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MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Strategies and Lessons Learned in Deriving ADaM Datasets for Pregnancy in Clinical Trials

Lauren Ziemba, Biostatistician/Statistical Project Manager
Mauricio Pinilla, Biostatistician/Manager of Statistical Training
Center of Biostatistics in AIDS Research, Harvard TH Chan School of Public Health

Speaker



Lauren is a biostatistician at the Center for Biostatistics in AIDS Research (CBAR). She has 10 years of experience conducting clinical trials for pregnant women and children with HIV through the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network.

Lauren Ziemba

Biostatistician/Statistical Project Manager
Center for Biostatistics in AIDS Research
Harvard TH Chan School of Public Health

Agenda

“Pregnant and lactating individuals must be protected through research, not from research.”¹

Pregnancy-related Data

- Helpful resources for collecting and mapping data
- Key analysis and data considerations
- Strategies for traceability when deriving key ADaM variables
- ADaM use cases from clinical trials that enroll pregnant or neonatal participants

Established Guides for Pregnancy in Clinical Trials

- HIV Clinical Trials
 - Trials in pregnant women with HIV are crucial in HIV research since antiretrovirals in pregnancy reduce risk of vertical transmission of HIV to neonate
 - WHO Antiretrovirals in Pregnancy Research Toolkit
 - Includes examples of data to collect and key endpoints
 - Highlights importance of collecting information from both pregnant women and infant(s)
 - HIV Therapeutic Area User Guide (TAUG) v1.0
 - Guidelines for linking data within family units and mapping pregnancy-related SDTM data
 - Provides an example of pregnancy outcomes ADaM
- Pediatrics User Guide v1.0
 - Further SDTM mapping examples for pediatric and pregnancy-related data using CDISC standards
 - Presents some key data elements of studies with pregnancy such as estimated date of delivery and birth vital signs
- Very few ADaM examples

Types of Pregnancy Data Collection

Pregnant participant and infants enrolled in study

- Mother and infant each receive USUBJID and RELSUB domain links related participants using RSUBJID
- Population flags are key to differentiate between adults and infants

VS

Pregnant participant enrolled, infants not enrolled

or

Neonates enrolled and mothers not enrolled

- Mother or infant is considered associated person with data collected in AP domains and assigned an APID

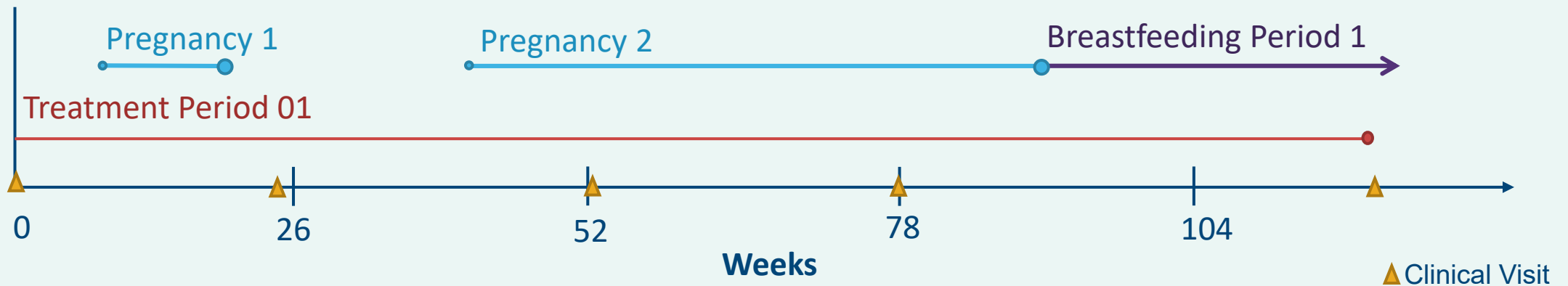


Key Considerations for Pregnancy Data

Special Considerations for Pregnancy Data: Time



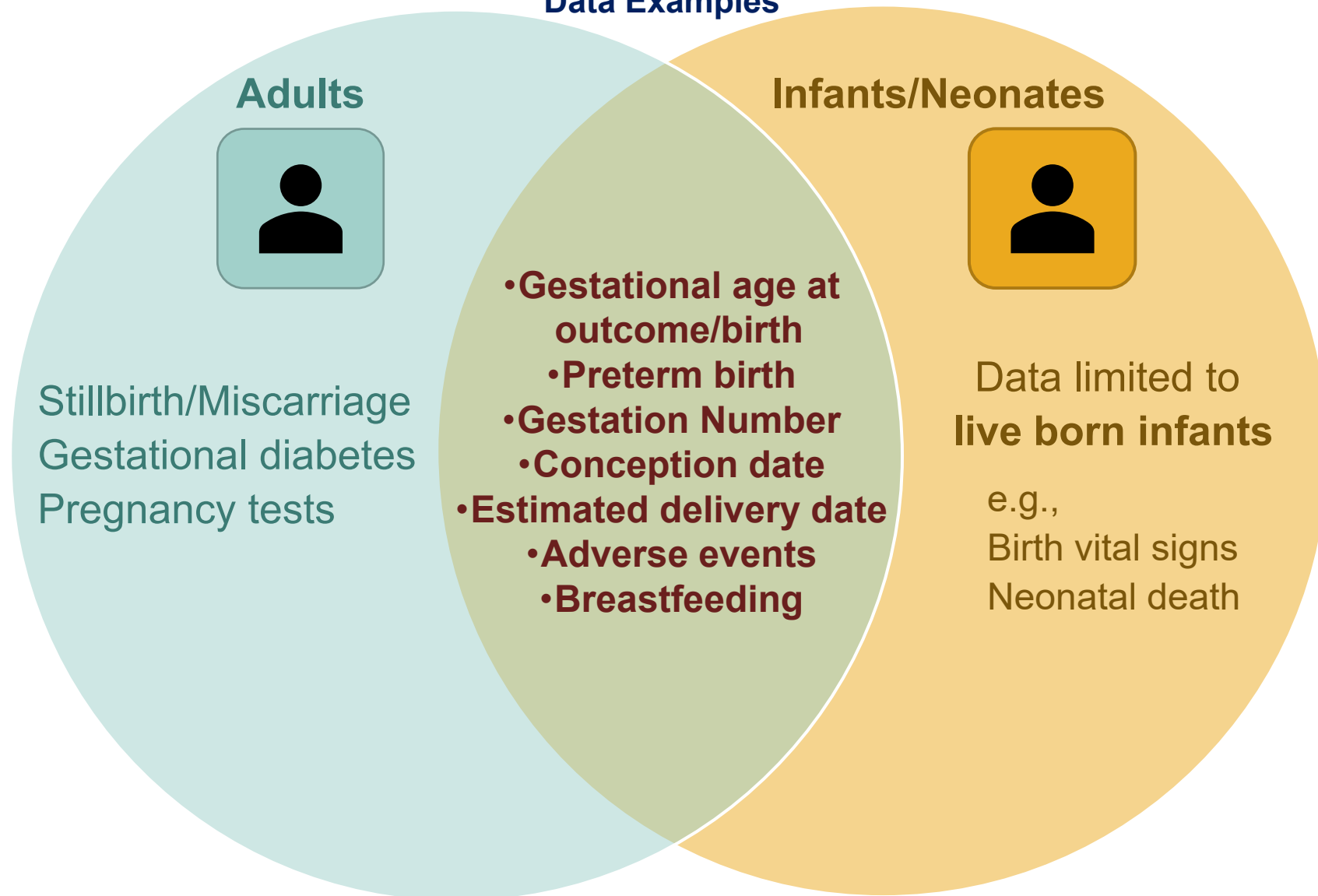
- Pregnancy as intercurrent event: biological changes during pregnancy, postpartum, and breastfeeding may impact observed measurements (e.g., creatinine, pharmacokinetic concentrations)
- Additional timescales for gestational age, postpartum, breastfeeding periods
- Estimation of gestational age, pregnancy start, and expected delivery date



Special Considerations for Pregnancy Data: Associated Data

Data Examples

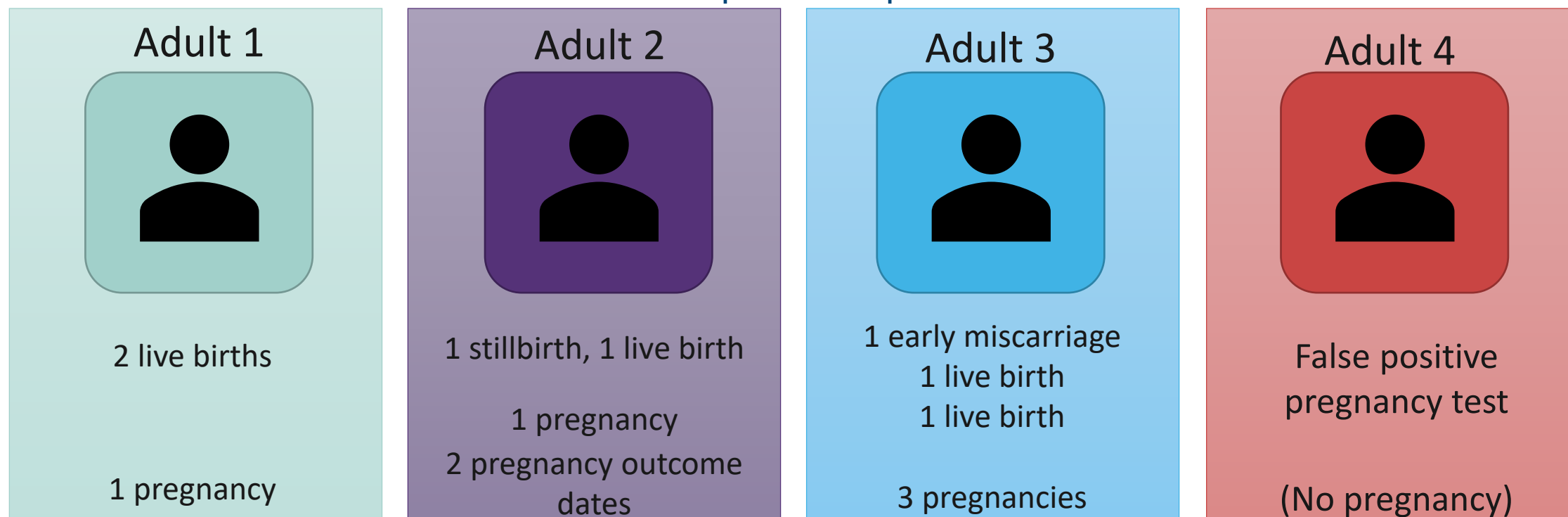
- Data between mother and infant need to be linked
- Pregnancy outcomes are collected both under mother and infant
- Data collection under one participant will usually be applied to all in family unit (e.g., gestational age at outcome/birth)



Special Considerations for Pregnancy Data: Multiple Outcomes

- **Multiple Gestations:** discordant outcomes, discordant outcome date, multiple infants for one pregnancy
- **Multiple Pregnancies**

Example Participants



ADaMs should be derived to handle varying number of fetuses, different outcomes and outcome dates per pregnancy, multiple pregnancies, and include traceability when pregnancy tests produce false positives



ADaM Use Cases

Helpful ADSL Variables

Variables Derived with CDISC Principles:

Mother and Infant(s) Enrolled

USUBJGR1

USUBJID Grouping Variable from HIV TAUG for family unit

Population Flags

- **Adult Flag (ADULTFL)**
- **Live Birth Flag (LVBIRTHFL)**

Positive Pregnancy Test Flag
(e.g., POSPGFL)

Pregnancy End and Start Dates
(PG01EDT/PG01SDT)

Estimated Delivery Date (ED01DT)
Deriving gestational age at measurement

Breastfeeding Flag (BFFL)
Ever/Never Breastfed
Breastfeeding start and stop dates (BFSDT,BFEDT) helpful in ADSL or occurrence ADaM

ADSL (Adult & Infant Enrolled)

USUBJID	USUBJGR1	ADULTFL	LVBIRTHFL	BRTHDT	PG01SDT	PG01EDT	ED01DT	BFFL
ADULT1	FAMILY1	Y	N	03FEB1990	31DEC2023	18SEP2024	21SEP2024	Y
INFANT1	FAMILY1	N	Y	18SEP2024	31DEC2023	18SEP2024	21SEP2024	Y
INFANT2	FAMILY1	N	Y	18SEP2024	31DEC2023	18SEP2024	21SEP2024	Y
ADULT2	FAMILY2	Y	N	17MAR1988	07JAN2025	01SEP2025	01NOV2025	Y
INFANT3	FAMILY2	N	N		07JAN2025	02JUL2025	01NOV2025	N
INFANT4	FAMILY2	N	Y	01SEP2025	07JAN2025	01SEP2025	01NOV2025	Y

Example BDS

Can derive BDS/OCCDS variables:
Antepartum Record Flag (APRFL)
Breastfeeding Record Flag (BFRFL)
Analysis Gestational Age (AAGEGA)

USUBJID	PARAM	PARAMCD	AVISIT	AVAL	APRFL	AAGEGA	AAGEGAU	BFRFL
ADULT1	Creatinine (umol/L)	CREAT	Week 4	56	Y	26	Weeks	N
ADULT1	Creatinine (umol/L)	CREAT	Week 12	38	Y	33	Weeks	N
ADULT1	Creatinine (umol/L)	CREAT	Week 48	70	N		Weeks	Y

USUBJGR1 is a variable specified in the HIV TAUG v1.0. All other variables are use case suggestions.

ADaM Occurrence Data for Pregnancies

- Deriving start and stop of pregnancies in an occurrence structure improves traceability for pregnancy time period
 - One record per pregnancy (even with multiple gestations)
 - Can count number of pregnancies per participant
 - Easier to trace if pregnancy overlaps with treatment period or observed measurement
 - Derive approximate start of pregnancy, if needed
 - Total gestation time and interval time between pregnancies can be derived

USUBJID	CETERM	ASTDT	AENDT	CETRTP	CETTPT	AOCFL	ADUR	ADURU	PREGINT	PREGINTU
ADULT1	Pregnancy	31DEC2023	18SEP2024	BEFORE	03FEB2024	Y	37	Weeks		
ADULT2	Pregnancy	07JAN2025	02SEP2025			Y	34	Weeks		
ADULT3	Pregnancy	03AUG2022	08OCT2022	BEFORE	10SEP2022	Y	9	Weeks		
ADULT3	Pregnancy	04MAY2023	01FEB2024				39	Weeks	7	Months
ADULT3	Pregnancy	10SEP2025	20MAY2026				36	Weeks	19	Months

ASTDT = best estimation of conception date

AENDT = latest outcome date per pregnancy (e.g., multiple gestations choose last to occur)

ADUR/ADURU = duration of pregnancy and units

PREGINT/PREGINTU = interval of time between pregnancies and units

Maternal Pregnancy Outcomes Dataset

Pregnancy outcome BDS

USUBJID	PARAM	PARAMCD	AVISIT	ATPT	ATPTN	ADT	AVALC
ADULT1	Pregnancy Outcome	PREGOUT	Pregnancy 1	First Outcome	1	18SEP2024	Live Birth
ADULT1	Pregnancy Outcome	PREGOUT	Pregnancy 1	Second Outcome	2	18SEP2024	Live Birth
ADULT2	Pregnancy Outcome	PREGOUT	Pregnancy 1	First Outcome	1	02JUL2025	Stillbirth
ADULT2	Pregnancy Outcome	PREGOUT	Pregnancy 1	Second Outcome	2	01SEP2025	Live Birth
ADULT3	Pregnancy Outcome	PREGOUT	Pregnancy 1	First Outcome	1	08OCT2022	Early Miscarriage
ADULT3	Pregnancy Outcome	PREGOUT	Pregnancy 2	First Outcome	1	01FEB2024	Live Birth
ADULT3	Pregnancy Outcome	PREGOUT	Pregnancy 3	First Outcome	1	20MAY2026	Live Birth
ADULT4	Pregnancy Outcome	PREGOUT	Pregnancy 1	First Outcome	1	21APR2025	False Pregnancy

- An overall outcome of a pregnancy includes data such as, live birth, stillbirth, early miscarriage, false pregnancy
- Reported for the adult
- AVISIT/AVISITN (analysis visit variables) describes each pregnancy
- ATPT/ATPTN (analysis timepoint description variables) describes which outcome per pregnancy



Summarizing Multiple Gestations

- A count of multiple gestations in a BDS is helpful for analyses and tracking the levels of outcomes
- Summary of pregnancy outcomes can also be summarized by gestation number

Example Table Summary

Number of Pregnant Participants	90
Number of Pregnancies	100
Singleton	94 (94%)
Multiple Gestation	6 (6%)
Twins	5 (5%)
Triplets	1 (1%)

USUBJID	USUBJGR1	PARAM	PARAMCD	AVISIT	AVAL	AVALC	CRIT1	CRIT1FL
ADULT1	FAMILY1	Multiple Gestation Description	MLTGAPRG	Pregnancy 1	2	Twins	>1 Gestation	Y
ADULT2	FAMILY2	Multiple Gestation Description	MLTGAPRG	Pregnancy 1	2	Twins	>1 Gestation	Y
ADULT3	FAMILY3	Multiple Gestation Description	MLTGAPRG	Pregnancy 1	1	Singleton	>1 Gestation	N
ADULT3	FAMILY3	Multiple Gestation Description	MLTGAPRG	Pregnancy 2	1	Singleton	>1 Gestation	N
ADULT3	FAMILY3	Multiple Gestation Description	MLTGAPRG	Pregnancy 3	1	Singleton	>1 Gestation	N

Infant Outcomes Dataset

USUBJID	USUBJGR1	PARAM	PARAMCD	AVISIT	AVALC
INFANT1	FAMILY1	Preterm Birth	PRETERM	Pregnancy 1	N
INFANT1	FAMILY1	Small for Gestational Age (<10 th Pctl)	SGA10	Pregnancy 1	N
INFANT1	FAMILY1	Neonatal Death	NEODTH	Pregnancy 1	N
INFANT2	FAMILY1	Preterm Birth	PRETERM	Pregnancy 1	N
INFANT2	FAMILY1	Small for Gestational Age (<10 th Pctl)	SGA10	Pregnancy 1	Y
INFANT2	FAMILY1	Neonatal Death	NEODTH	Pregnancy 1	N

- Outcomes such as preterm birth, small for gestational age, and neonatal death are generally analyzed among live birth infants
- Infant-participant BDS is helpful to retain information on each infant
- BDS is similar for infants not enrolled: APID instead of USUBJID

Family Unit: Adverse Pregnancy Outcomes ADaM

Maternal outcomes BDS

USUBJID	USUBJGR1	PARAM	AVISIT	ATPTN	AVALC
ADULT1	FAMILY1	Pregnancy Outcome	Pregnancy 1	1	Live Birth
ADULT1	FAMILY1	Pregnancy Outcome	Pregnancy 1	2	Live Birth

Infant outcomes BDS

USUBJID	USUBJGR1	PARAM	AVISIT	AVAL
INFANT1	FAMILY1	Preterm Birth	Pregnancy 1	N
INFANT1	FAMILY1	Small for Gestational Age (<10th pctl)	Pregnancy 1	N
INFANT2	FAMILY1	Preterm Birth	Pregnancy 1	N
INFANT2	FAMILY1	Small for Gestational Age (<10th pctl)	Pregnancy 1	Y

Family-unit Adverse Pregnancy Outcomes BDS

USUBJGR1	PARAM	AVISIT	AVALC
FAMILY1	Early Miscarriage (<20 weeks gestation)	Pregnancy 1	N
FAMILY1	Stillbirth (≥20 weeks gestation)	Pregnancy 1	N
FAMILY1	Preterm Birth (<37 weeks gestation)	Pregnancy 1	N
FAMILY1	Small for Gestational Age (<10th pctl)	Pregnancy 1	Y
FAMILY1	Composite Adverse Pregnancy Outcome	Pregnancy 1	Y

- Adverse pregnancy outcomes collected under mother and infant
 - E.g., mothers: early miscarriage, stillbirth
 - E.g., live born infants: preterm birth, small for gestational age, neonatal death
- HIV TAUG presents mother-child adverse outcome events ADaM Other
- AVALC Y/N: One per pregnancy, if occurred in one of the infants or in pregnancy then Y for family unit

Family Unit: Adverse Pregnancy Outcomes ADaM

- Composite Adverse Pregnancy Outcome provides summary of multiple adverse pregnancy outcomes for family unit and pregnancy

Maternal outcomes BDS

USUBJID	USUBJGR1	PARAM	AVISIT	ATPTN	AVALC
ADULT2	FAMILY2	Pregnancy Outcome	Pregnancy 1	1	Stillbirth
ADULT2	FAMILY2	Pregnancy Outcome	Pregnancy 1	2	Live Birth

Infant outcomes BDS

USUBJID	USUBJGR1	PARAM	AVISIT	AVAL
INFANT4	FAMILY2	Preterm Birth	Pregnancy 1	Y
INFANT4	FAMILY2	Small for Gestational Age (<10th pctl)	Pregnancy 1	N

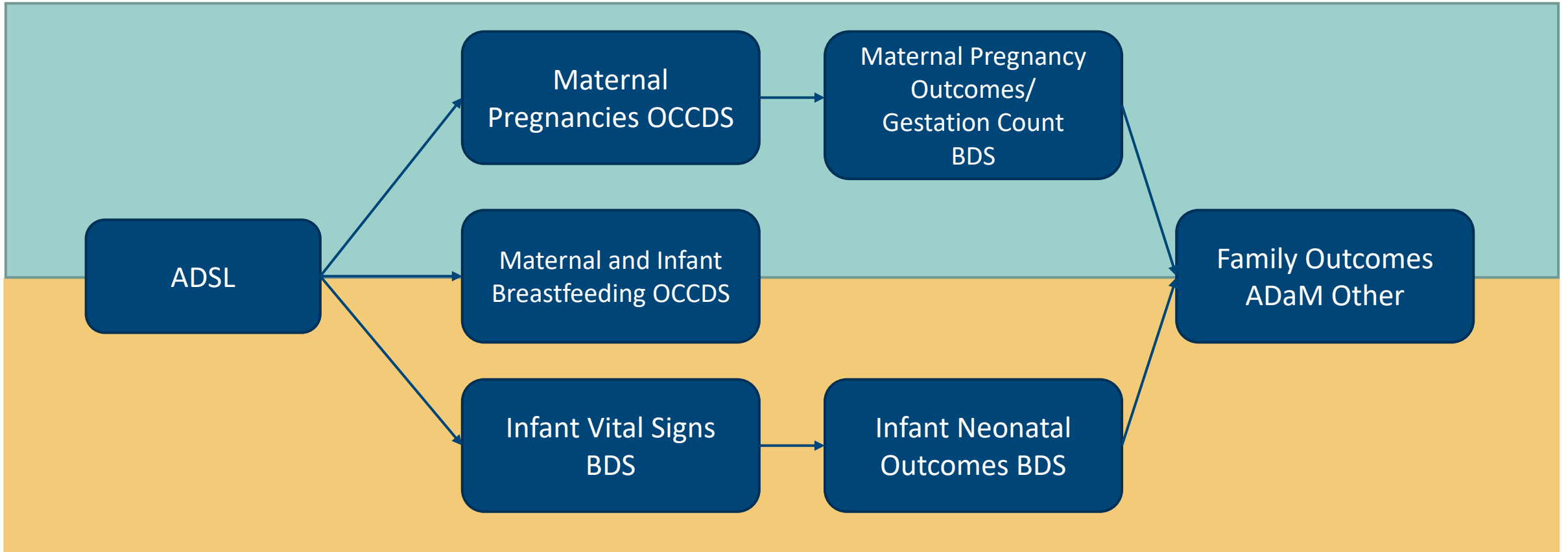
Family-unit Adverse Pregnancy Outcomes BDS

USUBJGR1	PARAM	AVISIT	AVALC
FAMILY2	Early Miscarriage (<20 weeks gestation)	Pregnancy 1	N
FAMILY2	Stillbirth (≥20 weeks gestation)	Pregnancy 1	Y
FAMILY2	Preterm Birth (<37 weeks gestation)	Pregnancy 1	Y
FAMILY2	Small for Gestational Age (<10th pctl)	Pregnancy 1	N
FAMILY2	Composite Adverse Pregnancy Outcome	Pregnancy 1	Y

ADaM Data Flow

Example ADaM work flow

Datasets Including Enrolled Adult/Maternal Participant/Associated Mother



Datasets Including Enrolled Live Born Infant/Associated Persons Live Born Infant

Conclusions

- Data standards for pregnancy-related data support need for increased representation of pregnant women and neonates in research
- HIV TAUG and Pediatric User Guide provide a good starting point for SDTMs
- Using CDISC best practices in ADaMs can help with traceability, in particular:
 - When pregnancy, postpartum, or breastfeeding are intercurrent events for estimand of interest
 - Participants have multiple gestations per pregnancy or multiple pregnancies
- ADaMs are driven by analysis needs but use cases can provide guidance when deriving pregnancy-related ADaMs
- Research would benefit from further CDISC standards in pregnancy-related data
 - Studies collecting pregnancy-related data
 - Studies with pregnant/breastfeeding women and neonates as main populations of interest



Thank You!



Questions?



END OF PRESENTATION