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Decentralized Semantics WG Weekly Meeting

8 September 2020

 THE **LINUX** FOUNDATION

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Agenda

1. Welcome (Paul—5 mins)
2. Newcomer Introductions (5 mins)
3. Task Force/Focus Group Updates (10 mins)
4. Presentation: Interoperable schema (Robert—10 mins)
5. Discussion: Schema extensions (Paul—10 mins)
6. Logistics (Paul—5 mins)
 - a. Chairs
 - b. Meeting schedule

Newcomer Introductions

(30 seconds!)

1. Name
2. Location / time zone
3. Affiliation(s)
4. One-sentence summary of your interest in Decentralized Semantics (or **one particular semantics-related** issue you personally want to see solved)

Task Force/Focus Group Updates

(10 mins)

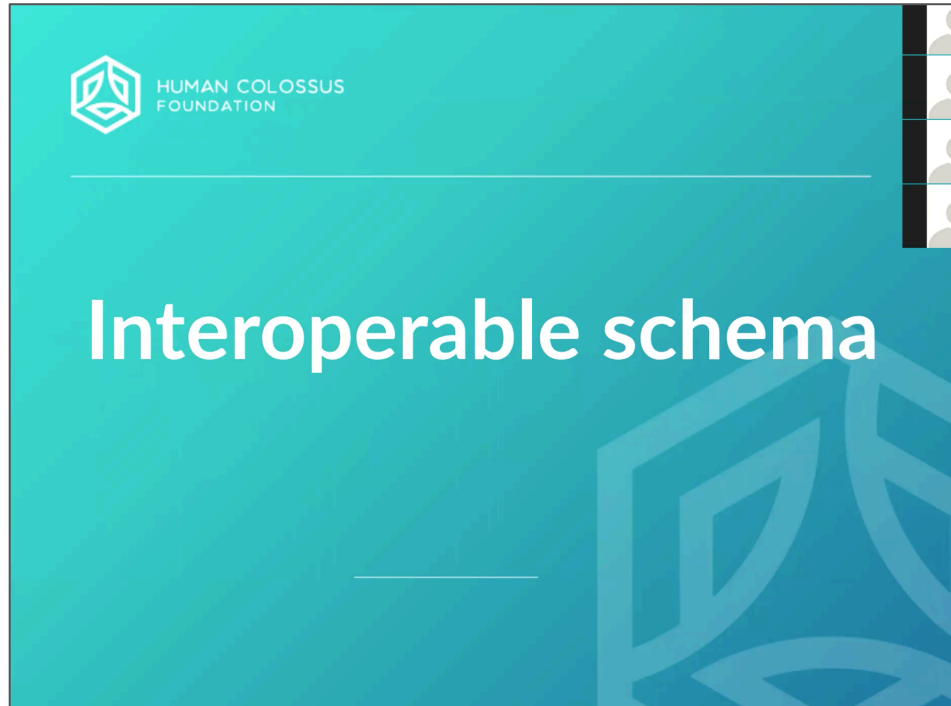
- Imaging TF (Scott/Moira)
- Medical Information TF (Scott/Moira)
- ✓ FHIR-OCA Object Transformation FG (John/Mukund)
- Notice & Consent TF (Mark/Sal)

Presentation: Interoperable schema (10 mins)

Presented by: R.Mitwicki

https://wiki.hyperledger.org/display/II/Agenda?preview=/36734080/39617940/20200902%20IIO%20Vision%20For%20Interoperable%20Schema_0.mp4

Interoperable schema



Zoom recording from *Indy Interop-athon*:

https://wiki.hyperledger.org/display/II/Agenda?preview=/36734080/39617940/20200902%20IIO%20Vision%20For%20Interoperable%20Schema_0.mp4

Discussion: Schema extensions (10 mins)

Presented by: P.Knowles

<https://editor.oca.argo.colossi.network>

“Demographics” dataset

Here is an SDTM dataset, DM (Demographics):

STUDYID	DOMAIN	USUBJID	AGE	SEX	RACE	INTTFL	PPROTFL
199840	DM	2254	37	F	American Indian or Alaska Native	N	N
199840	DM	2255	52	M	Black or African	Y	N
199840	DM	2256	48	F	Asian	Y	Y

SDTM Implementation Guide v.3.2: Demographics (DM)

SDTM defines a standard structure for human clinical trial data tabulations and for nonclinical study data tabulations that are to be submitted as part of a product application to a regulatory authority such as the United States Food and Drug Administration.

CDISC SDTM Implementation Guide (Version 3.2)

5 Models for Special-Purpose Domains

Demographics (DM)

DM – Description/Overview for the Demographics Domain Model

The Demographics domain includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects.

DM – Specification for the Demographics Domain Model

dm.xpt, Demographics — Version 3.2. One record per subject, Tabulation

Variable Name	Variable Label	Type	Controlled Terms, Codelist or Format	Role	CDISC Notes	Core
STUDYID	Study Identifier	Char		Identifier	Unique identifier for a study.	Req
DOMAIN	Domain Abbreviation	Char	DM	Identifier	Two-character abbreviation for the domain.	Req
USUBJID	Unique Subject Identifier	Char		Identifier	Identifier used to uniquely identify a subject across all studies for all applications or submissions involving the product. This must be a unique number, and could be a compound identifier formed by concatenating STUDYID-SITEID-SUBJID.	Req
SUBJID	Subject Identifier for the Study	Char		Topic	Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.	Req
RFSTDTDC	Subject Reference Start Date/Time	Char	ISO 8601	Record Qualifier	Reference Start Date/time for the subject in ISO 8601 character format. Usually equivalent to date/time when subject was first exposed to study treatment. Required for all randomized subjects; will be null for all subjects who did not meet the milestone the date requires, such as screen failures or unassigned subjects.	Exp
RFENDTC	Subject Reference End Date/Time	Char	ISO 8601	Record Qualifier	Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time when subject was determined to have ended the trial, and often equivalent to date/time of last exposure to study treatment. Required for all randomized subjects; null for screen failures or unassigned subjects.	Exp
RFXSTDTDC	Date/Time of First Study Treatment	Char	ISO 8601	Record Qualifier	First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTDC.	Exp
RFXENDTC	Date/Time of Last Study Treatment	Char	ISO 8601	Record Qualifier	Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTDC if EXENDTC was not collected or is missing).	Exp

“Demographics” dataset: Standard variables

Here is an SDTM dataset, DM (Demographics):

STUDYID	DOMAIN	USUBJID	AGE	SEX	RACE	INTTFL	PPROTFL
199840	DM	2254	37	F	American Indian or Alaska Native	N	N
199840	DM	2255	52	M	Black or African	Y	N
199840	DM	2256	48	F	Asian	Y	Y

In DM we have the standard SDTM data:

- STUDYID – this is the Study ID
- DOMAIN – the dataset domain code
- USUBJID – the unique subject identifier
- AGE, SEX, RACE – the patient’s age, sex and race

“Demographics” dataset: Supplementary variables

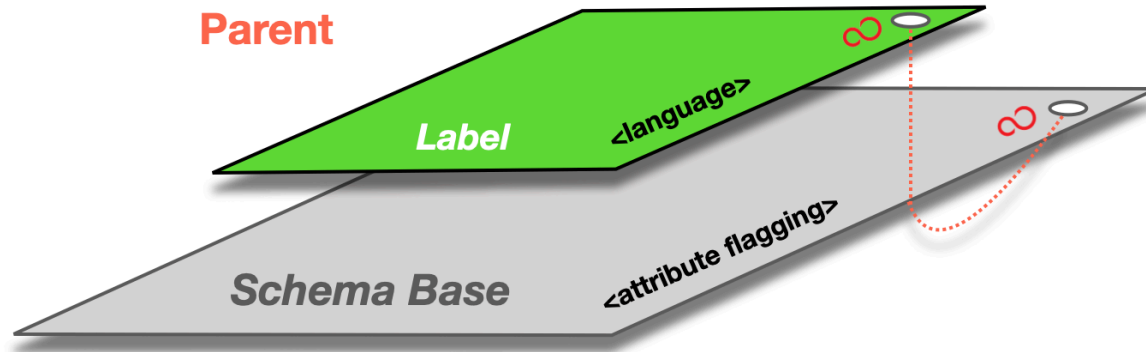
Here is an SDTM dataset, DM (Demographics):

STUDYID	DOMAIN	USUBJID	AGE	SEX	RACE	INTTFL	PPROTFL
199840	DM	2254	37	F	American Indian or Alaska Native	N	N
199840	DM	2255	52	M	Black or African	Y	N
199840	DM	2256	48	F	Asian	Y	Y

And in addition, we have two population flag variables that aren't included in the SDTM:

- INTTFL - Intent to Treat
- PPROTFL - Per Protocol

Option 1: Parent schema



Option 1: Parent schema base: “Demographics-DM”

Unique DRI for “Demographics-DM” schema base :

hl:b6MPrSsq35AxinSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK

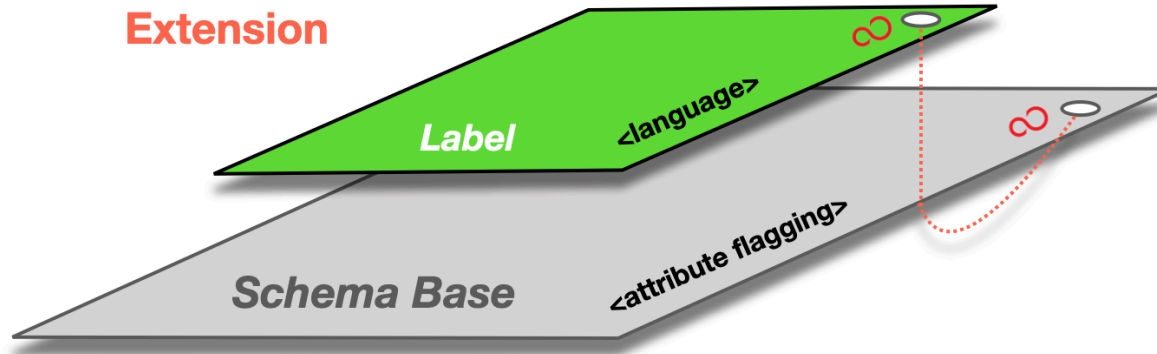
```
{
  "@context": "https://odca.tech/v1",
  "name": "Demographics-DM",
  "type": "spec/schema_base/1.0",
  "description": "The DM (Demographics) domain includes a set of essential standard variables that describe",
  "classification": "GICS:35202010",
  "daisy_chain": "",
  "issued_by": "",
  "attributes": {
    "STUDYID": "Text",
    "DOMAIN": "Text",
    "USUBJID": "Text",
    "AGE": "Number",
    "SEX": "Text",
    "RACE": "Text"
  },
  "attr_blinding": [
    "STUDYID",
    "USUBJID"
  ]
}
```

Option 1: Label overlay for “Demographics-DM”

```
{
  "@context": "https://odca.tech/overlays/v1",
  "type": "spec/overlay/label/1.0",
  "issued_by": "",
  "role": "",
  "purpose": "",
  "schema_base": "hl:b6MPrSsq35AxiNSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK",
  "language": "en_US",
  "attr_labels": {
    "STUDYID": "Study Identifier",
    "DOMAIN": "Domain Abbreviation",
    "USUBJID": "Unique Subject Identifier",
    "SUBJID": "Subject Identifier for the Study",
    "AGE": "Age",
    "SEX": "Sex",
    "RACE": "Race"
  },
  "attr_categories": [
  ],
  "cat_labels": {
  },
  "cat_attributes": {
  }
}
```

Reference parent
schema base

Option 1: Schema extension



Option 1: Schema extension: “DM population flags”

Unique DRI for “DM population flags” schema base:

hl:zQmbYhSNM7c9bM1KFGecETDjfERJiqj9abWGPkzHqYo1ZMY

```
{
  "@context": "https://odca.tech/v1",
  "name": "DM population flags",
  "type": "spec/schema_base/1.0",
  "description": "A schema extension for the DM (Demographics) domain used to capture population flags",
  "classification": "GICS:35202010",
  "daisy_chain": "hl:b6MPrSsq35AxiNSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK",
  "issued_by": "",
  "attributes": {
    "INTTFL": "Boolean",
    "PPROTFL": "Boolean"
  },
  "attr_blinding": [
  ]
}
```

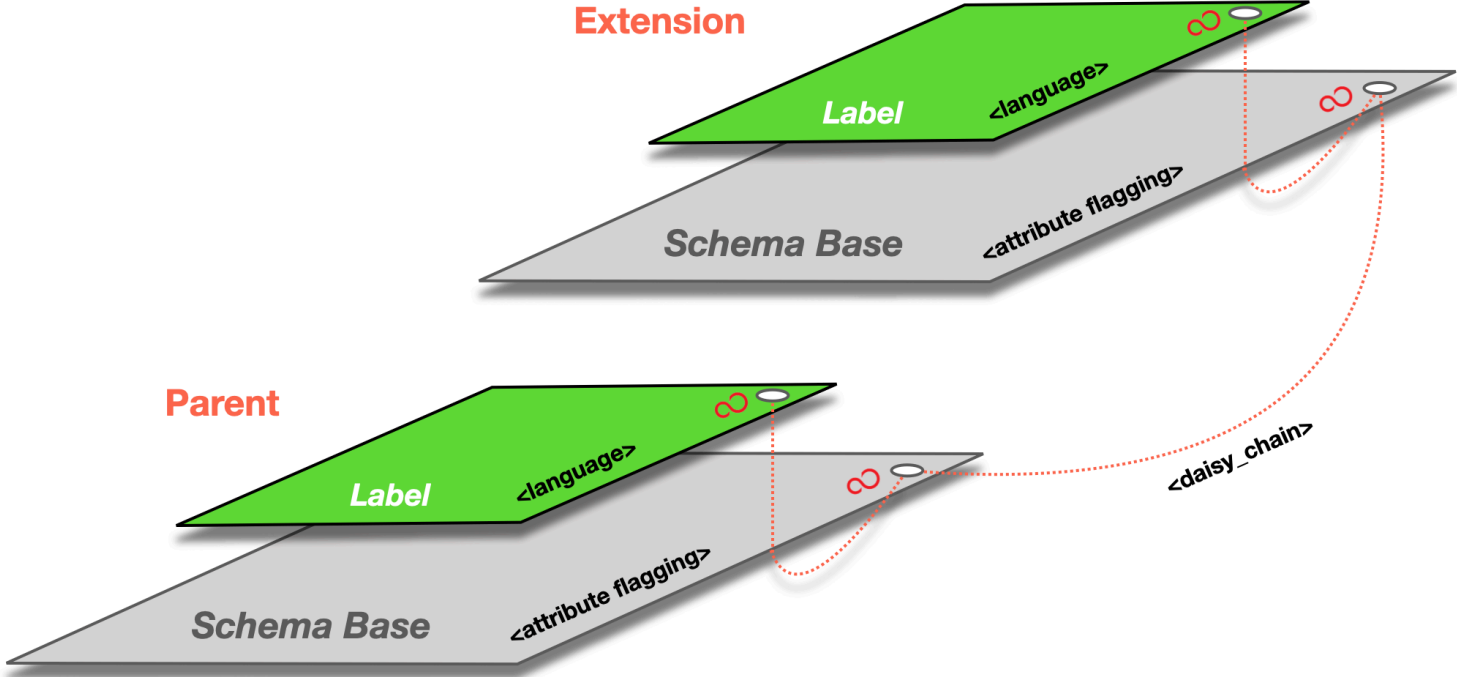
Reference parent schema base
(“Demographics-DM”)

Option 1: Label overlay for “DM population flags”

```
{
  "@context": "https://odca.tech/overlays/v1",
  "type": "spec/overlay/label/1.0",
  "issued_by": "",
  "role": "",
  "purpose": "",
  "schema_base": "h1:zQmbYhSNM7c9bM1KFGecETDjfERJiqj9abWGpKzHqYo1ZMY",
  "language": "en_US",
  "attr_labels": {
    "INTTFL": "Intent to Treat Population Flag",
    "PPROTFL": "Per Protocol Population Flag"
  },
  "attr_categories": [
  ],
  "cat_labels": {
  },
  "cat_attributes": {
  }
}
```

Reference extension
schema base

Option 1: Daisy-chaining a parent schema and an extension schema



Option 2: Schema extension: “DM population flags”

Unique DRI for “DM population flags” schema base:

hl:zQmbYhSNM7c9bM1KFGecETDjfERJiqj9abWGPkzHqYo1ZMY

```
{
  "@context": "https://odca.tech/v1",
  "name": "DM population flags",
  "type": "spec/schema_base/1.0",
  "description": "A schema extension for the DM (Demographics) domain used to capture population flags",
  "classification": "GICS:35202010",
  "issued_by": "",
  "@id": "hl:b6MPrSsq35AxinSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK",
  "attributes": {
    "INTTFL": "Boolean",
    "PPROTFL": "Boolean"
  },
  "attr_blinding": [
  ]
}
```

Reference parent schema base
("Demographics-DM")

Option 2: Label overlay for “DM population flags”

```
{
  "@context": "https://odca.tech/overlays/v1",
  "type": "spec/overlay/label/1.0",
  "issued_by": "",
  "role": "",
  "purpose": "",
  "schema_base": "h1:zQmbYhSNM7c9bM1KFGecETDjfERJiqj9abWGpKzHqYo1ZMY",
  "language": "en_US",
  "@id": "bsrS9qoxMKznXZ6emG9C3eRarZzPDNde8ysw43DYfMrG",
  "attr_labels": {
    "INTTFL": "Intent to Treat Population Flag",
    "PPROTFL": "Per Protocol Population Flag"
  },
  "attr_categories": [
  ],
  "cat_labels": {
  },
  "cat_attributes": {
  }
}
```

Reference extension
schema base

Reference parent
Label overlay

Chairs

- › As a Working Group, we elect our own chairs
 - › At least one, and up to three
 - › Two or three is recommended to spread out the load
- › We can periodically rotate chairs as needed
- › Volunteers now?

Meeting schedule

- › Call timing
 - › **ToIP Decentralized Semantics WG**
Every Tuesday starting
09:00 PT, 12:00 ET, 17:00 UK, 18:00 CET
- › Next meeting
 - › September 15th, 2020



Closing Q & A

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