

Data sharing and Interoperability

The c4c approach

Rebecca Leary-WP5 lead- Newcastle University

ERICA Webinar

Why Share data?

- Despite scientific advances, safety and efficacy data on the use of medicines in children is scarce.



- There is increasing awareness about the importance of data sharing, particularly in publicly funded research.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2019
EMA/144064/2019

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clinic

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CENTER FOR GLOBAL CLINICAL RESEARCH DATA



Several regulators, research bodies, learned societies and EFPIA have published on the importance, principles and challenges of data sharing and data reuse.

American Medical Association Journal of Ethics

December 2015, Volume 17, Number 12: 1152-1159

POLICY FORUM

US Federal Government Efforts to Improve Clinical Trial Transparency with Expanded Trial Registries and Open Data Sharing

Daniel L. Shaw and Joseph S. Ross, MD, MHS

Why use data standards?

- Data standards provide structure and meaning to data
- Allows for easier data-reuse
- Interoperability and data sharing
- Adherence to FAIR data principles

cdisc

Clinical
Data
Interchange
Standards
Consortium

Solution 1 Standardise your data!

Paediatric User Guide in collaboration with CDISC

The image shows the front cover of a document titled "Data Standards User Guide for Pediatrics Version 1.0 (Final)". At the top is the CDISC logo. Below it, the title and version are centered. Underneath, it says "Prepared by the Pediatrics Standards Development Team". A thick black horizontal bar is present below the team name. Below that is a grey box with the heading "Notes to Readers" and two bullet points. At the bottom of the cover, there are several lines of small text regarding funding and disclaimers, followed by logos for IMI, EFPIA, and Conect 4children.

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Data Standards User Guide for Pediatrics
Version 1.0 (Final)

Prepared by the
Pediatrics Standards Development Team

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).

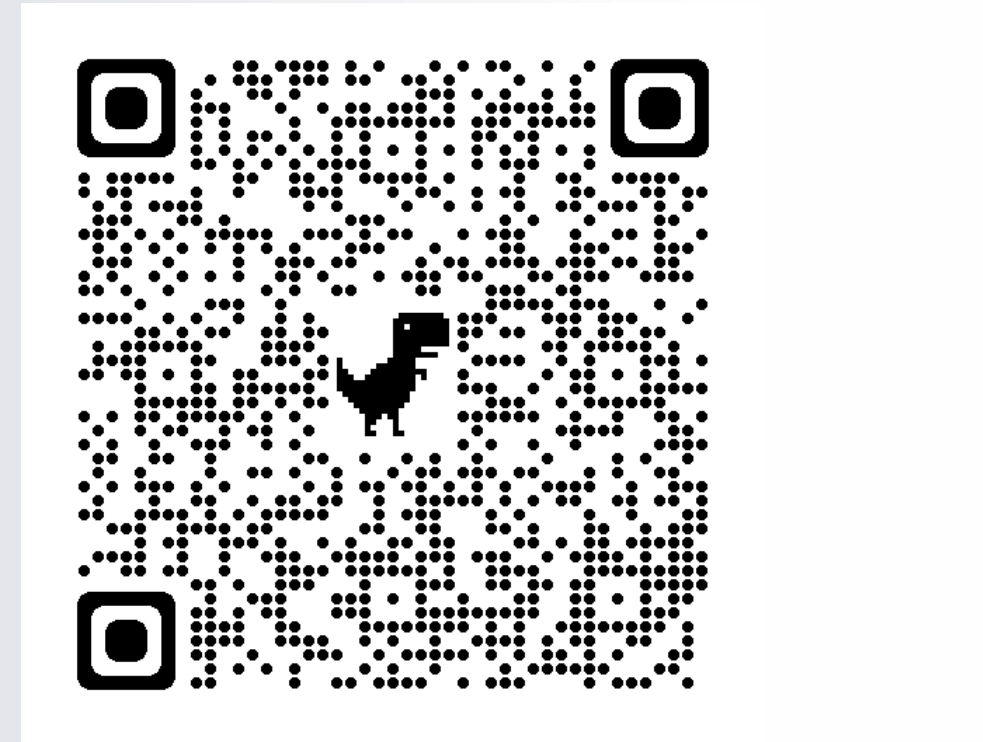
See [Appendix E](#) for representations and warranties, limitations of liability, and disclaimers.

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.

innovative medicines initiative

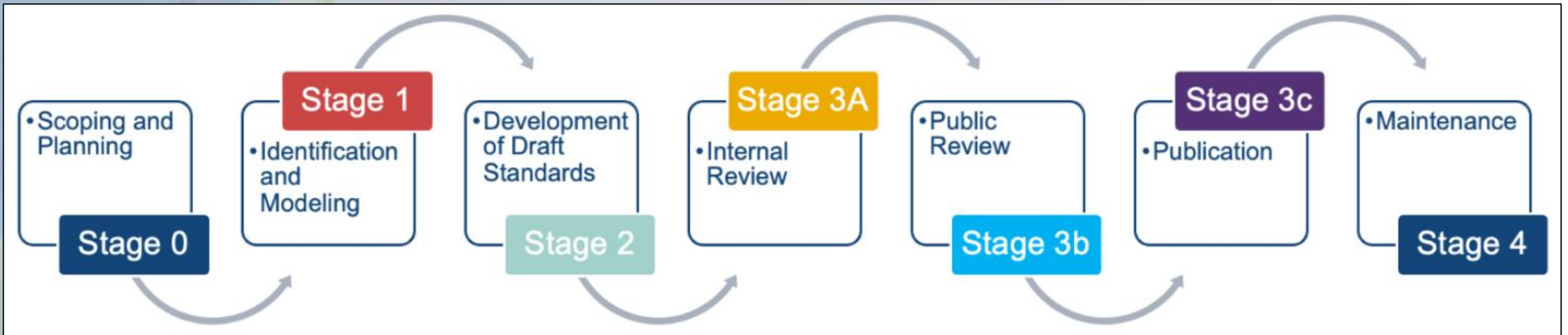


Development of the Paediatric User Guide (PUG)

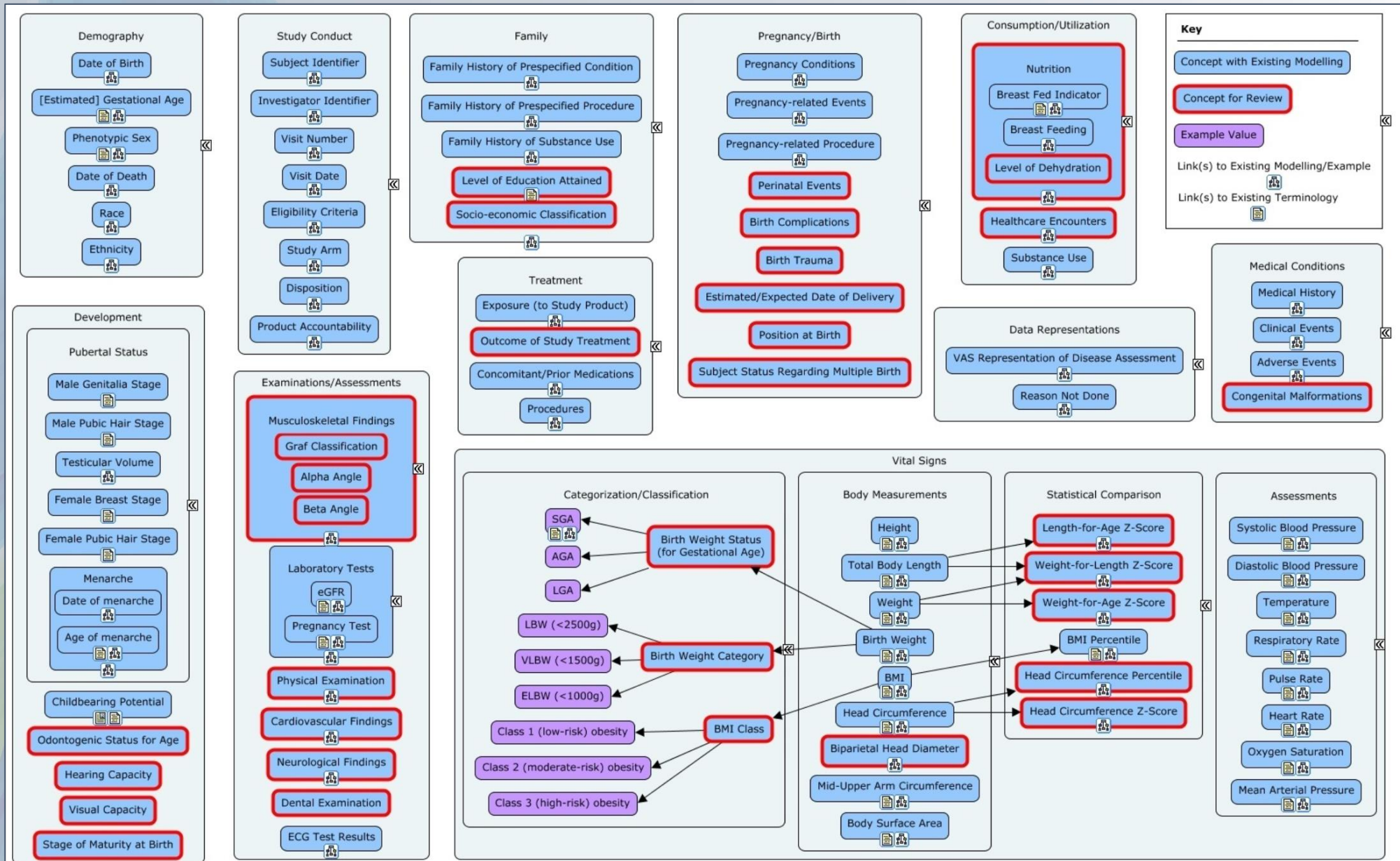
Data items had to be cross-cutting and frequently used in clinical trials

A group of expert volunteers from c4c and CDISC was established

Weekly calls were held for 26 Months!



Scoping, Modelling and Standards Development





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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

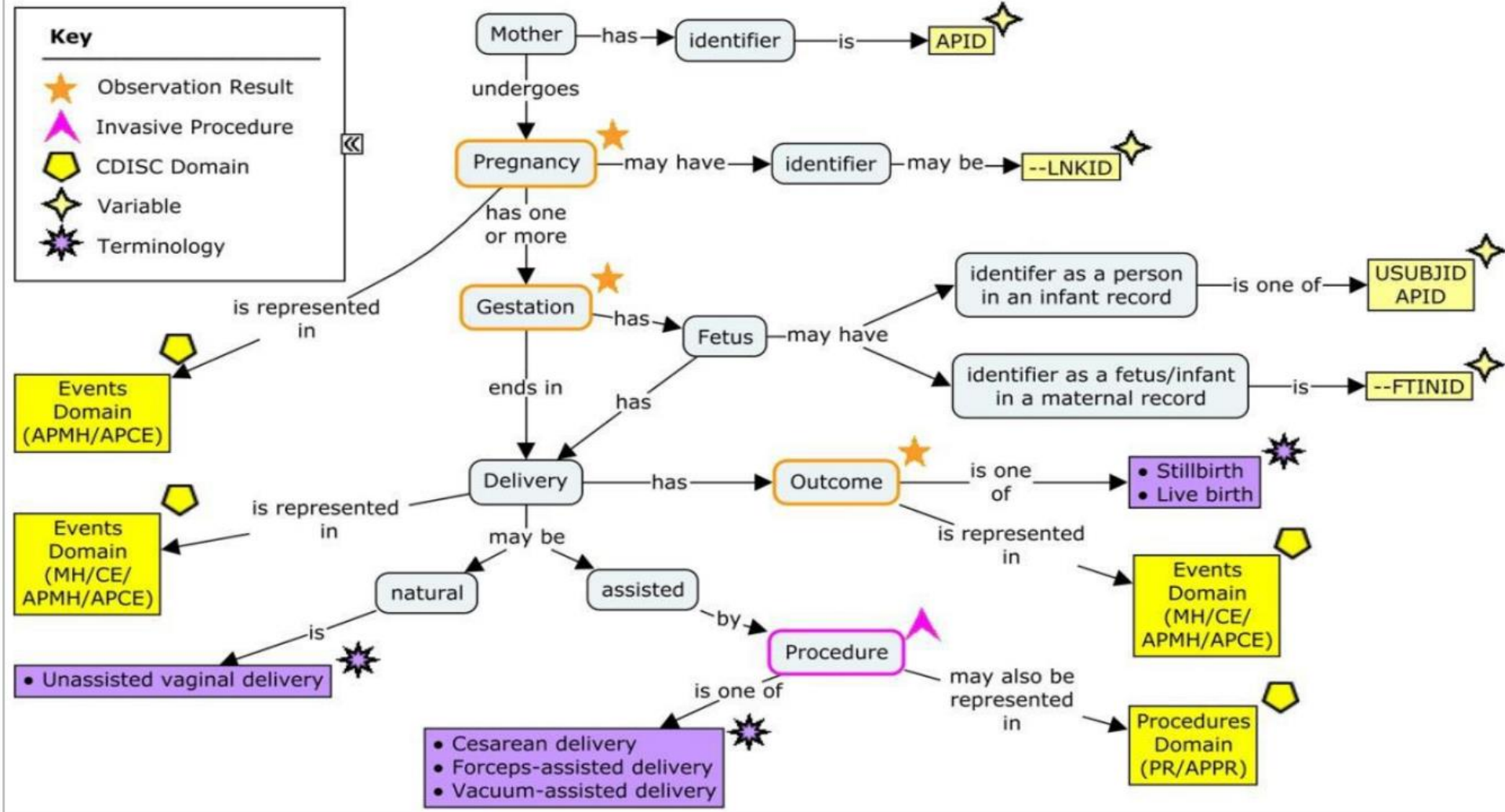
- Estimation of gestational age
- Fetal measurements such as head circumference

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 caesarean delivery and assisted delivery that are performed on both the mother and the subject

Representation of Pregnancy and Birth Data

Concept Map. Pregnancy and Birth



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

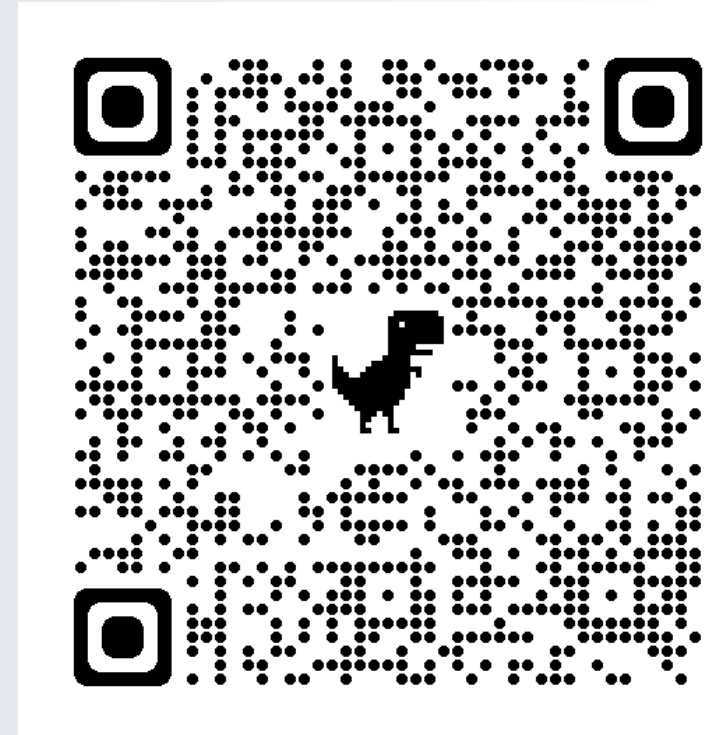
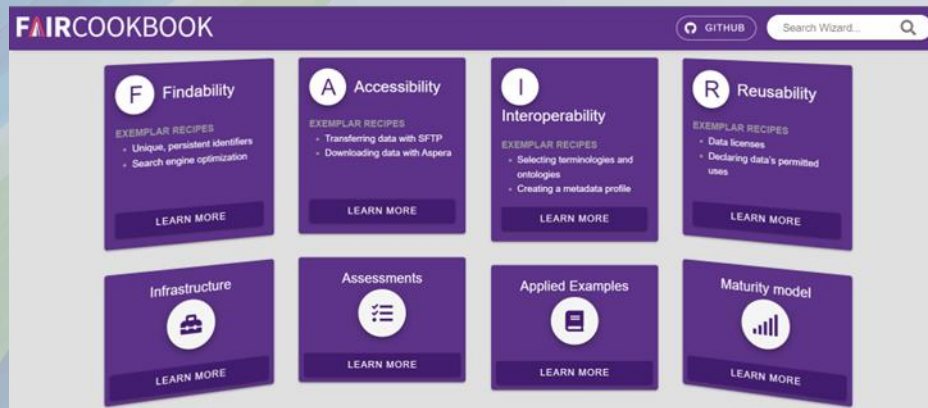
Row	STUDYID	DOMAIN	APID	VSSEQ	RSUBJID	SREL	VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VISITNUM	VSDTC	VSFTINID
1	PED-789	APVS	103M	1	MULTIPLE	MULTIPLE	FTHDCIRC	Fetal Head Circumference	25	cm	25	25	cm	3	2016-04-16	1
2	PED-789	APVS	103M	2	MULTIPLE	MULTIPLE	FTHDCIRC	Fetal Head Circumference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

Solution 2- Apply the FAIR principles

Increase the FAIR-ness of paediatric metadata



Solution 3- Reuse your data

Work ongoing to explore linking EHR data with clinical trial data to improve trial planning and delivery.

Publication Expected later year.

Early results show:

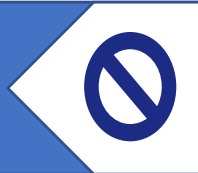
- a lack of coding in EHR
- Diversity of systems used
- Gaps in disease specific data



Solution 4- Share learning!

Create a global paediatric data forum (GLOPAD)

Avoid duplication in the field



Identify collaborative opportunities

Ensure c4c can address the paediatric-specific aspects of data harmonisation, by partnering with others.



Ensure relevant initiatives and projects meet the needs of the paediatric / RD population

Ensure that the paediatric clinical research community is both using and shaping the best possible tools and resources.



Create and maintain a log of each initiative, vision and opportunities

Consider scaling capabilities for a 'Rosetta stone' type of solution



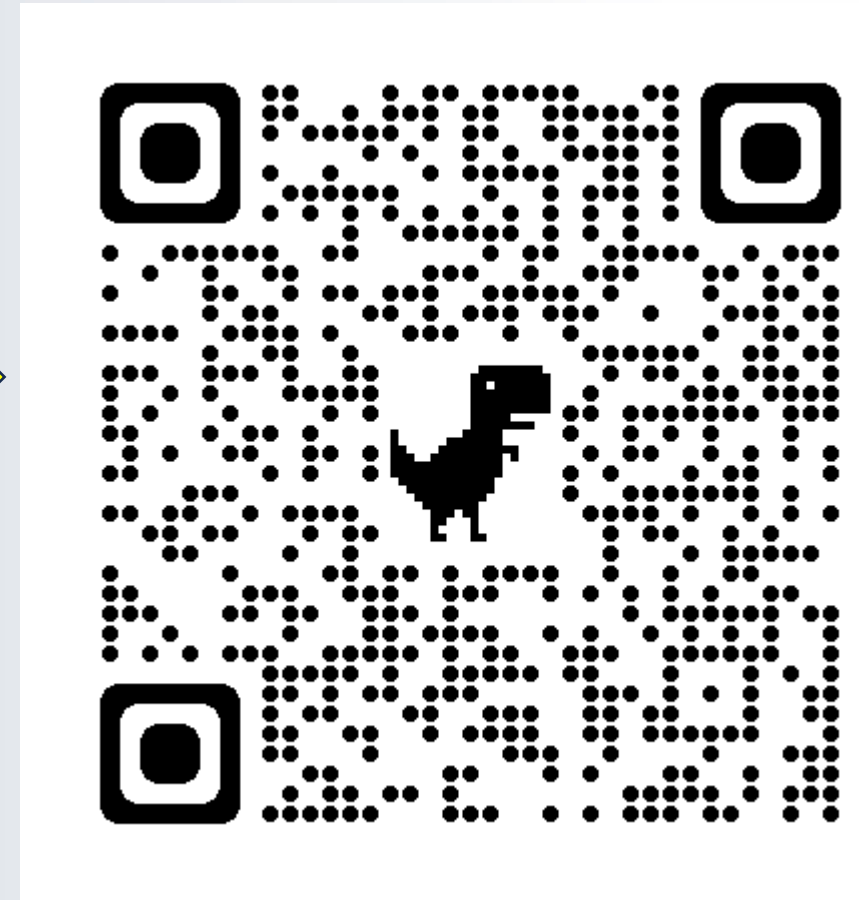
Raise awareness of data interoperability and the FAIR principles

Lobbying?



Long term: Service brokerage.

Read Our Papers here



Thank you for your attention!

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