

**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, 2024, 5106 children and 3844 caregivers enrolled in SMARTT ([Table 1](#)). As shown in the table, there were 3627 children in the dynamic cohort and 1240 in the static cohort. For the static cohort, the enrollment was closed on July 31, 2009; the last completed in-person follow-up visit on Nov. 15, 2021, and the follow-up data collection was closed in May 2023. 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-old children. 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.

The dynamic children enrolled and followed in SMARTT V6 includes two cohorts, the intensive and extended cohort, The intensive cohort includes all currently and newly enrolled dynamic children ≤ 5 years of age who will be followed through the age 5 year visit, The extended cohort included all children meeting criteria for cases in specific domains of interest (growth, metabolic, neurologic, neurodevelopmental, and language) by the age 5 visit, either previously during SMARTT V5 or during follow-up in V6, as well as a random sample of approximately 1000 dynamic children enrolled in V5 (some of whom may also be cases). In addition, siblings over age 5 of those selected for the Extended Cohort (and also over age 5) who wish to remain on study may be approved for inclusion in the Extended Cohort through the QNS query system. This cohort will be followed through 17 years of age.

The overall enrollment by site is summarized in [Table 2](#). The numbers of dynamic children expected to continue in SMARTT V6 at each site are shown in [Table 3](#). There were 38 new enrollees under V6 and 1243 children selected for Extended cohort are expected to continue on study in V6; in addition, 432 children who were enrolled under V5 and were not selected for Extended cohort and were ≤ 5 years of age at the time of this data retrieval are also expected to continue on study in V6. The submission and completion of select CRFs in V6 are summarized in [Table 4](#).

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 5](#)). Approximately half of the children enrolled were male ([Table 6](#)). 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 7](#), 78% of all infants enrolled were reported to be born full-term (≥ 37 weeks gestation) and the majority weighed more than 2500 g (80%), although the prematurity status was unknown for 220 (4%). 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 dynamic cohort, 52% are still on study as of the time of this data retrieval; 905 (25%) 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 8](#)). Twelve dynamic children have gone off study due to HIV infection. Among dynamic children who were still on study, the median ages at the last scheduled clinic visit were 7.1 years ([Table 9](#)). Of the dynamic children, 97% completed the entry visit and 89% of visits were done on time or early; 11 children missed the entry visit and 77 (2%) dropped out of the study before any study visit ([Table 10](#)).

As shown in [Table 11](#), there were 126 maternal deaths, 22 fetal losses and 29 child deaths (20 of 29 died before 2 years of age). The percent of deaths or fetal losses which occurred among African Americans (67%) was similar to their overall representation in the SMARTT study (66%, see Table 6). Similarly, the percent of deaths which occurred among those reporting Hispanic ethnicity (27%) was similar to their representation in the overall study (30%, see Table 6). Thirteen percent of the maternal deaths were due to HIV infection or HIV-related diagnosis; the causes of death were unknown for 68% of the maternal deaths.

Tables 12-16 contain some initial summaries of key measures across domains of interest for SMARTT, including cognitive assessments (Tables 12-13), hearing and language assessments (Tables 14-15), and growth data (Table 16).

[Table 12](#) summarizes the results of the Bayley scales of infant and toddler development - screening test (Bayley Screen, discontinued in SMARTT V6) 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 79 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 13](#), including the Full Bayley-III (1-year-old), Wechsler Preschool And Primary Scale Of Intelligence - III (WPPSI-III, 5-year-old), Wechsler Abbreviated Scale of Intelligence (WASI), Wechsler Individual Achievement Test - Second Edition (WIAT-II) - Abbreviated and Behavior Rating Inventory of Executive Function - Parent Report (BRIEF-PR), and newly added assessments in SMARTT V6 including Child Behavior Checklist – Parent Report (CBCL-PR) and CBCL-SR (Self-Report); the BRIEF-II-PR was used in V6 to replace BRIEF-PR in V5. Ages of

administration of the WASI, WIAT-II and BRIEF-PR have changed across the different versions of protocol. The normative scores for the Bayley-III, WPPSI-III, WASI and WIAT-II 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 and CBCL 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 14](#). Among participants who submitted a demographic form at the entry visit, 29% of children (29% of dynamic cohort, 29% of static cohort and 21% of reference cohort) had an audiologic exam before enrolling in the study, of whom 10 (3 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 15](#), including the MacArthur-Bates Communicative Development Inventory: Words And Gestures (CDI, 1-year-old), Ages and Stages Questionnaire (ASQ: 2-year-old), Test of Early Language Development – Third Edition (TELD-3, 3-year-old), Test Of Language Development - Primary Third Edition (TOLD-P3, 5-year-old), Clinical Evaluation of Language Fundamentals - Fourth Edition (CELF-4, 9-year-old) in SMARTT V5, and CELF-4-II (5- and 9-year-old) in SMARTT V6. The normative scores are 50th percentile for the CDI, and 100 (standard deviation: 15) for TELD, TOLD and CELF. 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 except for the CELF-4-II, for which the mean sum core and expressive language scores were both > 1 SD below the normative score; the mean scores for the ASQ were 44 for dynamic and 45 for static children.

The growth measurements in [Table 16](#) suggest that infants enrolled in the dynamic cohort were below average length and weight at birth/entry visit, 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 17](#) and [Table 18](#) 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, 978 (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. In both cohorts, 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). Substance use during pregnancy is assessed via online survey in SMARTT V6, and these data have not yet been incorporated into the summaries noted above.

In utero ARV exposures by birth year are presented in [Table 19](#) for the dynamic and in [Table 20](#) for the static cohort. Of the 3521 dynamic children who completed a scheduled study visit, 3422 (97%) were exposed *in utero* to an ARV; 29 (1%) were exposed to ARV during labor and delivery only; while 20 (1%) were not exposed to any ARV during pregnancy, labor, or delivery. For 43% of the dynamic children, their mother received ARVs at the time of 14 days after the last menstrual period, and this percentage has increased steadily over time. Of the 1199 static children, 1119 (93%) were exposed *in utero* to an ARV; 28 (2%) were exposed to ARV during labor and delivery only; while 25 (2%) were not exposed to any ARV during pregnancy, labor, or delivery. For only 28% of the static children, their mother received ARVs at the time of 14 days after the last menstrual period.

[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 2023); 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, and then started increasing again in 2022; 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 73% in 2023); emtricitabine (FTC) use increased steadily from about 1% in 2004 to above 90% in 2020 and 2021, and then showed a decreasing trend since 2021; 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 1% in 2023. 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 almost 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 to about 20% in 2022 and then decreased to less than 5% in 2023. 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 about 25% in 2020, and decreased to about 11% in 2023. Dolutegravir (DTG) use was first reported in 2014 at about 2% and increased to more than 45% in 2022. Use of bictegravir (BIC) in combination with FTC and TAF as Biktarvy emerged in 2018 and increased to more than 35% in 2023. 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 follow-up duration in SMARTT was 11.8 years among the static and 7.6 years 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=3844)	Dynamic (N=3627)	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 (11%)	327 (9%)	262 (21%)	0 (0%)
2010	293 (8%)	267 (7%)	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 (7%)	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	64 (2%)	107 (3%)	0 (0%)	0 (0%)
2023 Q1	18 (0%)	24 (1%)	0 (0%)	0 (0%)
2023 Q2	34 (1%)	45 (1%)	0 (0%)	0 (0%)
2023 Q3	13 (0%)	19 (1%)	0 (0%)	0 (0%)
2023 Q4	18 (0%)	24 (1%)	0 (0%)	0 (0%)
2024 Q1	17 (0%)	19 (1%)	0 (0%)	0 (0%)

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Table 2: SMARTT - Study Enrollment by Site

Enrollment site	Cohort			
	Total (N=5106)	Dynamic (N=3627)	Static (N=1240)	Reference (N=239)
NYU MEDICAL CTR/BELLEVUE	158 (3%)	100 (3%)	58 (5%)	0 (0%)
UNIVERSITY OF ALABAMA AT BIRMINGHAM	263 (5%)	210 (6%)	29 (2%)	24 (10%)
UNIVERSITY OF SOUTHERN CALIFORNIA	431 (8%)	347 (10%)	84 (7%)	0 (0%)
SAN JUAN RESEARCH HOSPITAL	143 (3%)	82 (2%)	61 (5%)	0 (0%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	400 (8%)	332 (9%)	44 (4%)	24 (10%)
SUNY DOWNSTATE MEDICAL CENTER	307 (6%)	166 (5%)	119 (10%)	22 (9%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	282 (6%)	218 (6%)	64 (5%)	0 (0%)
NEW JERSEY MEDICAL CENTER	142 (3%)	134 (4%)	8 (1%)	0 (0%)
SUNY STONY BROOK MEDICAL CENTER *	25 (0%)	8 (0%)	17 (1%)	0 (0%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	175 (3%)	127 (4%)	22 (2%)	26 (11%)
BRONX/LEBANON HOSPITAL CENTER	499 (10%)	321 (9%)	137 (11%)	41 (17%)
UNIVERSITY OF FLORIDA HEALTH SCIENCE CTR	362 (7%)	264 (7%)	98 (8%)	0 (0%)
UNIVERSITY OF ILLINOIS (CHICAGO) *	246 (5%)	137 (4%)	88 (7%)	21 (9%)
UNIVERSITY OF PUERTO RICO MEDICAL CENTER	260 (5%)	170 (5%)	90 (7%)	0 (0%)
CHILDREN'S HOSPITAL OF PHILADELPHIA *	27 (1%)	20 (1%)	7 (1%)	0 (0%)
UNIVERSITY OF MIAMI	465 (9%)	386 (11%)	40 (3%)	39 (16%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	281 (6%)	175 (5%)	82 (7%)	24 (10%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	142 (3%)	113 (3%)	11 (1%)	18 (8%)
UCSD MEDICAL CENTER	137 (3%)	99 (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	284 (6%)	182 (5%)	102 (8%)	0 (0%)

Sites with * were discontinued in V6

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Table 3: SMARTT - Number of Dynamic Children Expected to Continue in SMARTT V6 by Site

Site	Total (n=1713)	Newly Enrolled in V6 (n=38)	Not-selected for Extended Cohort and ≤ 5 Years of Age (n=432)	Extended Cohort (N=1243)			
				Randomly Selected, Not a Case (n=635)	Randomly Selected and also a Case (n=210)	Case, Not Randomly Selected (n=314)	Not-randomly Selected Siblings (n=84)
NYU MEDICAL CTR/BELLEVUE	53 (3%)	3 (8%)	7 (2%)	12 (2%)	8 (4%)	19 (6%)	4 (5%)
UNIVERSITY OF ALABAMA AT BIRMINGHAM	132 (8%)	1 (3%)	34 (8%)	55 (9%)	11 (5%)	29 (9%)	2 (2%)
UNIVERSITY OF SOUTHERN CALIFORNIA	165 (10%)	3 (8%)	29 (7%)	72 (11%)	21 (10%)	25 (8%)	15 (18%)
SAN JUAN RESEARCH HOSPITAL	27 (2%)	0 (0%)	5 (1%)	16 (3%)	3 (1%)	3 (1%)	0 (0%)
ST. JUDE CHILDREN'S RESEARCH HOSPITAL	238 (14%)	0 (0%)	57 (13%)	91 (14%)	25 (12%)	42 (13%)	23 (27%)
SUNY DOWNSTATE MEDICAL CENTER	94 (5%)	4 (11%)	17 (4%)	25 (4%)	13 (6%)	29 (9%)	6 (7%)
UNIV OF COLORADO HEALTH SCIENCES CENTER	128 (7%)	3 (8%)	36 (8%)	40 (6%)	18 (9%)	31 (10%)	0 (0%)
NEW JERSEY MEDICAL CENTER	48 (3%)	0 (0%)	17 (4%)	22 (3%)	5 (2%)	4 (1%)	0 (0%)
CHILDREN'S DIAG AND TREAT CTR (S FLOR)	34 (2%)	2 (5%)	9 (2%)	11 (2%)	2 (1%)	10 (3%)	0 (0%)
BRONX/LEBANON HOSPITAL CENTER	181 (11%)	3 (8%)	27 (6%)	66 (10%)	36 (17%)	44 (14%)	5 (6%)
UNIVERSITY OF FLORIDA HEALTH SCIENCE CTR	121 (7%)	6 (16%)	33 (8%)	47 (7%)	10 (5%)	17 (5%)	8 (10%)
UNIVERSITY OF PUERTO RICO MEDICAL CENTER	90 (5%)	3 (8%)	29 (7%)	27 (4%)	12 (6%)	11 (4%)	8 (10%)
UNIVERSITY OF MIAMI	154 (9%)	2 (5%)	52 (12%)	57 (9%)	22 (10%)	12 (4%)	9 (11%)
TEXAS CHILDREN'S HOSPITAL (BAYLOR)	62 (4%)	3 (8%)	15 (3%)	26 (4%)	5 (2%)	13 (4%)	0 (0%)
UNIVERSITY HEALTH SCIENCE CTR (TULANE)	47 (3%)	0 (0%)	15 (3%)	19 (3%)	5 (2%)	6 (2%)	2 (2%)
UCSD MEDICAL CENTER	56 (3%)	0 (0%)	18 (4%)	30 (5%)	2 (1%)	6 (2%)	0 (0%)
CHILDREN'S MEMORIAL HOSPITAL OF CHICAGO	83 (5%)	5 (13%)	32 (7%)	19 (3%)	12 (6%)	13 (4%)	2 (2%)

Expected number included 1) Newly enrolled in V6; 2) enrolled in V5 and selected for Extended cohort in V6 and still on study at the time preparing the monitoring report; 3) enrolled in V5 and not selected for Extended cohort and ≤ 5 years of age and still on study at the time preparing the monitoring report.

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Table 4: SMARTT - Submission and completion of select forms in SMARTT V6

Form	Form Description	Submitted¹	Completed²
Assessment for child			
NE4182	Child behavior checklist-parent report (CBCL-PR) for age 1.5 - 5 years	32	29
NE7123	Child behavior checklist-parent report (CBCL-PR) for age 6 - 18 years	85	77
NE7124	Child behavior checklist-self report (CBCL-SR) for age >= 11 years	49	37
NE7127	Pediatric adverse childhood experiences and related life events screener (PEARLS)-parent report	13	13
NE7128	Pediatric adverse childhood experiences and related life events screener (PEARLS)-self report	13	13
NE4183	Child and youth resilience measure-revised (CYRM-R)	35	34
QLW0334	Patient health questionnaire (PHQ-9)	35	34
QLW0368	Life events checklist	33	32
Child online survey tracking form			
TRK0209	Sexual behavior and drug use survey	50	49
Maternal online survey tracking form			
TRK0208	Maternal licit and illicit drug, tobacco, and alcohol use survey	35	29
TRK0210	Internalized HIV stigma assessment	50	42
TRK0211	Maternal and caregiver stress and discrimination survey	183	167
TRK0212	COVID-19 impact survey	54	41

¹ The submitted count includes all forms submitted regardless of the visit and keying windows.

² The completed count includes all forms submitted and indicated as completed.

Above table presents the number of unique participants.

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Table 5: 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%)

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Table 6: SMARTT - Enrollment Demographics

		Total (N=5106)	Dynamic (N=3627)	Static (N=1240)	Reference (N=239)
Sex	Male	2,600 (51%)	1,838 (51%)	643 (52%)	119 (50%)
	Female	2,426 (48%)	1,709 (47%)	597 (48%)	120 (50%)
	Missing - Form not submitted	80 (2%)	80 (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**	3,656 (72%)	3,627 (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 (5%)	0 (0%)	206 (17%)	71 (30%)
	7-12	411 (8%)	0 (0%)	362 (29%)	49 (21%)
Race	Asian	25 (0%)	14 (0%)	7 (1%)	4 (2%)
	Native Hawaiian or other Pacific Islander	4 (0%)	3 (0%)	1 (0%)	0 (0%)
	Black or African American	3,377 (66%)	2,442 (67%)	765 (62%)	170 (71%)
	White	1,303 (26%)	894 (25%)	350 (28%)	59 (25%)
	American Indian	7 (0%)	6 (0%)	1 (0%)	0 (0%)
	More than One Race	146 (3%)	123 (3%)	23 (2%)	0 (0%)
	Participant does not want to report	11 (0%)	6 (0%)	4 (0%)	1 (0%)
	Participant does not know	105 (2%)	69 (2%)	32 (3%)	4 (2%)
	Race not available to clinic	128 (3%)	70 (2%)	57 (5%)	1 (0%)
Ethnicity	Hispanic or Latino	1,511 (30%)	1,025 (28%)	432 (35%)	54 (23%)
	Not Hispanic or Latino	3,574 (70%)	2,585 (71%)	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	13 (0%)	12 (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 7: SMARTT - Baseline Maternal Pregnancy and Delivery History Characteristics

Characteristic	Total (N=5106)	Dynamic (N=3627)	Cohort		
			Static (N=1240)	Reference (N=239)	
Gestational age (weeks) at birth	< 32	116 (2%)	73 (2%)	37 (3%)	6 (3%)
	32 - < 37	774 (15%)	542 (15%)	207 (17%)	25 (10%)
	≥ 37	3,996 (78%)	2,878 (79%)	927 (75%)	191 (80%)
	Unknown	220 (4%)	134 (4%)	69 (6%)	17 (7%)
Weight at birth	> 2500 grams	4,071 (80%)	2,910 (80%)	969 (78%)	192 (80%)
	between 2500 and 1500 grams	748 (15%)	520 (14%)	195 (16%)	33 (14%)
	< 1500 grams	96 (2%)	63 (2%)	30 (2%)	3 (1%)
	Unknown	191 (4%)	134 (4%)	46 (4%)	11 (5%)
Mode of delivery	Spontaneous Vaginal	2,210 (43%)	1,493 (41%)	569 (46%)	148 (62%)
	Assisted vaginal (forceps, vacuum)	82 (2%)	42 (1%)	25 (2%)	15 (6%)
	C-section before labor/membrane rupture	1,950 (38%)	1,464 (40%)	449 (36%)	37 (15%)
	C-section after labor/membrane rupture	652 (13%)	484 (13%)	140 (11%)	28 (12%)
	Unknown	212 (4%)	144 (4%)	57 (5%)	11 (5%)
Apgar score at one minute	< 7	452 (9%)	360 (10%)	92 (7%)	0 (0%)
	≥ 7	4,025 (79%)	3,070 (85%)	955 (77%)	0 (0%)
	Unknown	629 (12%)	197 (5%)	193 (16%)	239 (100%)
Apgar score at minute five	< 7	103 (2%)	86 (2%)	17 (1%)	0 (0%)
	≥ 7	4,380 (86%)	3,349 (92%)	1,031 (83%)	0 (0%)
	Unknown	623 (12%)	192 (5%)	192 (15%)	239 (100%)

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Table 8: SMARTT - Study Status

	Total (N=5106)	Dynamic (N=3627)	Static (N=1240)	Reference (N=239)
Study status Still on study	1,869 (37%)	1,869 (52%)	0 (0%)	0 (0%)
Completed study	1,627 (32%)	586 (16%)	810 (65%)	231 (97%)
Enrollment error / eligibility failure*	17 (0%)	15 (0%)	2 (0%)	0 (0%)
Death of participant/parent/guardian	55 (1%)	52 (1%)	3 (0%)	0 (0%)
Withdrawal / loss to follow-up	1,200 (24%)	905 (25%)	288 (23%)	7 (3%)
Site closure	301 (6%)	176 (5%)	125 (10%)	0 (0%)
Other reason	37 (1%)	24 (1%)	12 (1%)	1 (0%)

* 12 Dynamic children in the Enrollment error/eligibility failure category are HIV-infected
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Table 9: SMARTT - Age at Last Scheduled Clinic Visit Among Dynamic Participants Still on Study

Characteristic	Total (N=1868)
Age (years) at Last Scheduled Clinical Visit	Median (Min, Max) 7.1 (0.0, 26.5)
	0 141 (8%)
	1-2 198 (11%)
	3-4 275 (15%)
	5-6 288 (15%)
	7-12 641 (34%)
	13-15 305 (16%)
	>15 20 (1%)

* For participants who did not attend the scheduled study visits, the scheduled clinical visit date was used to calculate the age. For 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 10: SMARTT - Entry Visit Status

Visit status	Total	Cohort		
		Dynamic	Static	Reference
Visit reported	4956 (97%)	3520 (97%)	1200 (97%)	236 (99%)
Delinquent	1 (0%)	1 (0%)	0 (0%)	0 (0%)
Early	28 (1%)	3 (0%)	21 (2%)	4 (2%)
In window	4419 (87%)	3217 (89%)	999 (81%)	203 (85%)
Late	508 (10%)	299 (8%)	180 (15%)	29 (12%)
No visit reported	150 (3%)	107 (3%)	40 (3%)	3 (1%)
Delinquent	4 (0%)	4 (0%)	0 (0%)	0 (0%)
In window	15 (0%)	15 (0%)	0 (0%)	0 (0%)
Missed visit	11 (0%)	11 (0%)	0 (0%)	0 (0%)
Off study*	120 (2%)	77 (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

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Table 11: SMARTT - Deaths by Cohort and Demographic Characteristics

		Cohort			Total (N=180)
		Caregiver (N=126)	Dynamic (Incl. Fetal) (N=51)	Static (N=3)	
Age group	Fetal demise	0 (0%)	22 (43%)	0 (0%)	22 (12%)
	<1 month	0 (0%)	3 (6%)	0 (0%)	3 (2%)
	1 mon-2 years	0 (0%)	17 (33%)	0 (0%)	17 (9%)
	2-5 years	0 (0%)	6 (12%)	0 (0%)	6 (3%)
	6-11 years	0 (0%)	2 (4%)	1 (33%)	3 (2%)
	12-17 years	0 (0%)	1 (2%)	2 (67%)	3 (2%)
	18-24 years	6 (5%)	0 (0%)	0 (0%)	6 (3%)
	25-39 years	73 (58%)	0 (0%)	0 (0%)	73 (41%)
	40+ years	47 (37%)	0 (0%)	0 (0%)	47 (26%)
Sex	Male	3 (2%)	18 (35%)	3 (100%)	24 (13%)
	Female	123 (98%)	11 (22%)	0 (0%)	134 (74%)
	Unknown/not reported	0 (0%)	22 (43%)	0 (0%)	22 (12%)
Race	White	31 (25%)	11 (22%)	0 (0%)	42 (23%)
	Black	88 (70%)	34 (67%)	3 (100%)	125 (69%)
	Not known/not reported	7 (6%)	6 (12%)	0 (0%)	13 (7%)
Ethnicity	Hispanic or Latino	29 (23%)	14 (27%)	0 (0%)	43 (24%)
	Not Hispanic or Latino	96 (76%)	36 (71%)	3 (100%)	135 (75%)
	Unknown	1 (1%)	1 (2%)	0 (0%)	2 (1%)
Death Category	Unknown, no information available	24 (19%)	19 (37%)	1 (33%)	44 (24%)
	HIV infection or HIV-related diagnosis	16 (13%)	0 (0%)	0 (0%)	16 (9%)
	Non-HIV diagnosis	16 (13%)	10 (20%)	1 (33%)	27 (15%)
	Other, specify	8 (6%)	14 (27%)	1 (33%)	23 (13%)
	No death form submitted	62 (49%)	8 (16%)	0 (0%)	70 (39%)

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Table 12: SMARTT - Bayley Screen for 3-year-old Children

ND Assessment		Total (N=1684)	Dynamic (N=1366)	Cohort	
				Static (N=275)	Reference (N=43)
Cognitive	At Risk for Devl Delay/Further Eval Needed	69 (4%)	58 (4%)	11 (4%)	0 (0%)
	Some Risk for Devl Delay	864 (51%)	708 (52%)	135 (49%)	21 (49%)
	Low Risk for Devl Delay	751 (45%)	600 (44%)	129 (47%)	22 (51%)
Receptive Communication	At Risk for Devl Delay/Further Eval Needed	63 (4%)	52 (4%)	11 (4%)	0 (0%)
	Some Risk for Devl Delay	635 (38%)	524 (38%)	97 (35%)	14 (33%)
	Low Risk for Devl Delay	983 (58%)	787 (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	79 (5%)	70 (5%)	9 (3%)	0 (0%)
	Some Risk for Devl Delay	710 (42%)	592 (43%)	108 (39%)	10 (23%)
	Low Risk for Devl Delay	890 (53%)	699 (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	46 (3%)	38 (3%)	8 (3%)	0 (0%)
	Some Risk for Devl Delay	668 (40%)	565 (41%)	91 (33%)	12 (28%)
	Low Risk for Devl Delay	966 (57%)	759 (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	44 (3%)	38 (3%)	6 (2%)	0 (0%)
	Some Risk for Devl Delay	536 (32%)	451 (33%)	78 (28%)	7 (16%)
	Low Risk for Devl Delay	1,097 (65%)	870 (64%)	191 (69%)	36 (84%)
	Not Done	7 (0%)	7 (1%)	0 (0%)	0 (0%)

Bayley Screen assessment was discontinued in SMARTT V6.

Created by: /home/phacs/actgPH100/monitoring/detlprogs/NDassess.sas on April 26, 2024

Table 13: SMARTT - Age-specific ND Assessments

ND Assessment	Score	Dynamic		Static		Reference	
		N	Mean (S.D)	N	Mean (S.D)	N	Mean (S.D)
Bayley-III (1 year old)	Cognitive, Composite	1847	102.5 (14.2)	146	102.9 (15.2)	49	102.2 (14.0)
	Language, Composite	1844	94.7 (13.7)	145	93.2 (14.7)	49	95.1 (12.5)
	Motor, Composite	1835	97.1 (12.8)	145	96.9 (15.9)	49	100.9 (14.7)
	Social-Emotional, Composite	1800	101.7 (17.7)	142	101.6 (18.5)	49	100.5 (16.4)
	General Adaptive, Composite	1797	94.6 (14.2)	142	93.4 (15.0)	49	92.3 (11.3)
WPPSI-III (5 years old)	Full Scale IQ	1070	94.0 (15.6)	445	94.6 (14.5)	47	93.6 (15.6)
	Performance IQ	1095	96.3 (16.2)	447	97.3 (15.2)	47	95.6 (15.3)
	Verbal IQ	1089	92.1 (14.3)	447	92.1 (12.9)	47	91.6 (13.9)
	Processing Speed IQ	1045	94.5 (15.7)	442	96.3 (15.9)	47	95.0 (15.4)
WASI (7+ years old)	General Language IQ	660	92.5 (13.7)	210	91.0 (14.1)	19	91.1 (11.4)
	Full Scale IQ	433	100.6 (15.5)	781	97.9 (14.0)	48	100.8 (12.6)
	Performance IQ	433	96.5 (13.5)	781	95.2 (13.1)	49	95.3 (13.0)
WIAT-II (7+ years old)	Verbal IQ	434	104.4 (18.6)	781	101.0 (16.0)	48	105.8 (14.2)
	Word Reading, Standard Score	418	97.7 (17.7)	779	97.3 (16.1)	49	97.1 (15.0)
	Spelling, Standard Score	417	96.6 (18.8)	776	97.8 (16.5)	48	98.8 (15.8)
BRIEF PR (7+ years old), SMARTT V5	Numerical Operations, Standard Score	417	92.6 (17.4)	779	94.0 (16.6)	49	94.5 (15.5)
	Behavioral Regulation Index, T-Score	509	51.4 (11.7)	731	53.6 (12.2)	46	53.3 (12.2)
	Metacognition Index, T-Score	508	51.3 (12.0)	730	52.8 (11.8)	46	52.6 (11.8)
BRIEF-II PR (9+ years old), SMARTT V6	Global Executive Composite, T-Score	508	51.5 (12.0)	730	53.3 (12.1)	46	52.9 (11.7)
	Behavioral Regulation Index, T-Score	32	52.0 (11.8)	-	-	-	-
	Emotion Regulation Index, T-Score	32	54.1 (15.3)	-	-	-	-
CBCL-PR (3+ years old)	Cognitive Regulation Index, T-Score	32	52.3 (12.1)	-	-	-	-
	Global Executive Composite	32	53.7 (13.9)	-	-	-	-
	Internalizing Problems, T-score	106	52.0 (10.9)	-	-	-	-
	Externalizing Problems, T-score	106	51.6 (10.8)	-	-	-	-
CBCL-SR (11+ years old)	Total Problems, T-score	106	51.6 (12.6)	-	-	-	-
	Internalizing Problems, T-score	37	53.7 (10.0)	-	-	-	-
	Externalizing Problems, T-score	37	48.8 (10.3)	-	-	-	-
	Total Problems, T-score	37	52.4 (10.2)	-	-	-	-

*For participants completing an assessment at more than one time point, the earliest assessment is used.
Assessments of WASI, WIAT and BRIEF are only for Extended cohort in SMARTT V6.
New assessments in SMARTT V6: CBCL-PR and CBCL-SR.*

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Table 14: SMARTT - Caregiver-Reported Hearing Information at Entry

Characteristic		Total (N=4910)	Dynamic (N=3479)	Cohort	
				Static (N=1195)	Reference (N=236)
Concerns about hearing	Yes	143 (3%)	57 (2%)	77 (6%)	9 (4%)
	No	4,675 (95%)	3,338 (96%)	1,111 (93%)	226 (96%)
	Unknown	92 (2%)	84 (2%)	7 (1%)	1 (0%)
Child has repeated ear infections	Yes	125 (3%)	1 (0%)	102 (9%)	22 (9%)
	No	4,693 (96%)	3,394 (98%)	1,086 (91%)	213 (90%)
	Unknown	92 (2%)	84 (2%)	7 (1%)	1 (0%)
Child failed hearing screening	Yes	166 (3%)	90 (3%)	65 (5%)	11 (5%)
	No	4,652 (95%)	3,305 (95%)	1,123 (94%)	224 (95%)
	Unknown	92 (2%)	84 (2%)	7 (1%)	1 (0%)
Child tested by audiologist	Yes	1,404 (29%)	1,005 (29%)	349 (29%)	50 (21%)
	No	3,414 (70%)	2,390 (69%)	839 (70%)	185 (78%)
	Unknown	92 (2%)	84 (2%)	7 (1%)	1 (0%)
Perm hearing loss in 1-2 ears	Yes	10 (0%)	3 (0%)	7 (1%)	0 (0%)
	No	1,393 (28%)	1,001 (29%)	342 (29%)	50 (21%)
	Test not done	3,414 (70%)	2,390 (69%)	839 (70%)	185 (78%)
	Unknown	93 (2%)	85 (2%)	7 (1%)	1 (0%)

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Table 15: SMARTT - Age-Specific Language Assessments

Language Assessment	Score	Dynamic		Static		Reference	
		N	Mean (S.D)	N	Mean (S.D)	N	Mean (S.D)
CDI (1 year old)	Phrases Understood, percentile	2157	57.1 (27.7)	178	50.8 (28.1)	48	53.5 (28.2)
	Vocabulary Comprehension, percentile	2156	48.0 (30.2)	178	44.1 (30.0)	48	45.5 (31.3)
	Words Production, percentile	2156	48.7 (22.2)	178	45.5 (21.8)	48	56.4 (19.8)
	A-E Total Gestures, percentile	2157	49.3 (28.6)	178	40.9 (29.3)	48	56.8 (31.2)
ASQ (2 years old)	Total Score	1983	43.8 (15.8)	269	45.1 (15.7)	-	
TELD-3 (3 years old)	Receptive Language, quotients	38	98.3 (16.1)	294	98.3 (14.7)	39	96.7 (12.1)
	Expressive Language, quotients	38	98.9 (13.1)	293	98.9 (16.0)	38	102.4 (10.8)
	Spoken Language, quotients	38	95.3 (22.4)	293	98.7 (18.6)	38	97.9 (19.6)
TOLD-P:3 (5 years old)	Spoken Language, quotients	994	91.2 (15.5)	438	89.7 (14.3)	45	87.9 (14.3)
	Listening, quotients	999	96.7 (15.3)	439	94.2 (13.9)	45	92.0 (13.4)
	Speaking, quotients	994	91.4 (15.7)	438	91.2 (14.1)	45	90.2 (13.6)
	Syntax, quotients	994	88.5 (15.1)	438	88.9 (14.7)	45	89.0 (13.7)
CELF-4 (9 years old), SMARTT V5	Sum of Core Language, standard score	412	88.0 (17.4)	509	86.2 (17.0)	39	86.9 (11.6)
	Sum of Expressive Language, standard score	412	91.0 (17.3)	509	88.5 (17.4)	39	90.6 (12.1)
CELF-4-II (5 and 9 years old), SMARTT V6	Sum of Core Language, standard score	22	79.2 (16.2)	-		-	
	Sum of Expressive Language, standard score	22	80.5 (16.0)	-		-	

TELD assessment was discontinued in SMARTT V4.

ASQ and TOLD assessments were discontinued in SMARTT V6.

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Table 16: 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	3451	-0.09 (1.05)	1191	0.31 (1.13)	235	0.34 (1.15)
Weight Z-score	3457	-0.54 (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-old.

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

The growth data for newly enrolled dynamic children in SMARTT V6 are not included in above table as the data collected using the new CRF have not yet been incorporated in the DMC growth z-score table.

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Table 17: SMARTT - Maternal Substance Use During Pregnancy in Dynamic Cohort

		Trimester			
		Any Trimester (N=3373)	First (N=3373)	Second (N=3373)	Third (N=3373)
Any Substance Use	Yes	978 (29%)	842 (25%)	553 (16%)	510 (15%)
	No	2,393 (71%)	2,529 (75%)	2,818 (84%)	2,861 (85%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Tobacco	Yes	571 (17%)	535 (16%)	355 (11%)	303 (9%)
	No	2,800 (83%)	2,822 (84%)	3,002 (89%)	3,054 (91%)
	Unknown	2 (0%)	16 (0%)	16 (0%)	16 (0%)
Alcohol	Yes	293 (9%)	262 (8%)	78 (2%)	56 (2%)
	No	3,078 (91%)	3,107 (92%)	3,291 (98%)	3,313 (98%)
	Unknown	2 (0%)	4 (0%)	4 (0%)	4 (0%)
Marijuana	Yes	318 (9%)	281 (8%)	149 (4%)	114 (3%)
	No	3,053 (91%)	3,086 (91%)	3,218 (95%)	3,253 (96%)
	Unknown	2 (0%)	6 (0%)	6 (0%)	6 (0%)
Cocaine	Yes	71 (2%)	59 (2%)	38 (1%)	28 (1%)
	No	3,300 (98%)	3,312 (98%)	3,333 (99%)	3,343 (99%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Antidepressants	Yes	150 (4%)	98 (3%)	80 (2%)	85 (3%)
	No	3,219 (95%)	3,269 (97%)	3,287 (97%)	3,282 (97%)
	Unknown	4 (0%)	6 (0%)	6 (0%)	6 (0%)
Pain Medications	Yes	142 (4%)	60 (2%)	69 (2%)	66 (2%)
	No	3,227 (96%)	3,308 (98%)	3,299 (98%)	3,302 (98%)
	Unknown	4 (0%)	5 (0%)	5 (0%)	5 (0%)
Methadone	Yes	22 (1%)	18 (1%)	20 (1%)	22 (1%)
	No	3,345 (99%)	3,351 (99%)	3,349 (99%)	3,347 (99%)
	Unknown	6 (0%)	4 (0%)	4 (0%)	4 (0%)
Heroin	Yes	16 (0%)	12 (0%)	7 (0%)	7 (0%)
	No	3,354 (99%)	3,358 (100%)	3,363 (100%)	3,363 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
Sedative	Yes	17 (1%)	10 (0%)	8 (0%)	7 (0%)
	No	3,353 (99%)	3,360 (100%)	3,362 (100%)	3,363 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
Methamphetamines	Yes	21 (1%)	18 (1%)	8 (0%)	5 (0%)
	No	3,350 (99%)	3,353 (99%)	3,363 (100%)	3,366 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Ecstasy	Yes	3 (0%)	3 (0%)	0 (0%)	0 (0%)
	No	3,368 (100%)	3,368 (100%)	3,371 (100%)	3,371 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
PCP	Yes	3 (0%)	3 (0%)	1 (0%)	1 (0%)
	No	3,367 (100%)	3,367 (100%)	3,369 (100%)	3,369 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)

		Trimester			
		Any Trimester (N=3373)	First (N=3373)	Second (N=3373)	Third (N=3373)
Opium	Yes	6 (0%)	2 (0%)	3 (0%)	3 (0%)
	No	3,365 (100%)	3,369 (100%)	3,368 (100%)	3,368 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Other Drug	Yes	20 (1%)	12 (0%)	10 (0%)	9 (0%)
	No	3,350 (99%)	3,358 (100%)	3,360 (100%)	3,361 (100%)
	Unknown	3 (0%)	3 (0%)	3 (0%)	3 (0%)
Stimulants	Yes	7 (0%)	5 (0%)	0 (0%)	0 (0%)
	No	3,364 (100%)	3,366 (100%)	3,371 (100%)	3,371 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Barbiturates	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,370 (100%)	3,370 (100%)	3,371 (100%)	3,371 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Amphetamines	Yes	3 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,368 (100%)	3,370 (100%)	3,371 (100%)	3,371 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Inhalants	Yes	1 (0%)	1 (0%)	1 (0%)	0 (0%)
	No	3,370 (100%)	3,370 (100%)	3,370 (100%)	3,371 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
LSD	Yes	2 (0%)	2 (0%)	0 (0%)	0 (0%)
	No	3,366 (100%)	3,368 (100%)	3,370 (100%)	3,370 (100%)
	Unknown	5 (0%)	3 (0%)	3 (0%)	3 (0%)
Other Hallucinogens	Yes	2 (0%)	2 (0%)	1 (0%)	0 (0%)
	No	3,366 (100%)	3,367 (100%)	3,368 (100%)	3,369 (100%)
	Unknown	5 (0%)	4 (0%)	4 (0%)	4 (0%)
Ketamine	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	3,370 (100%)	3,370 (100%)	3,371 (100%)	3,371 (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 18: SMARTT - Maternal Substance Use During Pregnancy in 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%)
	No	1,033 (100%)	1,034 (100%)	1,034 (100%)	1,035 (100%)
PCP	Yes	1 (0%)	1 (0%)	1 (0%)	1 (0%)
	No	1,032 (100%)	1,032 (100%)	1,032 (100%)	1,032 (100%)
	Unknown	2 (0%)	2 (0%)	2 (0%)	2 (0%)
Opium	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	1,034 (100%)	1,034 (100%)	1,035 (100%)	1,035 (100%)
Other Drug	Yes	5 (0%)	3 (0%)	2 (0%)	2 (0%)
	No	1,030 (100%)	1,032 (100%)	1,033 (100%)	1,033 (100%)

		Trimester			
		Any Trimester (N=1035)	First (N=1035)	Second (N=1035)	Third (N=1035)
Stimulants	No	1,034 (100%)	1,034 (100%)	1,034 (100%)	1,034 (100%)
	Unknown	1 (0%)	1 (0%)	1 (0%)	1 (0%)
Barbiturates	Yes	5 (0%)	3 (0%)	2 (0%)	2 (0%)
	No	1,030 (100%)	1,032 (100%)	1,033 (100%)	1,033 (100%)
Amphetamines	No	1,035 (100%)	1,035 (100%)	1,035 (100%)	1,035 (100%)
Inhalants	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	1,033 (100%)	1,033 (100%)	1,034 (100%)	1,034 (100%)
	Unknown	1 (0%)	1 (0%)	1 (0%)	1 (0%)
LSD	Yes	1 (0%)	1 (0%)	0 (0%)	0 (0%)
	No	1,033 (100%)	1,033 (100%)	1,034 (100%)	1,034 (100%)
	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 19: SMARTT - Maternal ARV Exposure by Birth Year in Dynamic Cohort

Year of birth	At the last menstrual period date + 14 days	During pregnancy	During labor/delivery only	No ARV during pregnancy or labor/delivery	Unknown ARV use during pregnancy or labor/delivery	Total pregnancy *
2007	28 (25%)	105 (94%)	2 (2%)	1 (1%)	4 (4%)	112
2008	87 (29%)	293 (97%)	4 (1%)	2 (1%)	2 (1%)	301
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	107 (52%)	203 (99%)	1 (0%)	1 (0%)	0 (0%)	205
2019	109 (56%)	190 (97%)	2 (1%)	3 (2%)	1 (1%)	196
2020	60 (53%)	112 (98%)	1 (1%)	0 (0%)	1 (1%)	114
2021	64 (58%)	108 (98%)	0 (0%)	1 (1%)	1 (1%)	110
2022	61 (59%)	100 (96%)	3 (3%)	1 (1%)	0 (0%)	104
2023	51 (47%)	100 (93%)	3 (3%)	2 (2%)	3 (3%)	108
2024	1 (20%)	3 (60%)	0 (0%)	1 (20%)	1 (20%)	5
Total exposure	1506 (43%)	3422 (97%)	29 (1%)	20 (1%)	50 (1%)	3521

Pregnancy period started from the last menstrual period date through 3 days before delivery.

Labor/delivery period started from 2 days before delivery through delivery.

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

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

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Table 20: SMARTT - Maternal ARV Exposure by Birth Year in Static Cohort

Year of birth	At the last menstrual period date + 14 days	During pregnancy	During labor/delivery only	No ARV during pregnancy or labor/delivery	Unknown ARV use during pregnancy or labor/delivery	Total pregnancy *
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	42 (34%)	118 (95%)	4 (3%)	0 (0%)	2 (2%)	124
2008	10 (19%)	44 (83%)	4 (8%)	0 (0%)	5 (9%)	53
Total exposure	333 (28%)	1119 (93%)	28 (2%)	25 (2%)	27 (2%)	1199

Pregnancy period started from the last menstrual period date through 3 days before delivery.

Labor/delivery period started from 2 days before delivery through delivery.

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

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

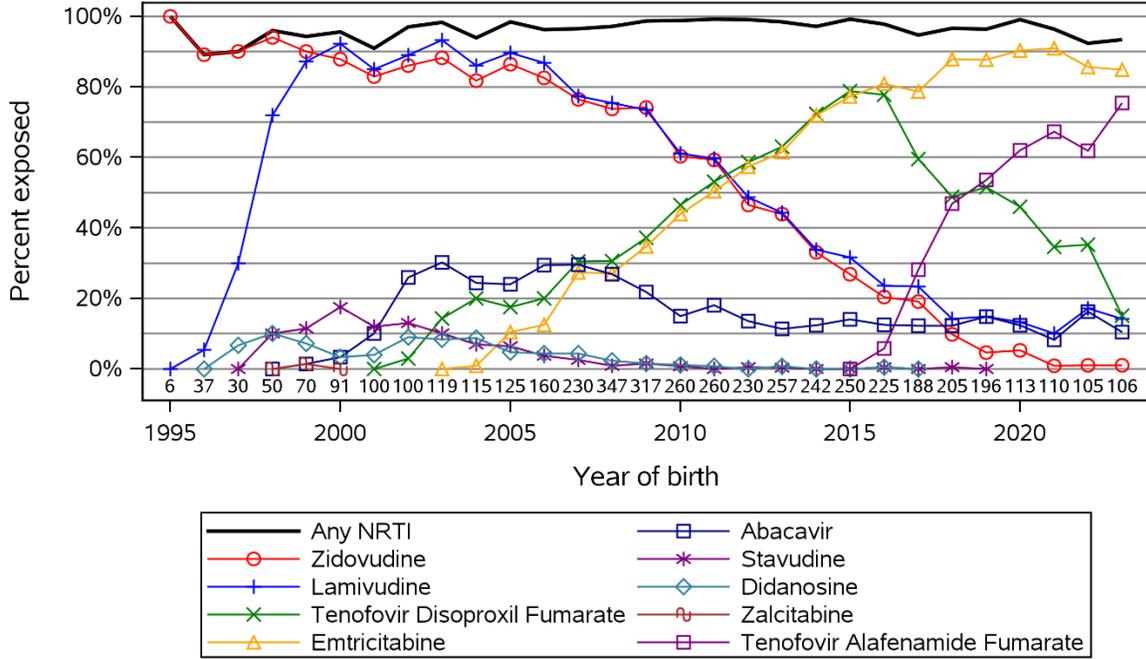


Figure 2: SMARTT - *In Utero* NNRTI Exposures by Year of Birth

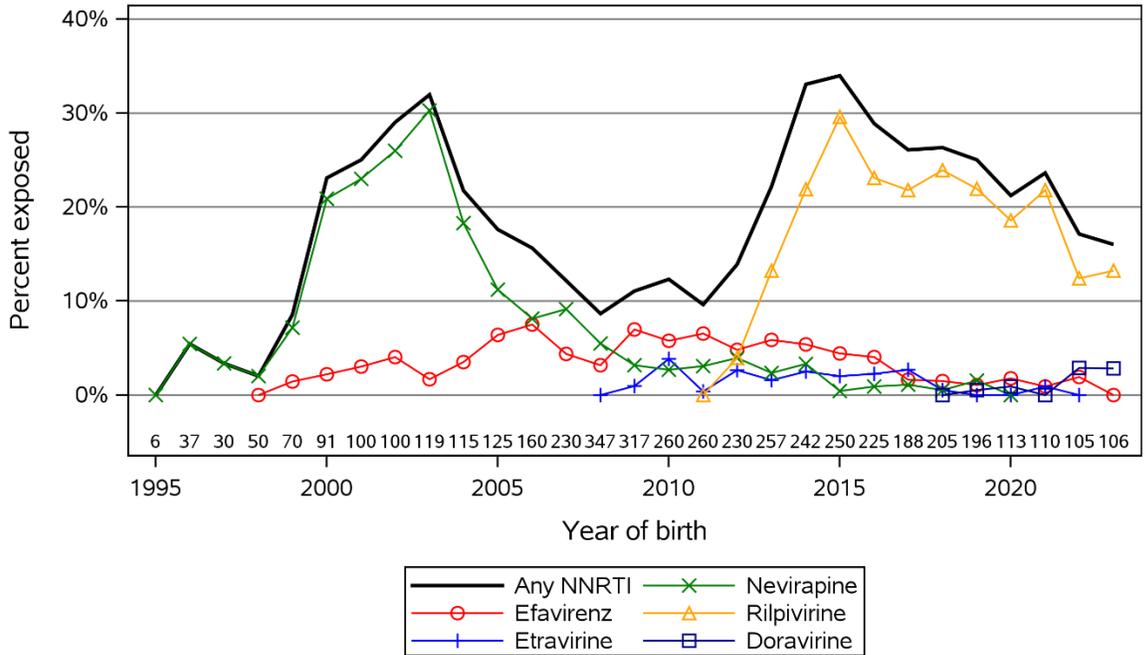
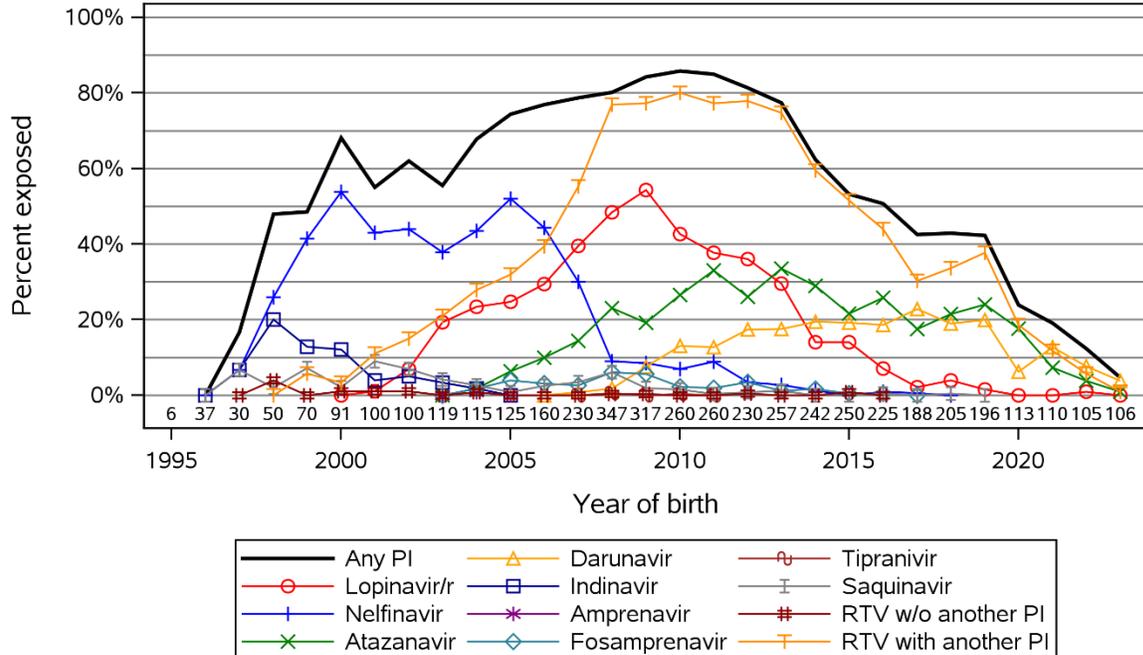
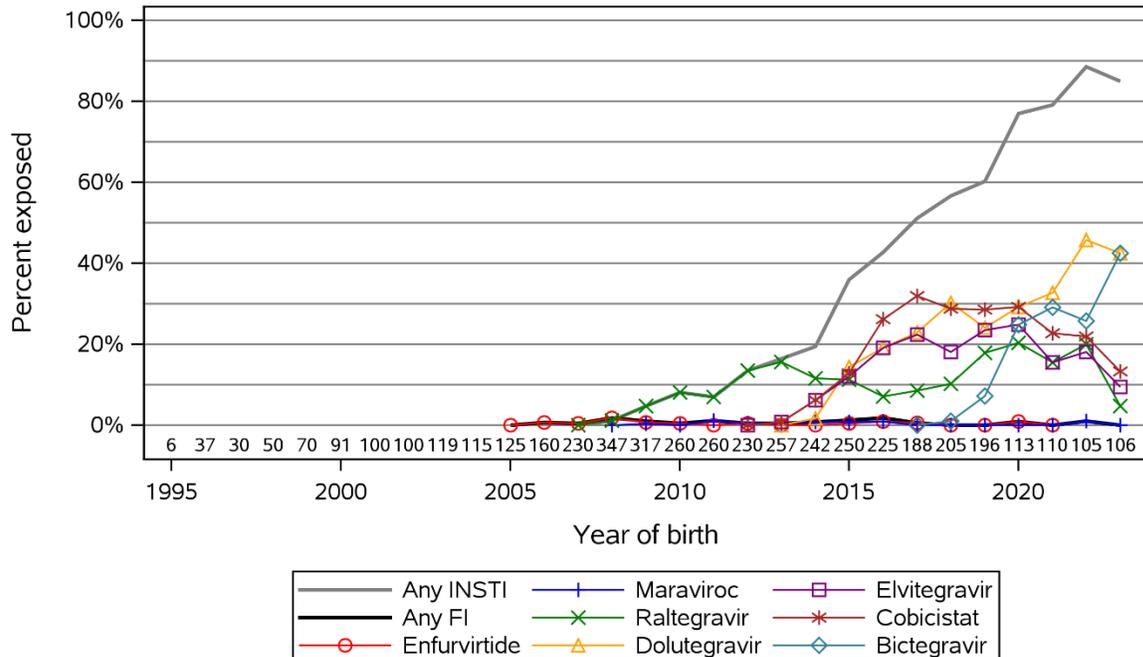


Figure 3: SMARTT - *In Utero* PI Exposures by Year of Birth



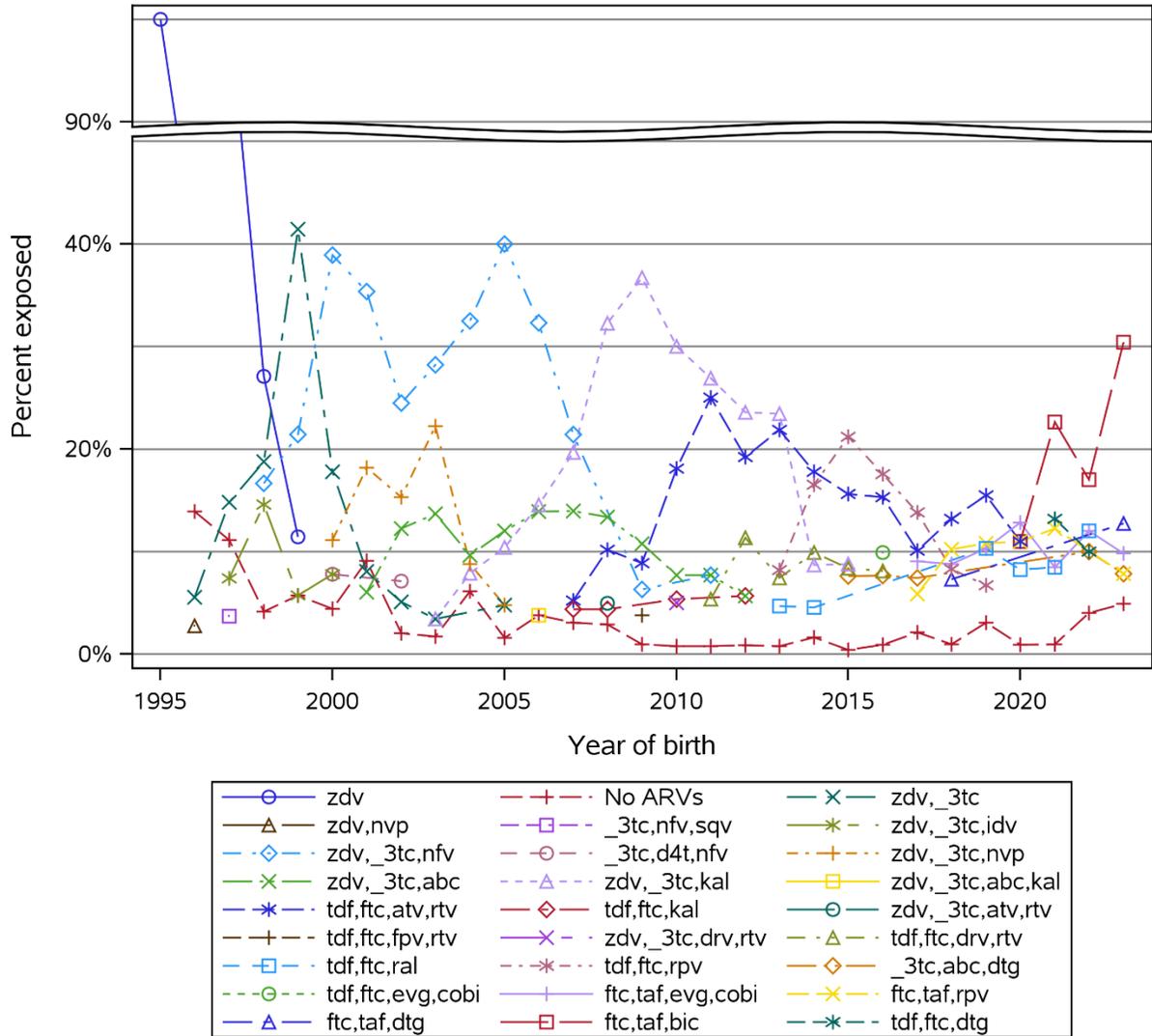
Number above the x-axis represents the number of children with in utero ARV exposure data available

Figure 4: SMARTT - *In Utero* FI/INSTI Exposures by Year of Birth



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

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



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

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