cdisc

2023
EUROPE
INTERCHANGE
COPENHAGEN | 26-27 APRIL

Infant Safety Data (Associated Persons' Data) Collection in HIV study

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Meet the Speaker

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SDTM Tabulate Certification

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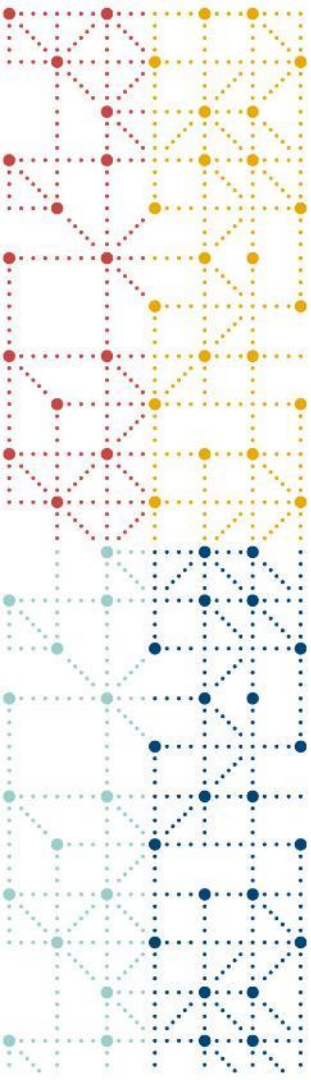
Agenda

1. Subject Data vs Associated Persons' Data
2. Associated Persons Identifier (APID) and Subject, Device, or Study Relationship (SREL)
3. Infant Safety Data Collection in HIV Study



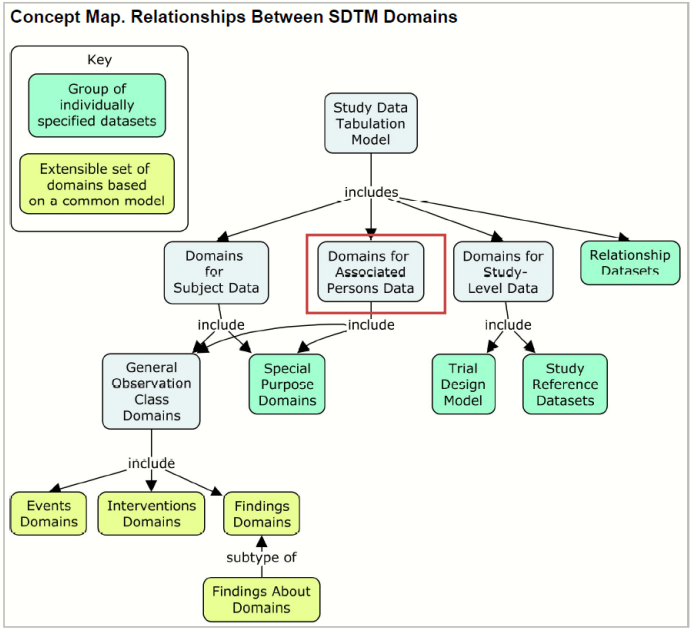
Module 1

Subject Data vs Associated Persons' Data

Subject Data vs Associated Persons' Data

Data may be collected about persons other than the subject under study.

- Associated persons are not themselves subjects in the trial, but data is collected about them.
- The data are about the Associated Person, not the subject (or device).
- The associated person does not have a subject identifier (SUBJID).

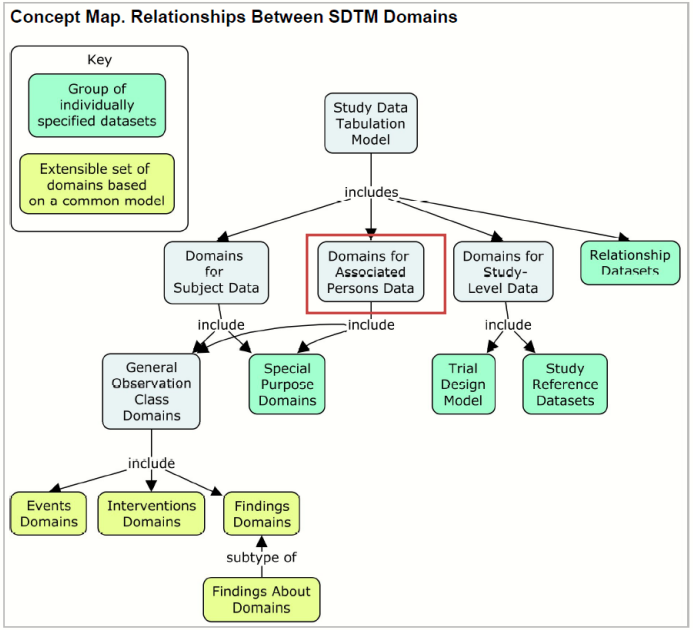


Concept map from SDTM 2.0

Subject Data vs Associated Persons' Data

It is necessary to distinguish associated person's data and keep AP data separate from subject data in submission.

- Associated Persons datasets are given a prefix of AP– .
- Associated Persons records require the population of the APID(Associated Persons Identifier) variable.
- APDM is not a required domain for associated person.



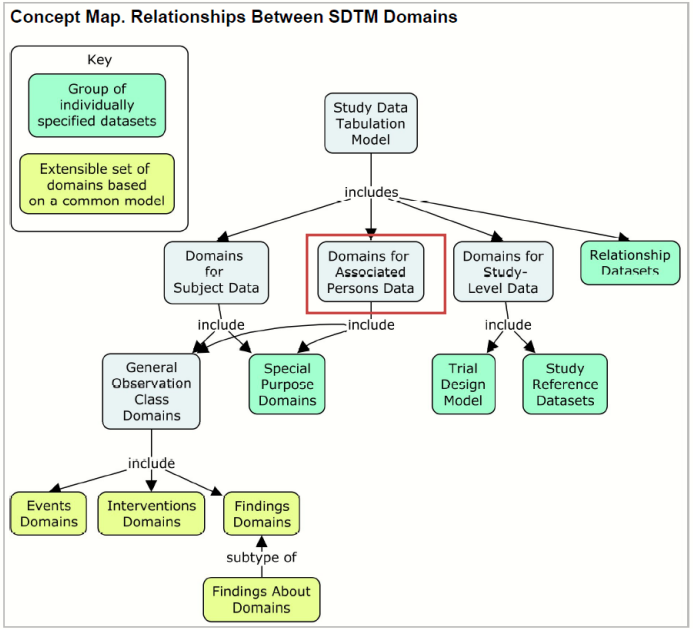
Concept map from SDTM 2.0

Subject Data vs Associated Persons' Data

Domains which describe the progress of a subject through a study(SE, SV, DS etc) are not relevant for associated persons because such persons are not in the study.

The following variables would not generally be used in AP domains because they are usually only applicable to subjects in the study:

- RFSTDTC
- RFXSTDTC
- RFICDTC
- ARMCD
- ACTARMCD
- RFENDTC
- RFXENDTC
- RFPENDTC
- ARM
- ACTARM



Concept map from SDTM 2.0

Module 2

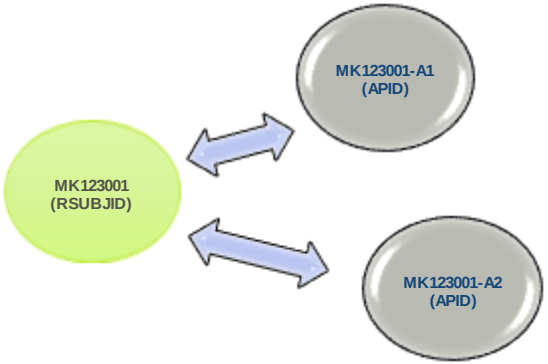
Associated Persons Identifier (APID) and Subject, Device, or Study Relationship (SREL)

Associated Persons Identifier(APID)

Associated Persons Identifier (APID)

--Identifier for a single associated person, a group of associated persons, or a pool of associated persons.

- The same APID should always identify the same associated person which is often a single person but can also be a group of people.
- APID is identifier variable except in APDM(it is a Topic variable in APDM)



A mother gave birth to twins and the assigned associated persons identifiers (APIDs) to infants by following a dash plus a letter and a number ("--A1" and "-A2") to the mother's USUBJID.

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX
MK123	APDM	MK123001-A1	MK123001	CHILD, BIOLOGICAL	M
MK123	APDM	MK123001-A2	MK123001	CHILD, BIOLOGICAL	F

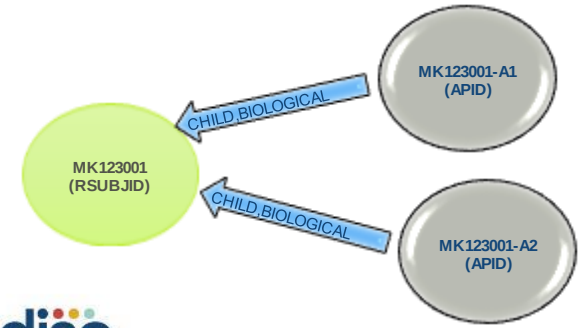
Subject, Device, or Study Relationship(SREL)

Subject, Device, or Study Relationship(SREL)

- *If RSUBJID(Related Subject)is populated, describes the relationship of the associated person(s) identified in APID(Associated Persons Identifier) to the subject or pool identified in RSUBJID (Related Subject).*

- *If RDEVID(Related Device) is populated, describes the relationship of the associated person(s) identified in APID (Associated Persons Identifier) to the subject or pool identified in RDEVID (Related Device).*

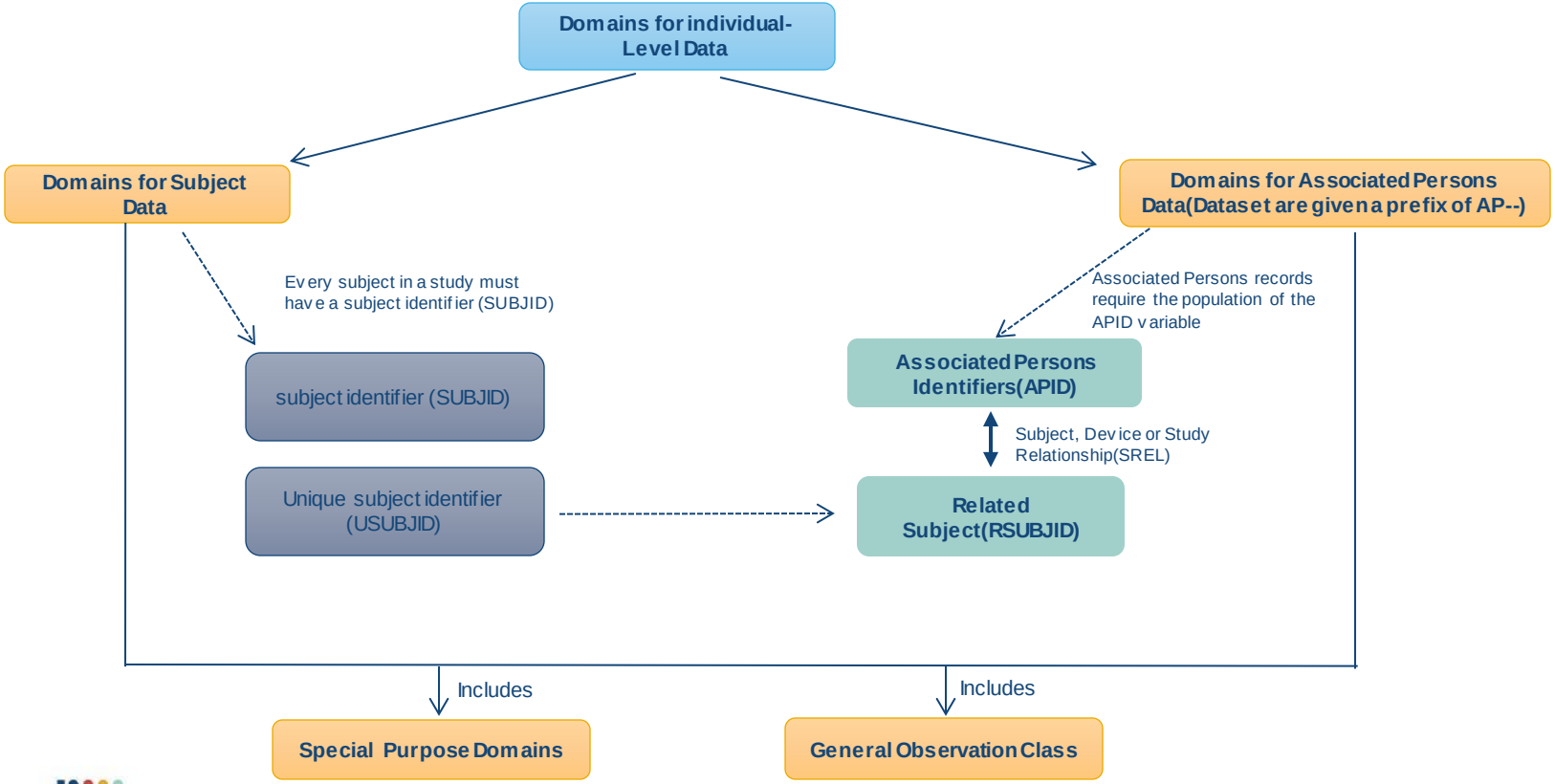
- *If RSUBJID (Related Subject) and RDEVID (Related Device) are null, SREL describes the relationship of the associated person(s) identified in APID (Associated Persons Identifier) to the study identified in STUDYID(Study Identifier).*



A mother gave birth to twins and the assigned associated person identifiers (APIDs) to infants by following a dash plus a letter and a number ("--A1" and "-A2") to the mother's USUBJID.

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX
MK123	APDM	MK123001-A1	MK123001	CHILD, BIOLOGICAL	M
MK123	APDM	MK123001-A2	MK123001	CHILD, BIOLOGICAL	F

Associated Persons Identifiers (APID) and Subject, Device, or Study Relationship (SREL)



Module 3

Infant Safety Data Collection in HIV Study

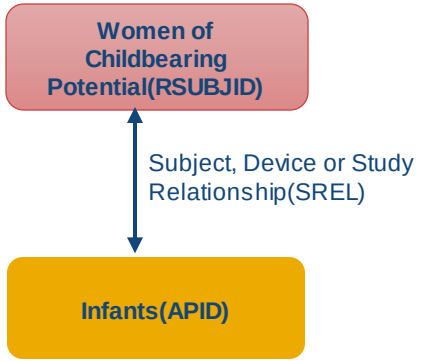
Rationale for Infant Safety Data Collection in HIV Study

- HIV Studies will enroll women of Childbearing Potential as the subject.
- When a subject is pregnant or becomes pregnant, it is important and may be necessary to collect both prenatal and postnatal data on the infant pertaining to overall health and HIV status.
- Infant safety data collection provides the ability to monitor growth and development of the infant as well as potential adverse effects that may be associated with prenatal drug exposure.

Studies that Enroll Women of Childbearing Potential

If a woman of childbearing potential becomes pregnant during a study, the protocol may call for collection of data about the minimal safety data about the infant(s). When the infant is not treated as a study subject, the infant will be considered as an associated person(a non-study subject).

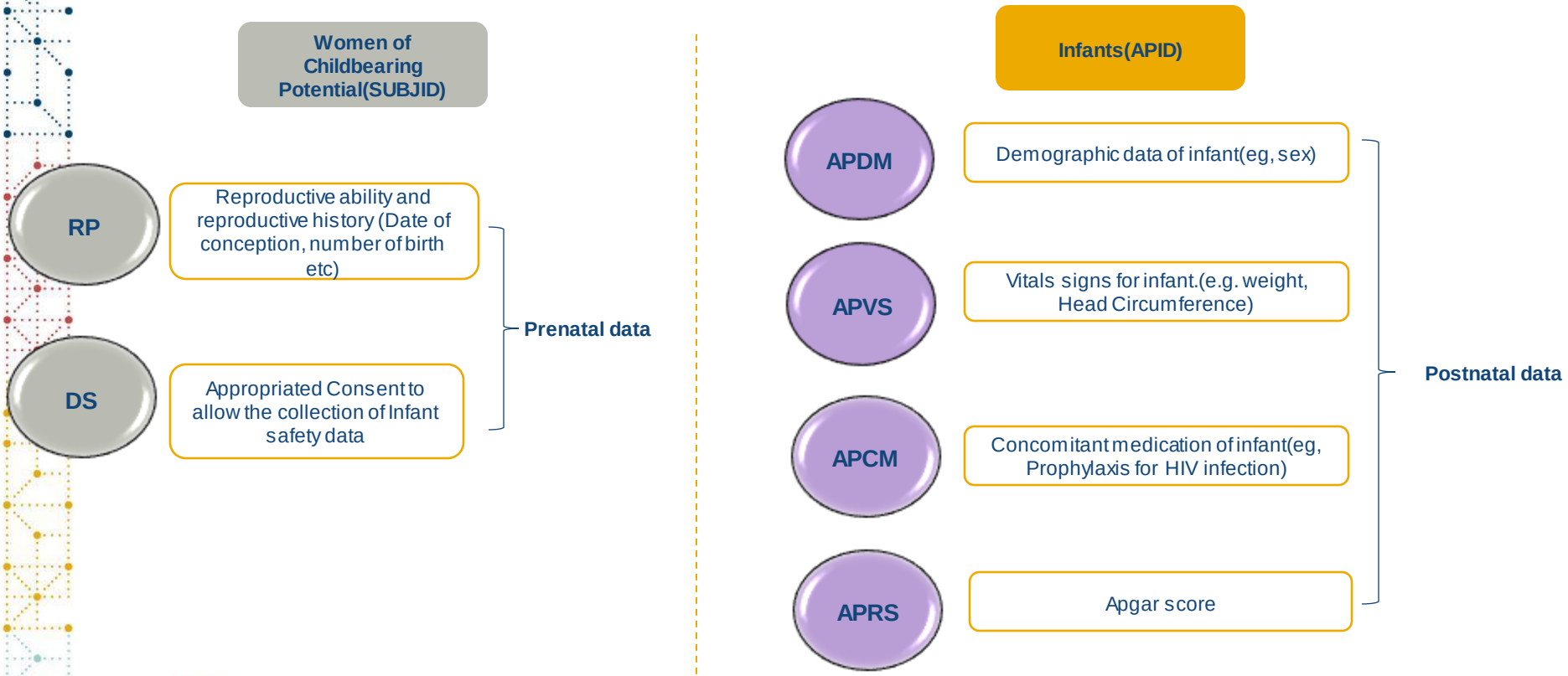
The infant is given an associated person identifier (APID), rather than a unique subject identifier (USUBJID). AP datasets include the APID, the USUBJID of the study subject with whom they are associated (RSUBJID), and a variable (SREL) that describes the relationship of the associated person to the study subject. SREL would be a value such as "CHILD, BIOLOGICAL" for infants of mothers in a study.



A mother gave birth to twins and the assigned associated person identifiers (APIDs) to infants by following a dash plus a letter and a number ("--A1" and "-A2") to the mother's SUBJID.

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX
MK123	APDM	MK123001-A1	MK123001	CHILD, BIOLOGICAL	M
MK123	APDM	MK123001-A2	MK123001	CHILD, BIOLOGICAL	F

Subject Data or Associated Person's Data



Infant data is collected from one single eCRF

For example, only demographic data will be collected for the infant.

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX	BRTHDTC
MK123	APDM	MK123001-A1	MK123001	CHILD, BIOLOGICAL	M	2022-07-21
MK123	APDM	MK123002-A1	MK123002	CHILD, BIOLOGICAL	F	2022-08-21

The eCRF could be designed to collect Infant demographic data only.

- As demographic data will be collected once only for an infant so APID can be derived directly instead of collecting from the eCRF.
- The SREL could be derived as the value will be always “CHILD, BIOLOGICAL’ in the given study.
- The benefit of the design is that less data entry is needed but the challenge is that the eCRF may not be used together with others eCRF for associated persons' data collection.

The infant data are collected from multiple eCRFs

For example, Demographic data and vitals signs are collected from two different eCRFs:

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX	BRTHDTC
MK123	APDM	MK123001-A1	MK123001	CHILD, BIOLOGICAL	M	2022-07-21

STUDYID	DOMAIN	APID	RSUBJID	SREL	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSDTC
MK123	APVS	MK123001-A1	MK123001	CHILD, BIOLOGICAL	WEIGHT	Weight	3.6	kg	3.6	3.6	kg	2022-07-21

As the eCRF may be developed at different time point or the request may come from different studies. Therefore, when designing a new AP–data related eCRF, one of the key point is to consider how to align the APID collection/generation with previous eCRFs.

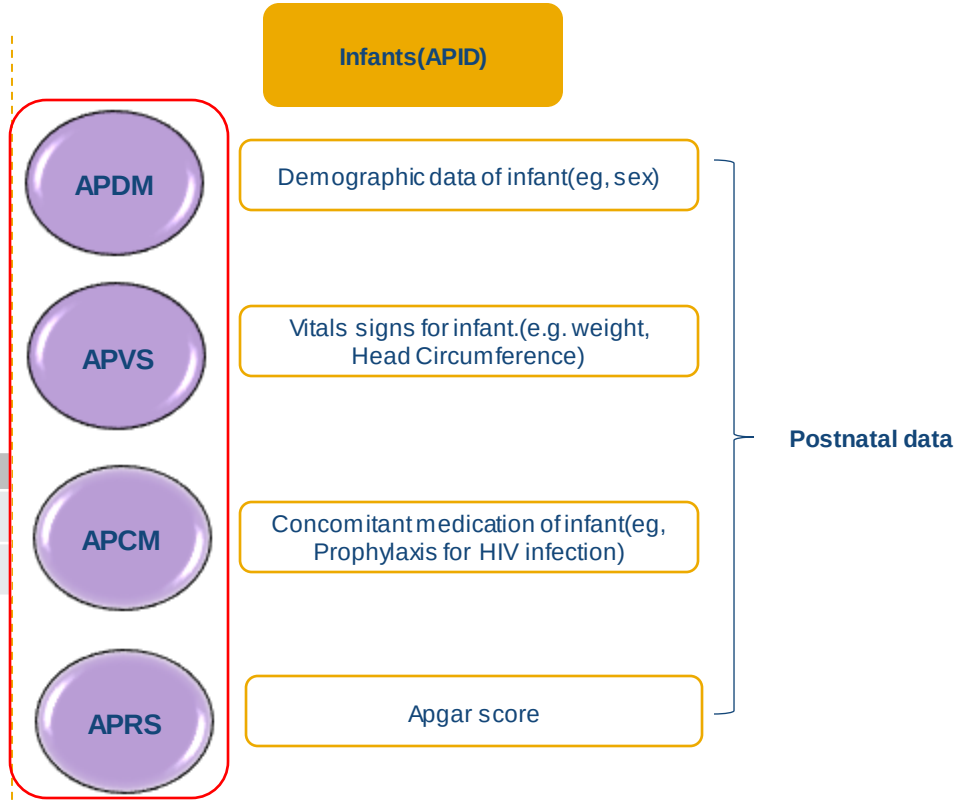
- If there is only one associated person, then the full APID could be derived in both eCRFs by following the same derivation rule.
- The unique identifier could be collected from the eCRF to save data entry efforts(for example, A1,A2) and the full APID could be derived by a derivation rule.

Multiple infants and their data are collected from multiple eCRFs:

There is a possibility that the subject has more than one infant in the study and the challenge is how to ensure the APID collected/generated appropriately for each infant.

A mother gave birth to twins and the assigned associated person identifiers (APIDs) to infants by following a dash plus a letter and a number ("--A1" and "-A2") to the mother's USUBJID.

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX
MK123	APDM	MK123001-A1	MK123001	CHILD, BIOLOGICAL	M
MK123	APDM	MK123001-A2	MK123001	CHILD, BIOLOGICAL	F



Multiple infants and their data are collected from multiple eCRFs:

STUDYID	DOMAIN	APID	RSUBJID	SREL	SEX	BRTHDTC
MK123	APDM	MK123001-A1	MK123001	CHILD, BIOLOGICAL	M	2022-07-21
MK123	APDM	MK123001-A2	MK123001	CHILD, BIOLOGICAL	F	2022-07-21

STUDYID	DOMAIN	APID	RSUBJID	SREL	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSDTC
MK123	APVS	MK123001-A1	MK123001	CHILD, BIOLOGICAL	WEIGHT	Weight	3.6	kg	3.6	3.6	kg	2022-07-21
MK123	APVS	MK123001-A1	MK123001	CHILD, BIOLOGICAL	HEIGHT	Height	45	cm	45	45	cm	2022-07-21
MK123	APVS	MK123001-A2	MK123001	CHILD, BIOLOGICAL	WEIGHT	Weight	3.2	kg	3.2	3.2	kg	2022-07-21
MK123	APVS	MK123001-A2	MK123001	CHILD, BIOLOGICAL	HEIGHT	Height	44	cm	44	44	cm	2022-07-21

- For APID,
  - It could be collected directly from all eCRFs to indicate the data collected is for which infant.
  - The same identifier (A1, A2 etc) could be collected from eCRF to indicate the data is collected for which infant, and a derivation could be used for APID generation.
  - Another method is to indicate associated sequence number to the initial eCRF which has the full APID and we can use the relationship to pull the APID from the initial eCRF.

Summary

In HIV study, the subject may have more than one infant(Associated person) in the data collection and the data could be collected from multiple eCRF.

1. It is important to understand that the data is subject data or associated person's data.
2. If the infant (associated person) data will be collected from multiple eCRFs, how to link those eCRF together to one APID(associated persons identifier) is critical for the eCRF design.
3. If a subject has multiple infants(associated person) and the corresponding data will be collected from multiple eCRF, it is important to consider how to distinguish the data for each associated person.
4. The standard eCRF creation for associated person would consider the flexibility to accommodate the use for different therapeutic area or protocol needs.

Thank You!