+TAF+EVG/c became the most frequently used regimen in 2020, FTC+TAF+BIC (Biktarvy) was the most commonly-used regimen since 2021 ([Figure 5](#)).

The median duration of follow-up in SMARTT was 142 months among the static and 88 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

Enrollment Year	Caregiver (N=3762)	Dynamic (N=3520)	Static (N=1240)	Reference (N=239)
2007	520 (14%)	130 (4%)	544 (44%)	0 (0%)
2008	581 (15%)	315 (9%)	434 (35%)	0 (0%)
2009	433 (12%)	327 (9%)	262 (21%)	0 (0%)
2010	293 (8%)	267 (8%)	0 (0%)	78 (33%)
2011	297 (8%)	263 (7%)	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 (6%)	0 (0%)	0 (0%)
2019	156 (4%)	204 (6%)	0 (0%)	0 (0%)
2020	60 (2%)	98 (3%)	0 (0%)	0 (0%)
2021	69 (2%)	113 (3%)	0 (0%)	0 (0%)
2022 Q1	20 (1%)	35 (1%)	0 (0%)	0 (0%)
2022 Q2	16 (0%)	24 (1%)	0 (0%)	0 (0%)
2022 Q3	16 (0%)	21 (1%)	0 (0%)	0 (0%)
2022 Q4	12 (0%)	27 (1%)	0 (0%)	0 (0%)
2023 Q1	18 (0%)	24 (1%)	0 (0%)	0 (0%)

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Table 2: SMARTT - Study Enrollment by Site

Enrollment site	Cohort			
	Total (N=4999)	Dynamic (N=3520)	Static (N=1240)	Reference (N=239)
NYU MEDICAL CTR/BELLEVUE	155 (3%)	97 (3%)	58 (5%)	0 (0%)
UNIVERSITY OF ALABAMA AT BIRMINGHAM *	252 (5%)	199 (6%)	29 (2%)	24 (10%)
UNIVERSITY OF SOUTHERN CALIFORNIA	422 (8%)	338 (10%)	84 (7%)	0 (0%)
SAN JUAN RESEARCH HOSPITAL	143 (3%)	82 (2%)	61 (5%)	0 (0%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL *	395 (8%)	327 (9%)	44 (4%)	24 (10%)
SUNY DOWNSTATE MEDICAL CENTER *	300 (6%)	159 (5%)	119 (10%)	22 (9%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	274 (5%)	210 (6%)	64 (5%)	0 (0%)
NEW JERSEY MEDICAL CENTER	131 (3%)	123 (3%)	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) *	168 (3%)	120 (3%)	22 (2%)	26 (11%)
BRONX/LEBANON HOSPITAL CENTER *	495 (10%)	317 (9%)	137 (11%)	41 (17%)
UNIVERSITY OF FLORIDA HEALTH SCIENCE CTR	352 (7%)	254 (7%)	98 (8%)	0 (0%)
UNIVERSITY OF ILLINOIS (CHICAGO) *	246 (5%)	137 (4%)	88 (7%)	21 (9%)
UNIVERSITY OF PUERTO RICO MEDICAL CENTER	253 (5%)	163 (5%)	90 (7%)	0 (0%)
CHILDREN'S HOSPITAL OF PHILADELPHIA	27 (1%)	20 (1%)	7 (1%)	0 (0%)
UNIVERSITY OF MIAMI *	461 (9%)	382 (11%)	40 (3%)	39 (16%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR) *	278 (6%)	172 (5%)	82 (7%)	24 (10%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE) *	140 (3%)	111 (3%)	11 (1%)	18 (8%)
UCSD MEDICAL CENTER	133 (3%)	95 (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	272 (5%)	170 (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%)

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=4999)	Dynamic (N=3520)	Static (N=1240)	Reference (N=239)
Sex	Male	2,544 (51%)	1,782 (51%)	643 (52%)	119 (50%)
	Female	2,374 (47%)	1,657 (47%)	597 (48%)	120 (50%)
	Missing - Form not submitted	81 (2%)	81 (2%)	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**	3,549 (71%)	3,520 (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 (8%)	0 (0%)	362 (29%)	49 (21%)
Race	Asian	25 (1%)	14 (0%)	7 (1%)	4 (2%)
	Native Hawaiian or other Pacific Islander	4 (0%)	3 (0%)	1 (0%)	0 (0%)
	Black or African American	3,307 (66%)	2,372 (67%)	765 (62%)	170 (71%)
	White	1,273 (25%)	864 (25%)	350 (28%)	59 (25%)
	American Indian	7 (0%)	6 (0%)	1 (0%)	0 (0%)
	More than One Race	144 (3%)	121 (3%)	23 (2%)	0 (0%)
	Participant does not want to report	9 (0%)	4 (0%)	4 (0%)	1 (0%)
	Participant does not know	102 (2%)	66 (2%)	32 (3%)	4 (2%)
	Race not available to clinic	128 (3%)	70 (2%)	57 (5%)	1 (0%)
Ethnicity	Hispanic or Latino	1,479 (30%)	993 (28%)	432 (35%)	54 (23%)
	Not Hispanic or Latino	3,501 (70%)	2,512 (71%)	806 (65%)	183 (77%)
	More than one ethnicity	4 (0%)	4 (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	10 (0%)	9 (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	Cohort				
	Total (N=4999)	Dynamic (N=3520)	Static (N=1240)	Reference (N=239)	
Gestational age (weeks) at birth	< 32	113 (2%)	70 (2%)	37 (3%)	6 (3%)
	32 - < 37	754 (15%)	522 (15%)	207 (17%)	25 (10%)
	≥ 37	3,873 (77%)	2,755 (78%)	927 (75%)	191 (80%)
	Unknown	259 (5%)	173 (5%)	69 (6%)	17 (7%)
Weight at birth	> 2500 grams	3,948 (79%)	2,787 (79%)	969 (78%)	192 (80%)
	between 2500 and 1500 grams	729 (15%)	501 (14%)	195 (16%)	33 (14%)
	< 1500 grams	92 (2%)	59 (2%)	30 (2%)	3 (1%)
	Unknown	230 (5%)	173 (5%)	46 (4%)	11 (5%)
Mode of delivery	Spontaneous Vaginal	2,134 (43%)	1,417 (40%)	569 (46%)	148 (62%)
	Assisted vaginal (forceps, vacuum)	81 (2%)	41 (1%)	25 (2%)	15 (6%)
	C-section before labor/membrane rupture	1,898 (38%)	1,412 (40%)	449 (36%)	37 (15%)
	C-section after labor/membrane rupture	638 (13%)	470 (13%)	140 (11%)	28 (12%)
	Unknown	248 (5%)	180 (5%)	57 (5%)	11 (5%)
Apgar score at one minute	< 7	438 (9%)	346 (10%)	92 (7%)	0 (0%)
	≥ 7	3,904 (78%)	2,949 (84%)	955 (77%)	0 (0%)
	Unknown	657 (13%)	225 (6%)	193 (16%)	239 (100%)
Apgar score at minute five	< 7	100 (2%)	83 (2%)	17 (1%)	0 (0%)
	≥ 7	4,247 (85%)	3,216 (91%)	1,031 (83%)	0 (0%)
	Unknown	652 (13%)	221 (6%)	192 (15%)	239 (100%)

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Table 6: SMARTT - Study Status

	Total (N=4999)	Dynamic (N=3520)	Static (N=1240)	Reference (N=239)
Study status Still on study	2,118 (42%)	2,106 (60%)	12 (1%)	0 (0%)
Completed study	1,388 (28%)	359 (10%)	798 (64%)	231 (97%)
Enrollment error / eligibility failure*	15 (0%)	13 (0%)	2 (0%)	0 (0%)
Death of participant/parent/guardian	52 (1%)	49 (1%)	3 (0%)	0 (0%)
Withdrawal / loss to follow-up	1,090 (22%)	795 (23%)	288 (23%)	7 (3%)
Site closure	301 (6%)	176 (5%)	125 (10%)	0 (0%)
Other reason	35 (1%)	22 (1%)	12 (1%)	1 (0%)

* 12 Dynamic children in the Enrollment error/eligibility failure category are HIV-infected
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Table 7: SMARTT - Age at Last Scheduled Clinic Visit Among Participants Still on Study

Characteristic		Cohort		
		Total (N=2118)	Dynamic (N=2106)	Static (N=12)
Age (years) at Last Scheduled Clinical Visit	Median (Min, Max)	5.7 (0.0, 16.2)	5.5 (0.0, 15.3)	13.6 (11.2, 16.2)
	0	160 (8%)	160 (8%)	0 (0%)
	1-2	225 (11%)	225 (11%)	0 (0%)
	3-4	341 (16%)	341 (16%)	0 (0%)
	5-6	374 (18%)	374 (18%)	0 (0%)
	7-12	766 (36%)	764 (36%)	2 (17%)
	13-15	249 (12%)	242 (11%)	7 (58%)
	>15	3 (0%)	0 (0%)	3 (25%)

* 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	Dynamic	Cohort	
			Static	Reference
Visit reported	4850 (97%)	3414 (97%)	1200 (97%)	236 (99%)
Early	27 (1%)	2 (0%)	21 (2%)	4 (2%)
In window	4342 (87%)	3140 (89%)	999 (81%)	203 (85%)
Late	481 (10%)	272 (8%)	180 (15%)	29 (12%)
No visit reported	149 (3%)	106 (3%)	40 (3%)	3 (1%)
Delinquent	8 (0%)	8 (0%)	0 (0%)	0 (0%)
In window	15 (0%)	15 (0%)	0 (0%)	0 (0%)
Missed visit	12 (0%)	12 (0%)	0 (0%)	0 (0%)
Off study*	114 (2%)	71 (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 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=1663)	Dynamic (N=1345)	Static (N=275)	Reference (N=43)
Cognitive	At Risk for Devl Delay/Further Eval Needed	68 (4%)	57 (4%)	11 (4%)	0 (0%)
	Some Risk for Devl Delay	851 (51%)	695 (52%)	135 (49%)	21 (49%)
	Low Risk for Devl Delay	744 (45%)	593 (44%)	129 (47%)	22 (51%)
Receptive Communication	At Risk for Devl Delay/Further Eval Needed	59 (4%)	48 (4%)	11 (4%)	0 (0%)
	Some Risk for Devl Delay	626 (38%)	515 (38%)	97 (35%)	14 (33%)
	Low Risk for Devl Delay	975 (59%)	779 (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	76 (5%)	67 (5%)	9 (3%)	0 (0%)
	Some Risk for Devl Delay	700 (42%)	582 (43%)	108 (39%)	10 (23%)
	Low Risk for Devl Delay	882 (53%)	691 (51%)	158 (57%)	33 (77%)
	Not Done	5 (0%)	5 (0%)	0 (0%)	0 (0%)
Fine Motor	At Risk for Devl Delay/Further Eval Needed	44 (3%)	36 (3%)	8 (3%)	0 (0%)
	Some Risk for Devl Delay	659 (40%)	556 (41%)	91 (33%)	12 (28%)
	Low Risk for Devl Delay	956 (57%)	749 (56%)	176 (64%)	31 (72%)
	Not Done	4 (0%)	4 (0%)	0 (0%)	0 (0%)
Gross Motor	At Risk for Devl Delay/Further Eval Needed	41 (2%)	35 (3%)	6 (2%)	0 (0%)
	Some Risk for Devl Delay	527 (32%)	442 (33%)	78 (28%)	7 (16%)
	Low Risk for Devl Delay	1,088 (65%)	861 (64%)	191 (69%)	36 (84%)
	Not Done	7 (0%)	7 (1%)	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	1805	102.5 (14.1)	146	102.9 (15.2)	49	102.2 (14.0)
	Language, Composite	1803	94.7 (13.6)	145	93.2 (14.7)	49	95.1 (12.5)
	Motor, Composite	1794	97.1 (12.7)	145	96.9 (15.9)	49	100.9 (14.7)
	Social-Emotional, Composite	1759	101.7 (17.7)	142	101.6 (18.5)	49	100.5 (16.4)
	General Adaptive, Composite	1755	94.6 (14.2)	142	93.4 (15.0)	49	92.3 (11.3)
WPPSI (5 years old)	Full Scale IQ	1036	94.0 (15.6)	445	94.6 (14.5)	47	93.6 (15.6)
	Performance IQ	1059	96.3 (16.2)	447	97.3 (15.2)	47	95.6 (15.3)
	Verbal IQ	1054	92.3 (14.4)	447	92.1 (12.9)	47	91.6 (13.9)
	Processing Speed IQ	1012	94.7 (15.6)	442	96.3 (15.9)	47	95.0 (15.4)
	General Language IQ	648	92.5 (13.7)	210	91.0 (14.1)	19	91.1 (11.4)
WASI (7+ odd years old)*	Full Scale IQ	413	100.8 (15.5)	781	97.9 (14.0)	48	100.8 (12.6)
	Performance IQ	413	96.6 (13.5)	781	95.2 (13.1)	49	95.3 (13.0)
	Verbal IQ	413	104.8 (18.6)	781	101.0 (16.0)	48	105.8 (14.2)
WIAT (7+ odd years old)*	Word Reading, Standard Score	408	98.0 (17.3)	779	97.3 (16.1)	49	97.1 (15.0)
	Spelling, Standard Score	407	96.8 (18.7)	776	97.8 (16.5)	48	98.8 (15.8)
	Numerical Operations, Standard Score	407	92.9 (17.4)	779	94.0 (16.6)	49	94.5 (15.5)
BRIEF Parent-Report (7+ odd years old)*	Behavioral Regulation Index, T-Score	498	51.4 (11.7)	731	53.6 (12.2)	46	53.3 (12.2)
	Metacognition Index, T-Score	497	51.2 (12.0)	730	52.8 (11.8)	46	52.6 (11.8)
	Global Executive Composite, T-Score	497	51.4 (12.0)	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=4822)	Dynamic (N=3391)	Static (N=1195)	Reference (N=236)
Concerns about hearing?	Yes	143 (3%)	57 (2%)	77 (6%)	9 (4%)
	No	4,610 (96%)	3,273 (97%)	1,111 (93%)	226 (96%)
	Unknown	69 (1%)	61 (2%)	7 (1%)	1 (0%)
Child has repeated ear infections?	Yes	124 (3%)	0 (0%)	102 (9%)	22 (9%)
	No	4,629 (96%)	3,330 (98%)	1,086 (91%)	213 (90%)
	Unknown	69 (1%)	61 (2%)	7 (1%)	1 (0%)
Child failed hearing screening?	Yes	165 (3%)	89 (3%)	65 (5%)	11 (5%)
	No	4,588 (95%)	3,241 (96%)	1,123 (94%)	224 (95%)
	Unknown	69 (1%)	61 (2%)	7 (1%)	1 (0%)
Child tested by audiologist?	Yes	1,362 (28%)	963 (28%)	349 (29%)	50 (21%)
	No	3,391 (70%)	2,367 (70%)	839 (70%)	185 (78%)
	Unknown	69 (1%)	61 (2%)	7 (1%)	1 (0%)
Perm hearing loss in 1-2 ears?	Yes	9 (0%)	2 (0%)	7 (1%)	0 (0%)
	No	1,352 (28%)	960 (28%)	342 (29%)	50 (21%)
	Test not done	3,391 (70%)	2,367 (70%)	839 (70%)	185 (78%)
	Unknown	70 (1%)	62 (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	2033	56.7 (27.6)	169	50.4 (27.8)	47	52.6 (27.8)
	Vocabulary Comprehension	2033	47.5 (30.0)	169	43.6 (29.7)	47	44.7 (31.1)
	Words Production	2033	48.9 (22.1)	169	45.0 (21.2)	47	56.3 (20.0)
	A-E Total Gestures	2034	49.4 (28.5)	169	40.6 (28.8)	47	55.9 (30.9)
ASQ (2 years old)	Total Score	1966	43.9 (15.7)	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	938	91.9 (15.0)	424	90.1 (14.1)	45	87.9 (14.3)
	Listening	940	97.3 (14.9)	424	94.6 (13.6)	45	92.0 (13.4)
	Speaking	939	92.1 (15.3)	424	91.6 (13.9)	45	90.2 (13.6)
	Syntax	938	89.2 (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	3351	-0.10	1.04	1191	0.31	1.13	235	0.34	1.15
Weight Z-score	3357	-0.55	0.88	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=3313)	First (N=3313)	Second (N=3313)	Third (N=3313)
Any Substance Use	Yes	962 (29%)	831 (25%)	544 (16%)	500 (15%)
	No	2,349 (71%)	2,480 (75%)	2,767 (84%)	2,811 (85%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Tobacco	Yes	565 (17%)	530 (16%)	353 (11%)	303 (9%)
	No	2,746 (83%)	2,768 (84%)	2,945 (89%)	2,995 (90%)
	Unknown	2 (0%)	15 (0%)	15 (0%)	15 (0%)
Alcohol	Yes	292 (9%)	262 (8%)	78 (2%)	55 (2%)
	No	3,019 (91%)	3,047 (92%)	3,231 (98%)	3,254 (98%)
	Unknown	2 (0%)	4 (0%)	4 (0%)	4 (0%)
Marijuana	Yes	312 (9%)	276 (8%)	146 (4%)	110 (3%)
	No	2,999 (91%)	3,031 (91%)	3,161 (95%)	3,197 (96%)
	Unknown	2 (0%)	6 (0%)	6 (0%)	6 (0%)
Cocaine	Yes	71 (2%)	59 (2%)	38 (1%)	28 (1%)
	No	3,240 (98%)	3,252 (98%)	3,273 (99%)	3,283 (99%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Antidepressants	Yes	144 (4%)	95 (3%)	78 (2%)	83 (3%)
	No	3,165 (96%)	3,213 (97%)	3,230 (97%)	3,225 (97%)
	Unknown	4 (0%)	5 (0%)	5 (0%)	5 (0%)
Pain Medications	Yes	138 (4%)	59 (2%)	68 (2%)	65 (2%)
	No	3,171 (96%)	3,250 (98%)	3,241 (98%)	3,244 (98%)
	Unknown	4 (0%)	4 (0%)	4 (0%)	4 (0%)
Methadone	Yes	21 (1%)	18 (1%)	20 (1%)	21 (1%)
	No	3,287 (99%)	3,292 (99%)	3,290 (99%)	3,289 (99%)
	Unknown	5 (0%)	3 (0%)	3 (0%)	3 (0%)
Heroin	Yes	15 (0%)	12 (0%)	7 (0%)	6 (0%)
	No	3,295 (99%)	3,298 (100%)	3,303 (100%)	3,304 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
Sedative	Yes	16 (0%)	10 (0%)	8 (0%)	7 (0%)
	No	3,294 (99%)	3,300 (100%)	3,302 (100%)	3,303 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
Methamphetamines	Yes	21 (1%)	18 (1%)	8 (0%)	5 (0%)
	No	3,290 (99%)	3,293 (99%)	3,303 (100%)	3,306 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Ecstasy	Yes	3 (0%)	3 (0%)	0 (0%)	0 (0%)
	No	3,308 (100%)	3,308 (100%)	3,311 (100%)	3,311 (100%)

		Trimester			
		Any Trimester (N=3313)	First (N=3313)	Second (N=3313)	Third (N=3313)
PCP	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	3 (0%)	3 (0%)	1 (0%)	1 (0%)
	No	3,307 (100%)	3,307 (100%)	3,309 (100%)	3,309 (100%)
Opium	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
	Yes	5 (0%)	2 (0%)	3 (0%)	2 (0%)
	No	3,306 (100%)	3,309 (100%)	3,308 (100%)	3,309 (100%)
Other Drug	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	17 (1%)	11 (0%)	8 (0%)	7 (0%)
	No	3,293 (99%)	3,299 (100%)	3,302 (100%)	3,303 (100%)
Stimulants	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
	Yes	7 (0%)	5 (0%)	0 (0%)	0 (0%)
	No	3,304 (100%)	3,306 (100%)	3,311 (100%)	3,311 (100%)
Barbiturates	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,310 (100%)	3,310 (100%)	3,311 (100%)	3,311 (100%)
Amphetamines	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	3 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,308 (100%)	3,310 (100%)	3,311 (100%)	3,311 (100%)
Inhalants	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	1 (0%)	1 (0%)	1 (0%)	0 (0%)
	No	3,310 (100%)	3,310 (100%)	3,310 (100%)	3,311 (100%)
LSD	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
	Yes	2 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,306 (100%)	3,309 (100%)	3,310 (100%)	3,310 (100%)
Other Hallucinogens	Unknown	5 (0%)	3 (0%)	3 (0%)	3 (0%)
	Yes	2 (0%)	2 (0%)	1 (0%)	0 (0%)
	No	3,306 (100%)	3,307 (100%)	3,308 (100%)	3,309 (100%)
Ketamine	Unknown	5 (0%)	4 (0%)	4 (0%)	4 (0%)
	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,310 (100%)	3,310 (100%)	3,311 (100%)	3,311 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (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	106 (52%)	202 (99%)	1 (0%)	1 (0%)	1 (0%)	205
2019	105 (54%)	186 (95%)	2 (1%)	3 (2%)	5 (3%)	196
2020	57 (50%)	104 (92%)	1 (1%)	0 (0%)	8 (7%)	113
2021	50 (47%)	89 (83%)	0 (0%)	1 (1%)	17 (16%)	107
2022	44 (47%)	75 (81%)	0 (0%)	1 (1%)	17 (18%)	93
Total	1748 (38%)	4381 (95%)	51 (1%)	42 (1%)	118 (3%)	4592

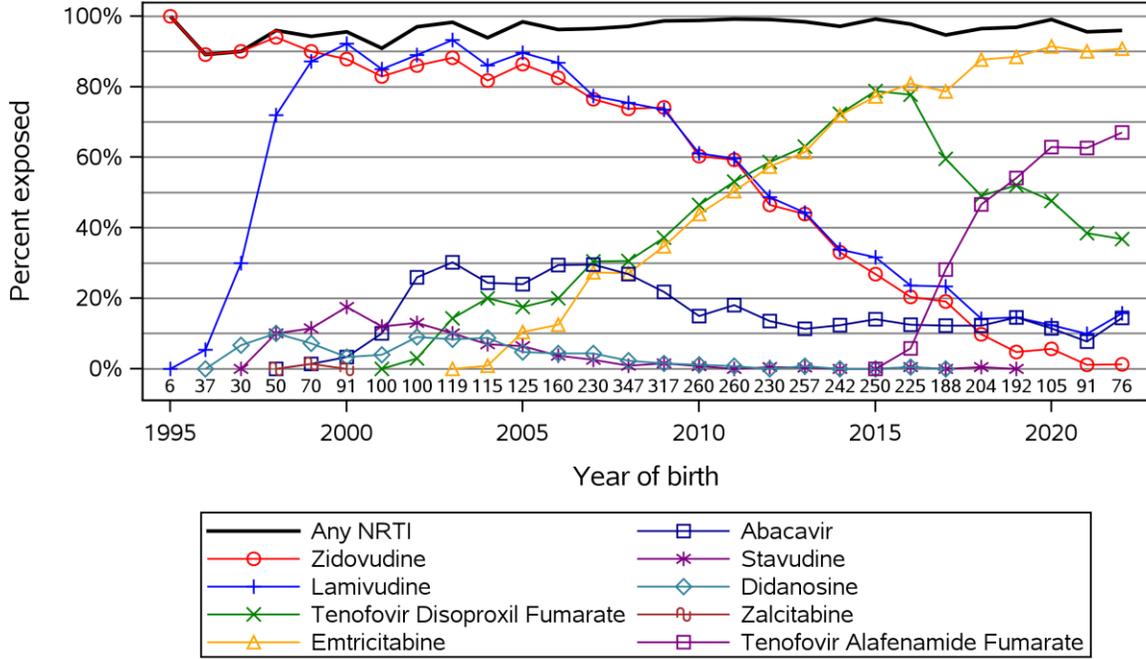
Includes participants who were born at least three months prior to current data download.

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.*

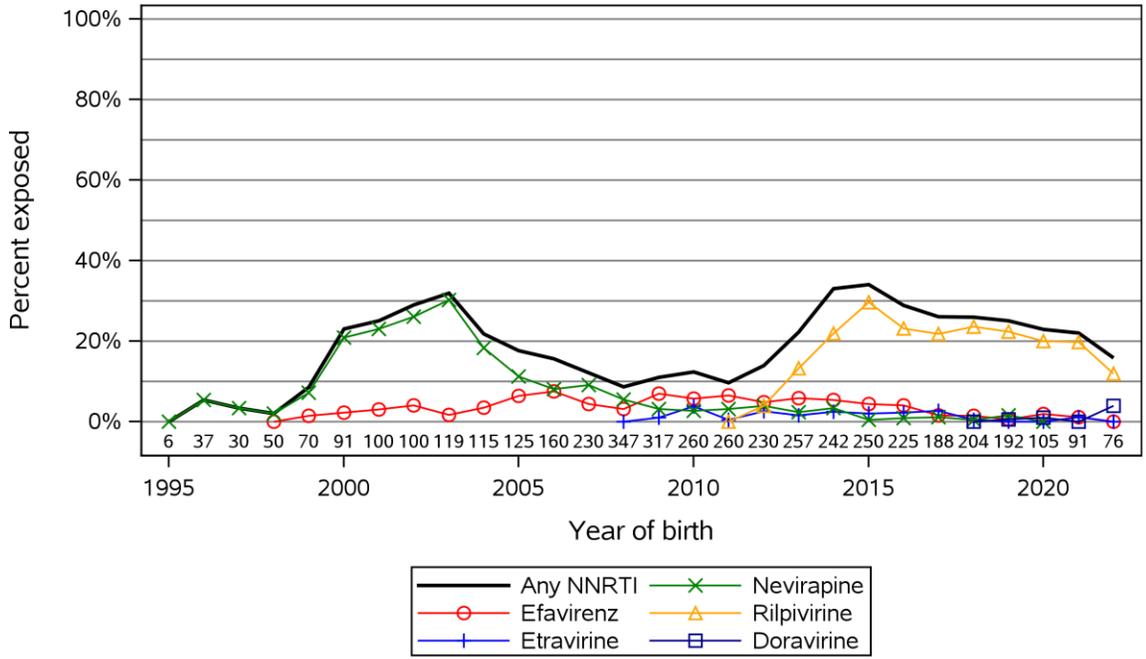
Created by: /home/phacs/actgPH100/monitoring/detlprogs/mat_arv.sas on April 5, 2023

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



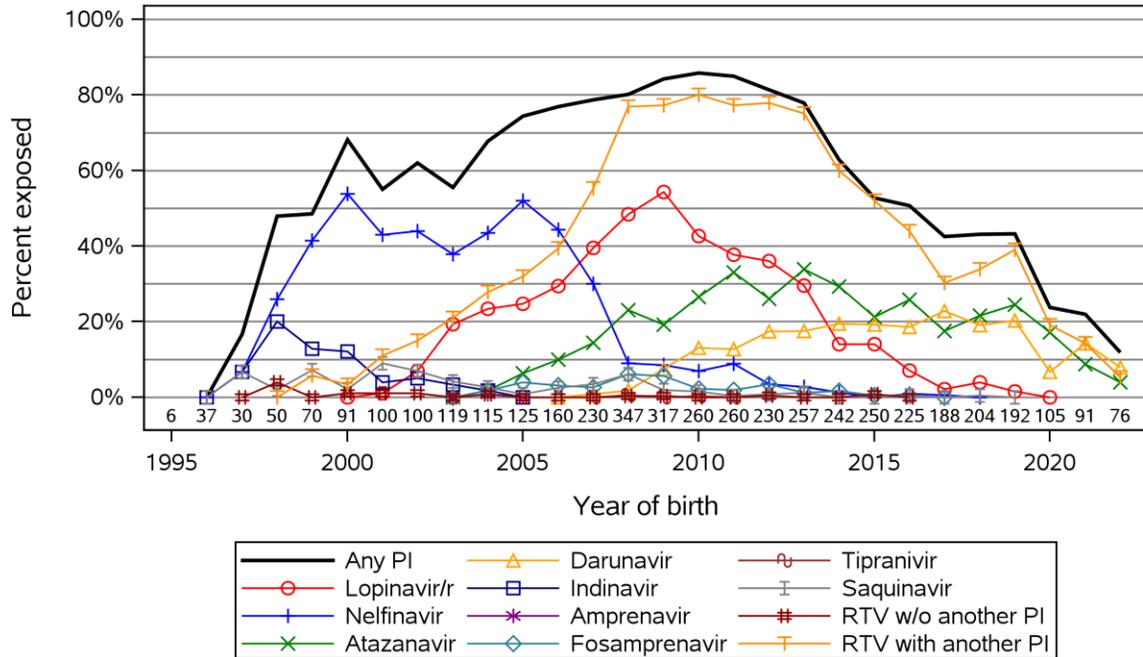
Number above the x-axis represents the number of children with in utero ARV exposure data available

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



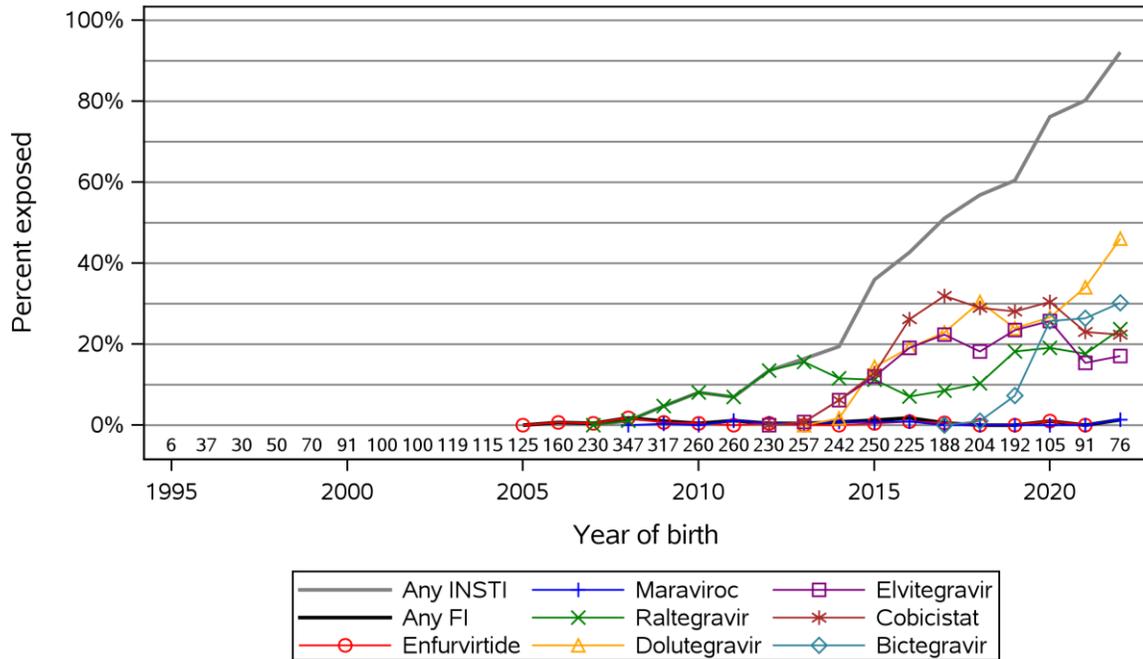
Number above the x-axis represents the number of children with in utero ARV exposure data available

Figure 3: *In Utero* PI Exposures by Year of Birth



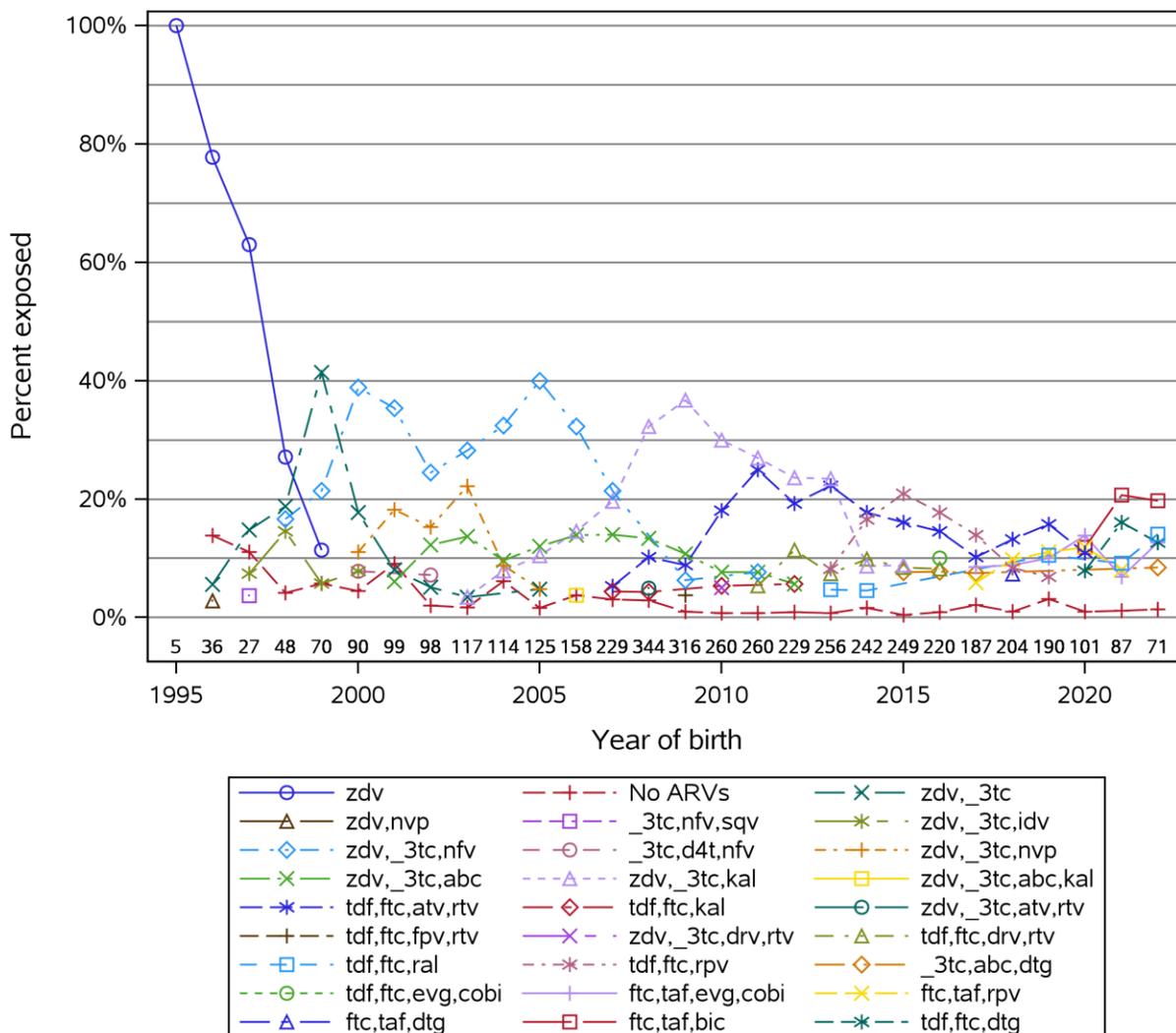
Number above the x-axis represents the number of children with in utero ARV exposure data available

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
 Above figure represents the top 5 in utero ARV regimens with longest cumulative duration

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