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INTERCHANGE
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CDISC Paediatric User Guide: a Successful Academic Collaboration to Improve Paediatric Data Standards

Presented by Becca Leary, Senior Project Manager, Newcastle University
John Owen, Head, PMO, CDISC

Meet the Speakers

John Owen

Title: Head, PMO

Organization: CDISC

John Owen has worked with CDISC for over 7-years. After supporting the project management of various Therapeutic Area User Guides, John now also works in identifying and growing CDISC's development activities to advance standards across a wide range of therapeutic areas and heads up the CDISC Project Management Office. John graduated from The University of Wales, Collage of Cardiff with a Bachelors Degree in Biology. Working within the pharmaceutical industry in clinical data management, clinical programming, and standards development roles

Rebecca Leary

Title: Senior Project Manager (conect4children)

Organization: Newcastle University

Rebecca Leary is a Senior Project Manager with responsibility for the IMI2 funded, conect4children (c4c) project. Rebecca is based in the John Walton Muscular Dystrophy Research Centre at Newcastle University c4c is creating a pan-European clinical trials network for paediatrics, which will address the barriers to delivering effective paediatric clinical trials Rebecca is the co-lead of the data work package in c4c, this work package has a focus on improving the interoperability and harmonisation of paediatric clinical data collecting in clinical trials. Recently she established the Global Paediatric Data Forum to encourage international collaboration around data harmonisation.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *Rebecca Leary and John Owen have no real or apparent conflicts of interest to report.*

Agenda

1. Introduction to c4c
2. What problems are we trying to tackle?
3. Overview of Paediatric User Guide
4. Future of Paediatric data standards

MENTIMETER Poll

Scan Me

Introduction to conect4children (c4c)

Why do we need clinical trials for children?

- There is a need to improve the health outcomes of children.
- 27% of the worlds population are children yet only 16% of trials registered on the WHO portal are paediatric.
- Only 30% of marketed drugs in Europe include a paediatric authorisation and around 50% of medications used in children's hospitals are not properly licensed for use in children.
- Children are not mini adults.
- Development need for age specific therapies.
- Safety and efficacy data on medicines in children is scarce.

Barriers

No network of sites

Varying standards of care across EU

Low interest from industry

Recruitment of patients

Fragmented infrastructure

Rare diseases

Lack of validated outcome measures

Lack of data

Failed Trials

Lack of expertise

Ethics

Increased regulations

conect4children

Better medicines for babies, children and young people through a pan-European clinical trial network

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conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

Expected long term impact of c4c

Access to new experimental therapies for children in well-designed clinical trials

Better training for research personnel and **improved trial readiness** at all participating sites

Improved efficiency in executing trials (faster, cheaper)

More interoperable paediatric data through **data standards**

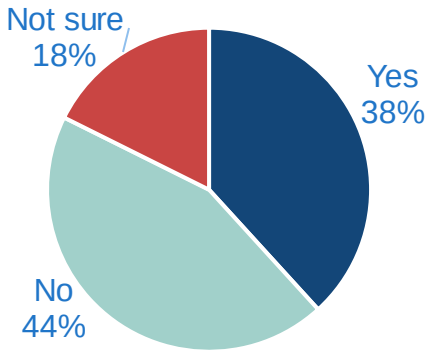
Enhanced role patient/parent advocacy groups in planning and designing studies

Better medicines for all children

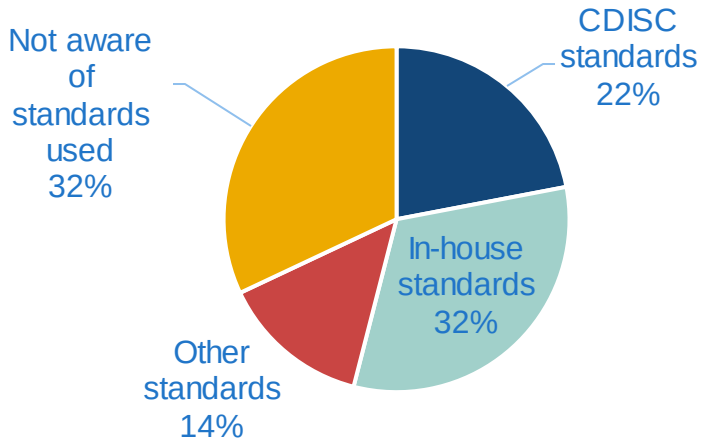
Awareness of data Standards in c4c

Very low awareness of data standards and CDISC among academia.

Thinking about clinical trials you have participated in, are you aware of any formal standards, such as CDISC, being used when constructing CRFs for your trial?

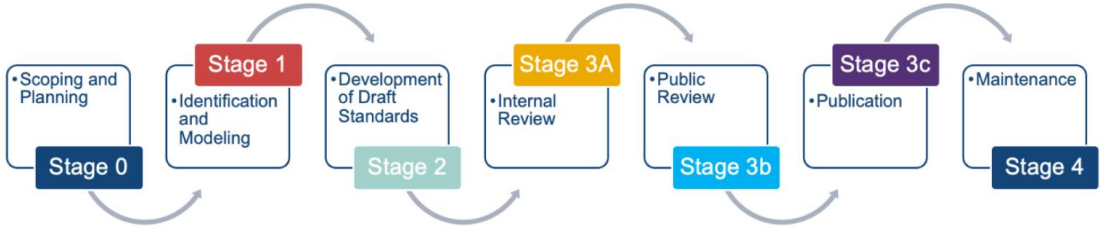


Are you aware of what type of standards have been used in clinical trials you have participated in?



Overview of the Pediatric User Guide

Timelines



CDISC_Standards_Development_Process COP-001

2020	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG												

2021	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG	Stage 0								W1 Stage 1		Stage 2	

2022	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Pediatrics TAUG	Stage 2			Stage 3a		W2 Stage 3b					Stage 3	W3

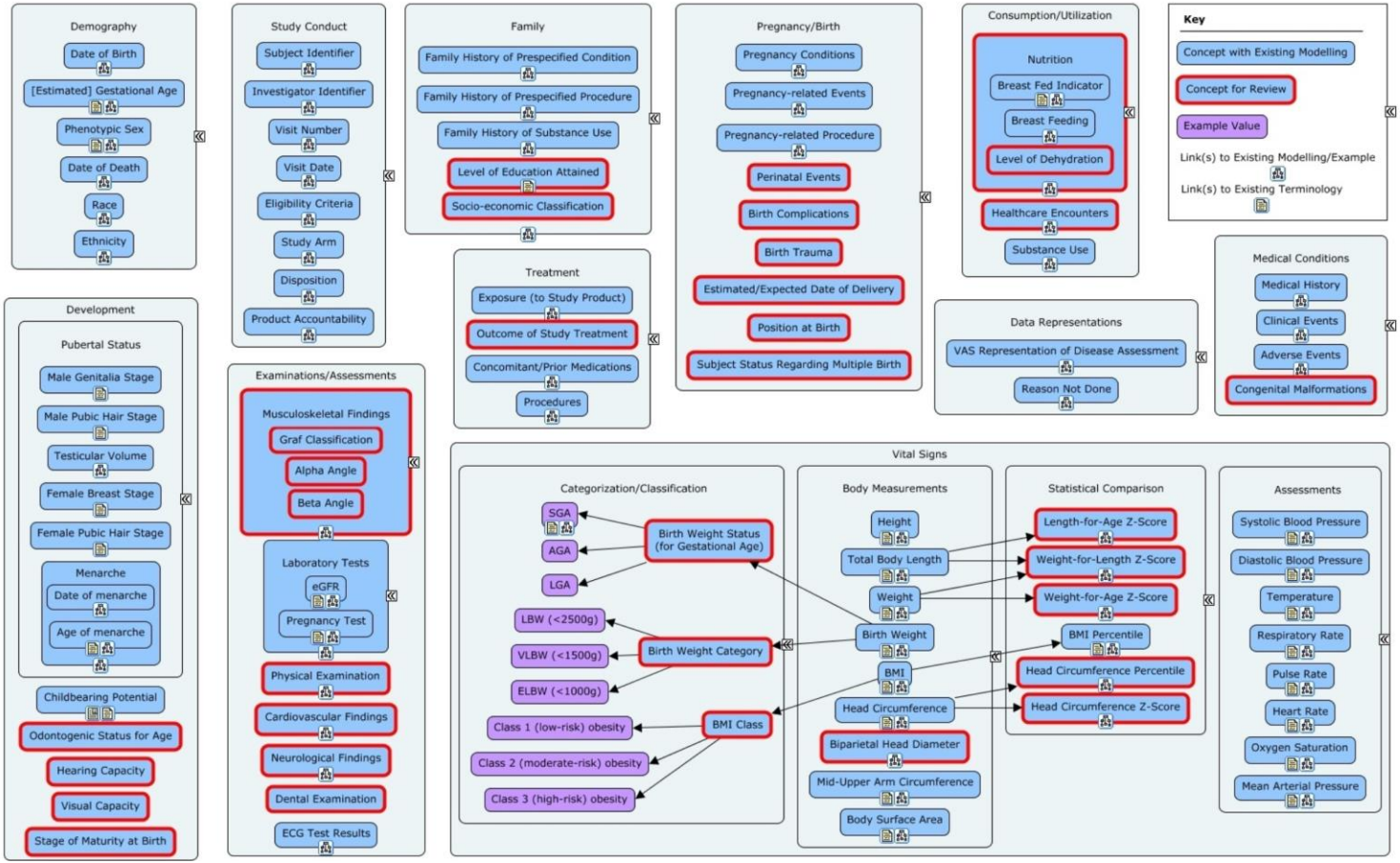
Stage 0	Scoping and Planning
Stage 1	Identification/Modeling of Concepts
Stage 2	Standards Development
Stage 3a	Internal Review
Stage 3b	Public Review
Stage 3c	Publication
W	Public Webinars 1 - Scoping Results 2 - Public Review 3 - Publication

TAUG Deliverable Feb 2023 (M58)
Submission required April 2023 (M60)

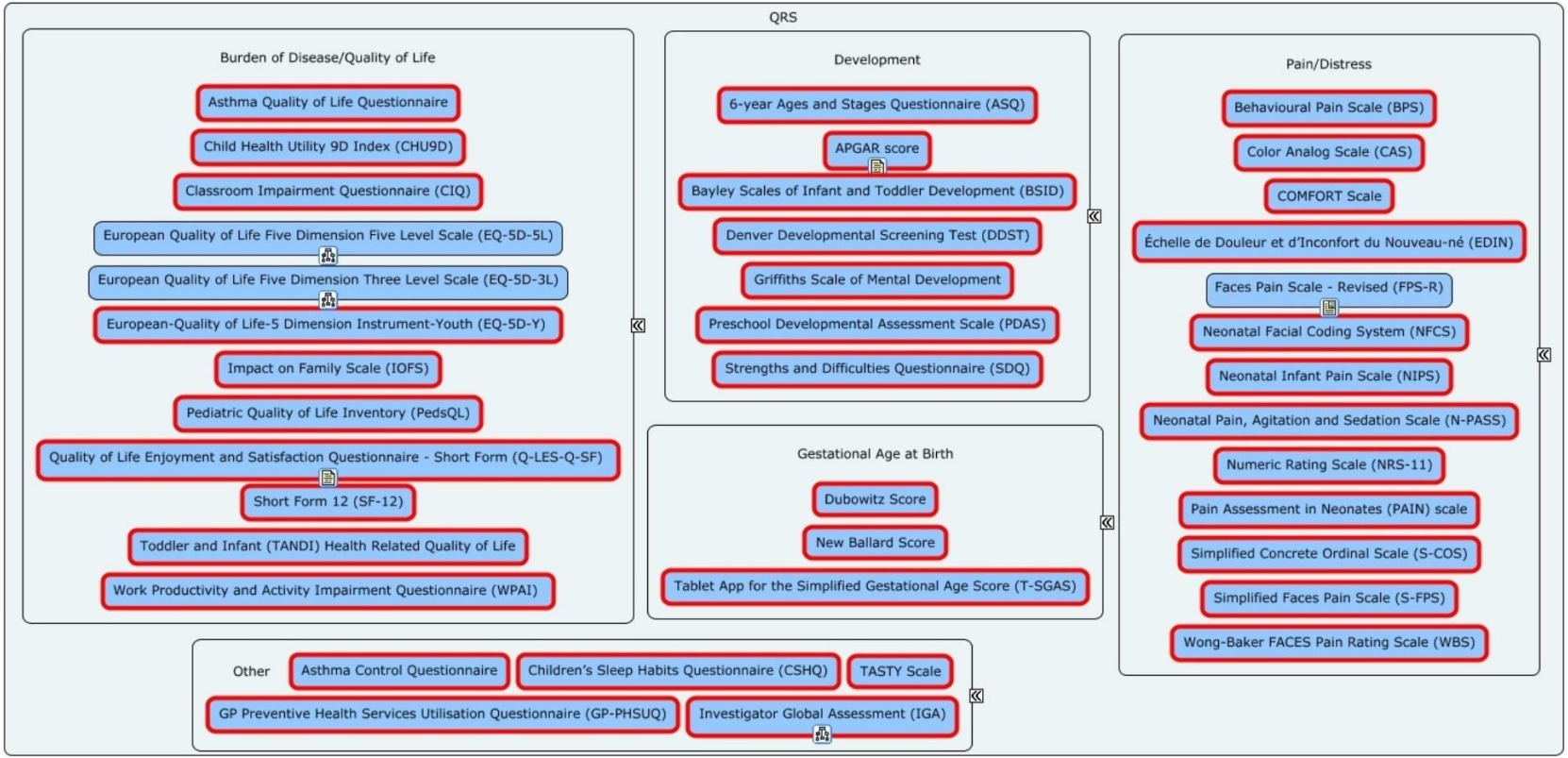
Scoping, Modeling and Standards Development

CDISC formed a cross-functional team with pediatric SMEs from the c4c consortium and CDISC volunteers

Identified pediatric cross-cutting concepts related to pediatric clinical trials



QRS Instruments



QRS Instruments

Group	Scale	Average	Ranking
Neonates	COMFORT Scale	2.683333	1
Neonates	APGAR score	2.75	2
Neonates	Denver Developmental Screening Test (DDST)	4.25	3
Neonates	Neonatal Facial Coding System (NFCS)	4.25	3
Toddlers	Bayley Scales of Infant and Toddler Development (BSID)	1.25	1
Toddlers	6-year Ages and Stages Questionnaire (ASQ)	2.666667	2
Toddlers	COMFORT Scale	2.666667	2
Toddlers	Denver Developmental Screening Test (DDST)	2.833333	3
Children	Denver Developmental Screening Test (DDST)	2.333333	1
Children	Pediatric Quality of Life Inventory (PedsQL)	3.5	2
Children	6-year Ages and Stages Questionnaire (ASQ)	3.777778	3
Children	Griffiths Mental Development Scales (GMDS)	4.111111	4
Adolescents	Pediatric Quality of Life Inventory (PedsQL)	1.833333	1
Adolescents	Impact on Family Scale (IOFS)	3.5	2
Adolescents	COMFORT Scale	3.708333	3
Adolescents	European Quality of Life Five Dimension Instrument-Youth (EQ-5D-Y	3.375	4

Data Standards User Guide for Pediatrics

Version 1.0 (Final)

Prepared by the
Pediatrics Standards Development Team

[redacted]

Notes to Readers

- This is the final Version 1.0 of the Data Standards User Guide for Pediatrics.
- This document is based on CDASH Model v1.2, CDASHIG v2.2, SDTM v2.0, and the SDTM Implementation Guides (SDTMIG v3.4, SDTMIG-AP v1.0, SDTMIG-MD v1.1).

See Appendix E for representations and warranties, limitations of liability, and disclaimers.

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 777389. The Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

The publication reflects input from its contributors and neither the IMI nor the European Union, EFPIA, or any Associated Partners are responsible for any use that may be made of the information contained therein.

CDISC would like to recognize the support of the subject matter experts from the consortium in development of this user guide.

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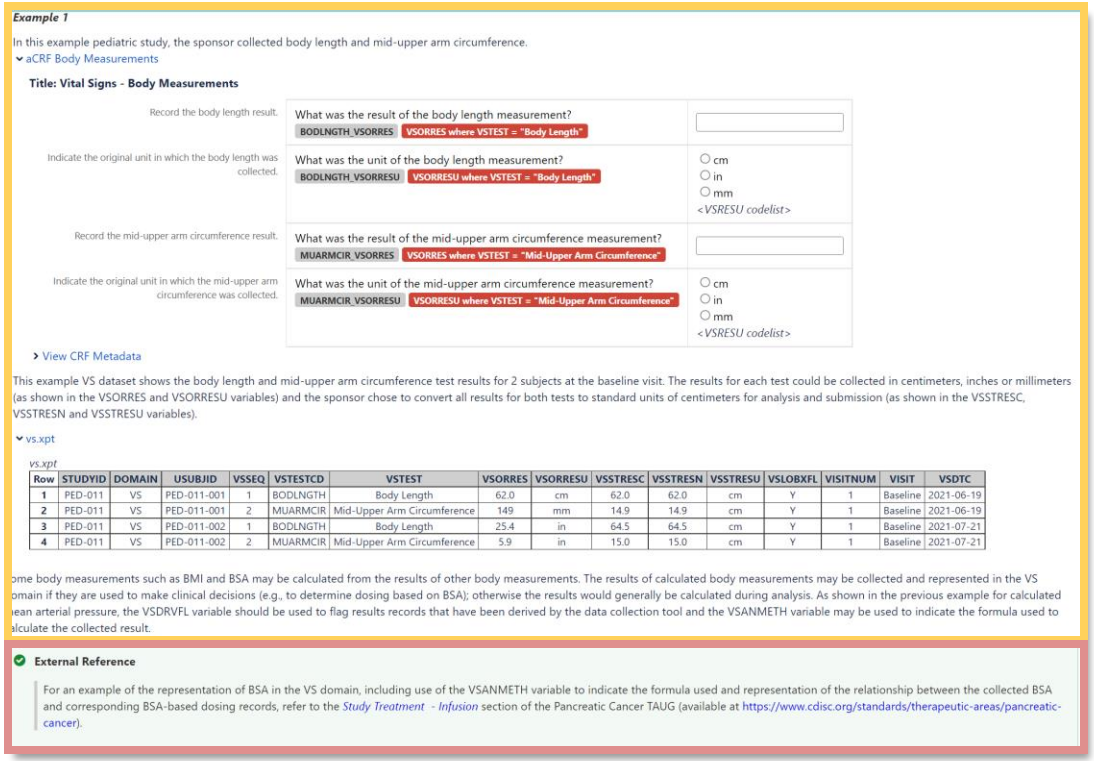
Standards Development

- Develop CDASH CRFs and SDTM Table examples for new concepts

- Links to existing examples of data collection (CDASH) and Data Tabulation (SDTM)



Example 1

In this example pediatric study, the sponsor collected body length and mid-upper arm circumference.

aCRF Body Measurements

Title: Vital Signs - Body Measurements

Record the body length result.	What was the result of the body length measurement? BODLNGTH_VSORRES VSORRES where VSTEST = "Body Length"	
Indicate the original unit in which the body length was collected.	What was the unit of the body length measurement? BODLNGTH_VSORRESU VSORRESU where VSTEST = "Body Length"	○ cm ○ in ○ mm <VSRESU codelist>
Record the mid-upper arm circumference result.	What was the result of the mid-upper arm circumference measurement? MUARMCIR_VSORRES VSORRES where VSTEST = "Mid-Upper Arm Circumference"	
Indicate the original unit in which the mid-upper arm circumference was collected.	What was the unit of the mid-upper arm circumference measurement? MUARMCIR_VSORRESU VSORRESU where VSTEST = "Mid-Upper Arm Circumference"	○ cm ○ in ○ mm <VSRESU codelist>

View CRF Metadata

This example VS dataset shows the body length and mid-upper arm circumference test results for 2 subjects at the baseline visit. The results for each test could be collected in centimeters, inches or millimeters (as shown in the VSORRES and VSORRESU variables) and the sponsor chose to convert all results for both tests to standard units of centimeters for analysis and submission (as shown in the VSSTRESC, VSSTRESN and VSSTRESU variables).

vs.xpt

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSLOBXFL	VISITNUM	VISIT	VSDTC
1	PED-011	VS	PED-011-001	1	BODLNGTH	Body Length	62.0	cm	62.0	62.0	cm	Y	1	Baseline	2021-06-19
2	PED-011	VS	PED-011-001	2	MUARMCIR	Mid-Upper Arm Circumference	149	mm	14.9	14.9	cm	Y	1	Baseline	2021-06-19
3	PED-011	VS	PED-011-002	1	BODLNGTH	Body Length	25.4	in	64.5	64.5	cm	Y	1	Baseline	2021-07-21
4	PED-011	VS	PED-011-002	2	MUARMCIR	Mid-Upper Arm Circumference	5.9	in	15.0	15.0	cm	Y	1	Baseline	2021-07-21

ome body measurements such as BMI and BSA may be calculated from the results of other body measurements. The results of calculated body measurements may be collected and represented in the VS omain if they are used to make clinical decisions (e.g., to determine dosing based on BSA); otherwise the results would generally be calculated during analysis. As shown in the previous example for calculated ean arterial pressure, the VSDRVFL variable should be used to flag results records that have been derived by the data collection tool and the VSANMETH variable may be used to indicate the formula used to alculate the collected result.

External Reference

For an example of the representation of BSA in the VS domain, including use of the VSANMETH variable to indicate the formula used and representation of the relationship between the collected BSA and corresponding BSA-based dosing records, refer to the *Study Treatment - Infusion* section of the Pancreatic Cancer TAUG (available at https://www.cdisc.org/standards/therapeutic-areas/pancreatic-cancer).

Modeling highlights

Gestational Age

Gestational Age

Use of the Subject Characteristics (SC) domain to record multiple assessments for the subject.

EGESTAGE
Estimated Gestational Age

- May be used for antenatal or postnatal assessments
- May be used for multiple assessments for a subject
- The date of estimation is recorded in SCDTC

GSTABRTH
Gestational Age at Birth

- May be used when gestational at birth is of specific interest.
- SCDTC may contain date of estimation or date of collection.
- Useful when
  - Subjects are enrolled after birth and only the subject's gestational age at the time of birth is of interest.
  - The exact date on which the estimation was made is either not available or not of interest.
  - Data privacy regulations prevent recording of a complete date that is identifiable as the subject's date of birth.

Gestational Age

- Collection format: weeks and days

Record the subject's estimated gestational age in completed weeks.	For the subject's estimated gestational age in completed weeks and additional days, what is the number of completed weeks? EGESTAGE_SCRESWKS SCORRES where SCTEST = "Estimated Gestational Age"	
For the subject's estimated gestational age, record the number of days (0-6) in addition to completed weeks.	For the subject's estimated gestational age in completed weeks and additional days, what is the number of additional days? EGESTAGE_SCRESDYS SCORRES where SCTEST = "Estimated Gestational Age"	

- SDTM does not support representation of results in mixed units.
- Gestational age is converted to a single unit (days or weeks) for representation in SDTM.
- SCORRES is used to represent the result in the original units and sponsors may convert the result to a standardized unit (represented in SCSTRESC/SCSTRESN/SCSTRESU) to support analysis.
- Sponsors may choose the appropriate unit to meet study needs.

Gestational Age

- Sponsors may also choose the format in which to represent gestational age results

sc.xpt

Row	STUDYID	DOMAIN	USUBJID	SCSEQ	SCTESTCD	SCTEST	SCORRES	SCORRESU	SCSTRESC	SCSTRESN	SCSTRESU
1	PED111	SC	PED111-01-103	1	GSTABRTH	Gestational Age at Birth	269	DAYS	269	269	DAYS
2	PED222	SC	PED222-01-103	1	GSTABRTH	Gestational Age at Birth	38 3/7	WEEKS	269	269	DAYS
3	PED444	SC	PED444-01-103	1	GSTABRTH	Gestational Age at Birth	38.43	WEEKS	269	269	DAYS
4	PED555	SC	PED555-01-103	1	GSTABRTH	Gestational Age at Birth	269	DAYS	38.43	38.43	WEEKS
5	PED666	SC	PED666-01-103	1	GSTABRTH	Gestational Age at Birth	38 3/7	WEEKS	38.43	38.43	WEEKS
6	PED888	SC	PED888-01-103	1	GSTABRTH	Gestational Age at Birth	38.43	WEEKS	38.43	38.43	WEEKS

- Points to consider when choosing a format:
  - The same standardized result unit (SCSTRESU) must be used for all records for a given test within a submission.
  - Gestational age should not be represented using a unit more precise than the collection unit (e.g. do not convert to days if only weeks were collected).
  - Representation format should be unambiguous (e.g., “38+3” may be misinterpreted as “41”)
  - When converting to weeks choose a precision that will not affect analysis.

Neurological Assessments

Neurological Assessments: Reflexes

- Flexible modelling allows for representation of:
  - A single overall normal/abnormal response for each reflex
  - A normal/abnormal response for each evaluated anatomical location for each reflex
  - A normal/abnormal response for each evaluated anatomical location for each type for stimulus used to elicit each reflex (where applicable).

nv.xpt

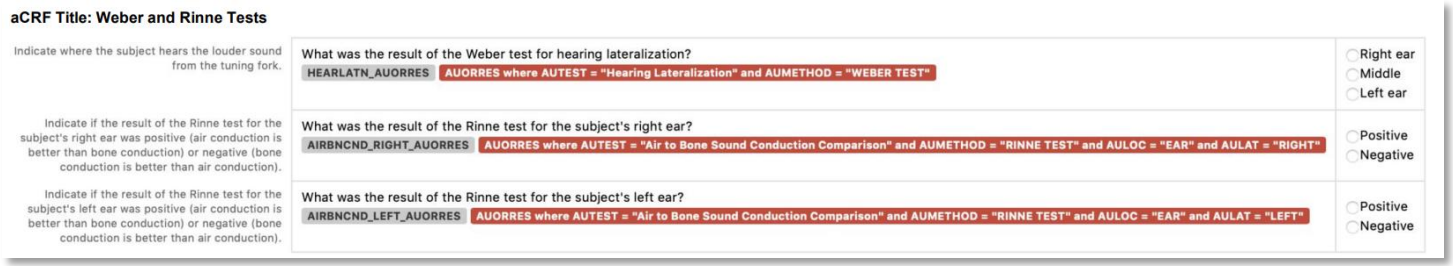
Row	STUDYID	DOMAIN	USUBJID	NVSEQ	NVTESTCD	NVTEST	NVCAT	NVORRES	NVSTRESC	NVLOC	NVLAT	VISITNUM	VISIT	NVDTC	NVSTMDTL
1	PED025	NV	PED025-002	1	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	LEFT	1	Screening	2020-08-05	HEAD TURNED TO RIGHT
2	PED025	NV	PED025-002	2	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	RIGHT	1	Screening	2020-08-05	HEAD TURNED TO RIGHT
3	PED025	NV	PED025-002	3	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	LEFT	1	Screening	2020-08-05	HEAD TURNED TO LEFT
4	PED025	NV	PED025-002	4	ATNR	Asymmetric Tonic Neck Reflex	REFLEXES	ABNORMAL	ABNORMAL	LIMB, UPPER	RIGHT	1	Screening	2020-08-05	HEAD TURNED TO LEFT
5	PED025	NV	PED025-002	5	PLMGRRFX	Palmar Grasp Reflex	REFLEXES	NORMAL	NORMAL	HAND	LEFT	1	Screening	2020-08-05	
6	PED025	NV	PED025-002	6	PLMGRRFX	Palmar Grasp Reflex	REFLEXES	NORMAL	NORMAL	HAND	RIGHT	1	Screening	2020-08-05	
7	PED025	NV	PED025-002	7	PLTGRRFX	Plantar Grasp Reflex	REFLEXES	NORMAL	NORMAL	FOOT	LEFT	1	Screening	2020-08-05	
8	PED025	NV	PED025-002	8	PLTGRRFX	Plantar Grasp Reflex	REFLEXES	NORMAL	NORMAL	FOOT	RIGHT	1	Screening	2020-08-05	
9	PED025	NV	PED025-002	9	MORORFLX	Moro Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	LEFT	1	Screening	2020-08-05	
10	PED025	NV	PED025-002	10	MORORFLX	Moro Reflex	REFLEXES	NORMAL	NORMAL	LIMB, UPPER	RIGHT	1	Screening	2020-08-05	
11	PED025	NV	PED025-002	11	ROOTRFLX	Rooting Reflex	REFLEXES	NORMAL	NORMAL			1	Screening	2020-08-05	RIGHT CHEEK STROKED
12	PED025	NV	PED025-002	12	ROOTRFLX	Rooting Reflex	REFLEXES	ABNORMAL	ABNORMAL			1	Screening	2020-08-05	LEFT CHEEK STROKED
13	PED025	NV	PED025-002	13	STEPRFLX	Stepping Reflex	REFLEXES	NORMAL	NORMAL	LIMB, LOWER	LEFT	1	Screening	2020-08-05	
14	PED025	NV	PED025-002	14	STEPRFLX	Stepping Reflex	REFLEXES	NORMAL	NORMAL	LIMB, LOWER	RIGHT	1	Screening	2020-08-05	
15	PED025	NV	PED025-002	15	GLNTRFLX	Galant Reflex	REFLEXES	NORMAL	NORMAL			1	Screening	2020-08-05	RIGHT OF SPINE STROKED
16	PED025	NV	PED025-002	16	GLNTRFLX	Galant Reflex	REFLEXES	ABSENT	ABSENT			1	Screening	2020-08-05	LEFT OF SPINE STROKED
17	PED025	NV	PED025-002	17	SUCKRFLX	Sucking Reflex	REFLEXES	NORMAL	NORMAL			1	Screening	2020-08-05	

NV NSV Metadata

Variable	Label	Type	Role	Origin
NVSTMDTL	Stimulus Detail	text	Non-standard Variable Qualifier of --TESTCD	CRF

Auricular Findings (AU) Domain

- **New Findings domain** for the representation of findings relating to the structure and function of the auditory system.
- Examples include:
  - Weber and Rinne Tests



au.xpt

Row	STUDYID	DOMAIN	USUBJID	AUSEQ	AUTESTCD	AUTEST	AUORRES	AUSTRESC	AULOC	AULAT	AUMETHOD	VISITNUM	VISIT	AUDTC
1	PED028	AU	PED028-001	1	HEARLATN	Hearing Lateralization	MIDDLE	MIDDLE			WEBER TEST	1	Screening	2013-09-28
2	PED028	AU	PED028-001	2	AIRBNCND	Air to Bone Sound Conduction Comparison	POSITIVE	POSITIVE	EAR	RIGHT	RINNE TEST	1	Screening	2013-09-28
3	PED028	AU	PED028-001	3	AIRBNCND	Air to Bone Sound Conduction Comparison	POSITIVE	POSITIVE	EAR	LEFT	RINNE TEST	1	Screening	2013-09-28
4	PED028	AU	PED028-002	1	HEARLATN	Hearing Lateralization	RIGHT	RIGHT			WEBER TEST	1	Screening	2013-10-05
5	PED028	AU	PED028-002	2	AIRBNCND	Air to Bone Sound Conduction Comparison	POSITIVE	POSITIVE	EAR	RIGHT	RINNE TEST	1	Screening	2013-10-05
6	PED028	AU	PED028-002	3	AIRBNCND	Air to Bone Sound Conduction Comparison	NEGATIVE	NEGATIVE	EAR	LEFT	RINNE TEST	1	Screening	2013-10-05

Pregnancy and Birth Data

Representation of Pregnancy and Birth Data

- Representation of data relating to pregnancy and birth can be challenging because the data can include information:

Primarily about the mother

- Medical conditions experienced by the mother during pregnancy
- Medications taken by the mother during pregnancy

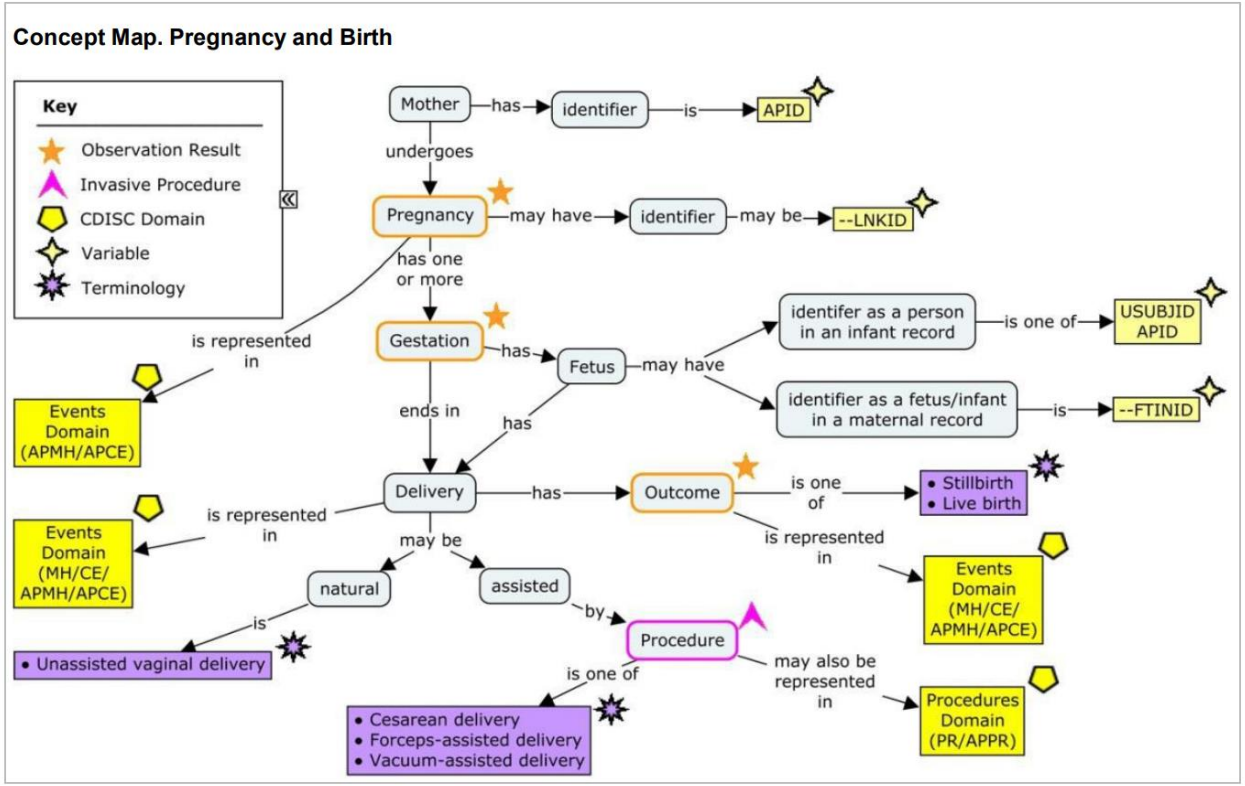
Primarily about the fetus/infant

- Estimation of gestational age
- Fetal measurements such as head circumference

Primarily about the Mother and fetus/infant

- Events such as delivery and pregnancy outcome that are experienced by both mother and subject,
- Delivery procedures such as cesarean delivery and assisted delivery that are performed on both the mother and the subject

Representation of Pregnancy and Birth Data



Representation of Pregnancy and Birth Data

- Information primarily about the mother is represented in Associated Persons (AP) domains.

apsu.xpt

Row	STUDYID	DOMAIN	APID	SUSEQ	RSUBJID	SREL	SULNKID	SUTRT	SUPRESP	SUOCCUR	VISITNUM	VISIT	SUDTC	SUEVINTX
1	PED15	APSU	PED15-001-M	1	PED15-001	MOTHER, BIOLOGICAL		OPIOIDS	Y	N	1	Screening	2020-07-17	DURING PREGNANCY
2	PED15	APSU	PED15-002-M	1	PED15-002	MOTHER, BIOLOGICAL	NAS	OPIOIDS	Y	Y	1	Screening	2020-07-23	DURING PREGNANCY
3	PED15	APSU	PED15-003-M	1	PED15-003	MOTHER, BIOLOGICAL	NAS	OPIOIDS	Y	Y	1	Screening	2020-08-05	DURING PREGNANCY

- When the subject is uniquely identifiable, information primarily about the subject is represented in subject-related domains.

vs.xpt

Row	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VISITNUM	VSDTC
1	PED-678	VS	103	1	HDCIRC	Head Circumference	25	cm	25	25	cm	3	2016-04-16
2	PED-678	VS	104	1	HDCIRC	Head Circumference	28	cm	28	28	cm	3	2016-04-16

- When the subject is not uniquely identifiable, information primarily about subjects may be represented in AP domains as information about the mother.

apvs.xpt

Row	STUDYID	DOMAIN	APID	VSSEQ	RSUBJID	SREL	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VISITNUM	VSDTC	VSFTINID
1	PED-789	APVS	103M	1	MULTIPLE	MULTIPLE	FTHDCIRC	Fetal Head Circumference	25	cm	25	25	cm	3	2016-04-16	1
2	PED-789	APVS	103M	2	MULTIPLE	MULTIPLE	FTHDCIRC	Fetal Head Circumference	28	cm	28	28	cm	3	2016-04-16	2

APVS NSV Metadata

Variable	Label	Type	Role	Origin
VSFTINID	Fetus/Infant Identifier	integer	Non-standard Identifier	CRF

Informed Consent / Assent

Informed Consent / Assent

- **Informed consent** may be obtained from the subjects parent(s), legal guardian/custodian, or other legally authorized representative (LAR).
- **Informed assent** may be obtained from subjects old enough to understand the purpose of the study, but below the age of maturity.
- Subjects may need to provide **informed consent** on their own behalf on reaching the age of maturity.
- The obtaining of informed consent is represented in the DS domain, even if consent is obtained from a parent/guardian, because consent is for the subject.

ds.xpt

Row	STUDYID	DOMAIN	USUBJID	DSSEQ	DSTERM	DSDECOD	DSCAT	EPOCH	DSSTDTC
1	PED767	DS	PED767-001	1	INFORMED CONSENT OBTAINED	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2016-02-22
2	PED767	DS	PED767-001	2	INFORMED ASSENT OBTAINED	INFORMED ASSENT OBTAINED	PROTOCOL MILESTONE	SCREENING	2016-02-22
3	PED767	DS	PED767-001	3	INFORMED CONSENT OBTAINED AT AGE OF LEGAL CONSENT	INFORMED CONSENT OBTAINED	PROTOCOL MILESTONE	TREATMENT	2017-04-12

Challenges, Successes and the Future

Challenges

- Varied SME group often new to standards (inc. CDISC Standards)
- Maintaining the scope to cross-cutting concepts
- Bridging the gaps between Pediatric care and clinical research
- Limited Funding
  - CDASH and SDTM only

Successes

- Rounded knowledge of Pediatric Research
- Maintaining the scope to cross-cutting concepts
- Building a cross-functional, engaged SME group
- 39 separate data collection /representation examples which:
  - Illustrate 34 of the items identified as concepts, and
  - Comprise 72 individually developed example components (33 CDASH and 39 SDTM examples)

The Future

- Creation of a CDISC Pediatric User Group
- c4c sustainability in the form of a new legal entity
- Continue engagement with c4c and CDISC to continue the momentum

Thank You!