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Decentralized Semantics WG Weekly Meeting

25 August 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. Demo: Parsing a .CSV file to create JSON files for OCA objects (Paul—15 mins)
5. FHIR-OCA FG: Scheduling a working call to discuss priority use cases (Mukund and John—10 mins)
6. OCA Specification document: Contribution and RFCs (Robert—10 mins)
7. 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

(15 mins)

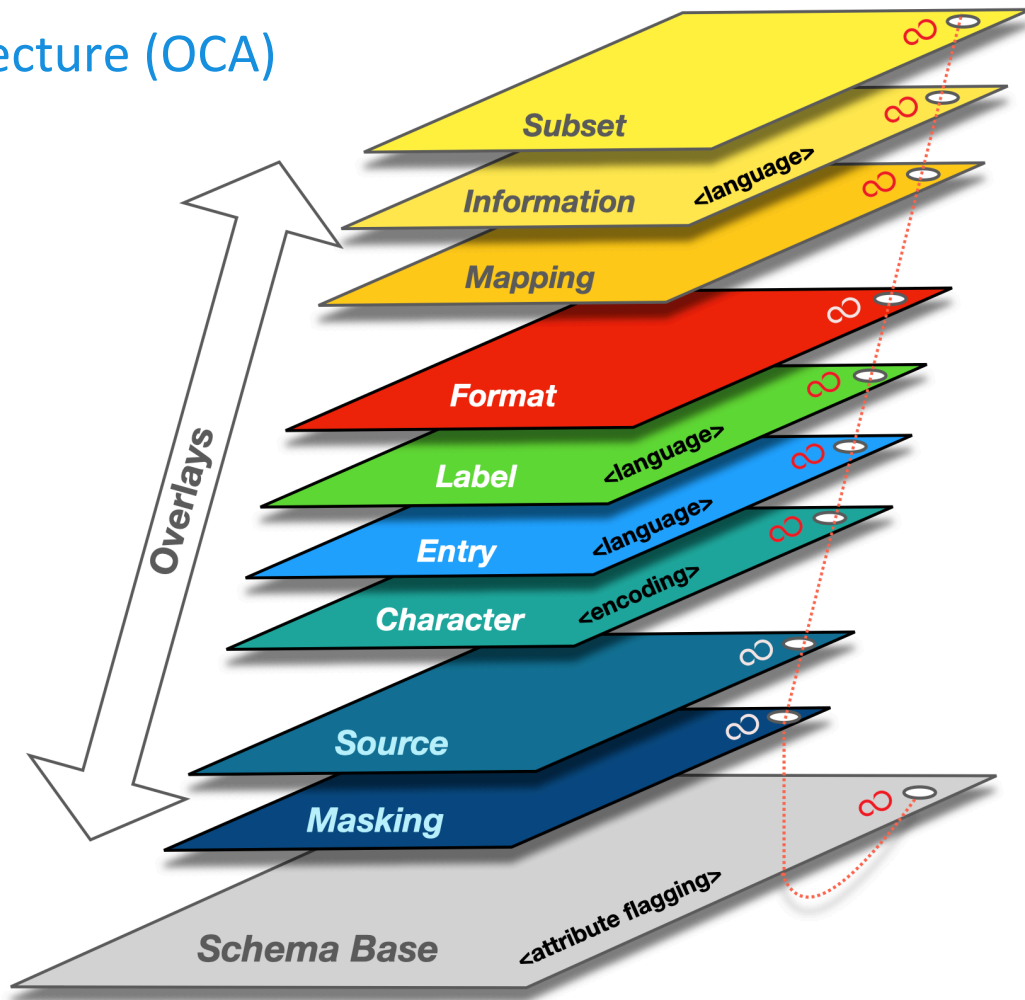
- Imaging TF (Scott/Moira)
- Medical Information TF (Scott/Moira)
- ✓ FHIR-OCA Object Transformation FG (John/Mukund)
- Notice & Consent TF (Mark/Sal)

Demo: Parsing a .CSV file to create JSON files for OCA objects (10 mins)

Presented by: P.Knowles

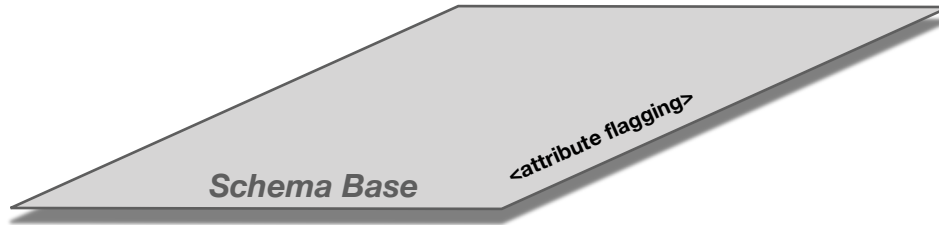
<https://editor.oca.argo.colossi.network>

Overlays Capture Architecture (OCA)



Schema Base

A stable base object that defines a single set of data in its purest form thus providing a standard base from which to decentralize data. A **Schema Base** facilitates a “Blinding” schema object which allows the issuer to flag attributes that could potentially unblind the identity of a governing entity.



Schema Base

“Demographics”

```
{
  "@context": "https://odca.tech/v1",
  "name": "Demographics",
  "type": "spec/schema_base/1.0",
  "description": "The Demographics domain includes a set of essential standard variables that describe each sub",
  "classification": "GICS:35202010",
  "issued_by": "",
  "attributes": {
    "STUDYID": "Text",
    "DOMAIN": "Text",
    "USUBJID": "Text",
    "SUBJID": "Text",
    "RFSTDTC": "Date",
    "RFENDTC": "Text",
    "RFXSTDTC": "Text",
    "RFXENDTC": "Text"
  },
  "attr_blinding": [
    "STUDYID",
    "USUBJID",
    "SUBJID",
    "RFSTDTC",
    "RFENDTC",
    "RFXSTDTC",
    "RFXENDTC"
  ]
}
```


Spreadsheet (Human-readable)

- Schema Base [Part 1]

A	B	C	D	E	F
Schema Base [SB]	SB: Description	SB: Classification	SB: Attribute Name	SB: Attribute Type	SB: Blinding Identity
Demographics	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	GICS:35202010	STUDYID	Text	Y
Demographics	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	GICS:35202010	DOMAIN	Text	
Demographics	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	GICS:35202010	USUBJID	Text	Y
Demographics	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	GICS:35202010	SUBJID	Text	Y
Demographics	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	GICS:35202010	RFSTDTC	Date	Y
Demographics	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	GICS:35202010	RFENDTC	Date	Y
Demographics	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	GICS:35202010	RFXSTDTC	Date	Y
Demographics	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	GICS:35202010	RFXENDTC	Date	Y

Schema Base

“Demographics”

```
{
  "@context": "https://odca.tech/v1",
  "name": "Demographics",
  "type": "spec/schema_base/1.0",
  "description": "The Demographics domain includes a set of essential standard variables that describe each sub",
  "classification": "GICS:35202010",
  "issued_by": "",
  "attributes": {
    "STUDYID": "Text",
    "DOMAIN": "Text",
    "USUBJID": "Text",
    "SUBJID": "Text",
    "RFSTDTC": "Date",
    "RFENDTC": "Text",
    "RFXSTDTC": "Text",
    "RFXENDTC": "Text"
  },
  "attr_blinding": [
    "STUDYID",
    "USUBJID",
    "SUBJID",
    "RFSTDTC",
    "RFENDTC",
    "RFXSTDTC",
    "RFXENDTC"
  ]
}
```

Spreadsheet (Human-readable)

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Demographics	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	GICS:35202010	SUBJID	Text	Y
Demographics	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	GICS:35202010	RFSTDTC	Date	Y
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Demographics	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	GICS:35202010	RFXSTDTC	Date	Y
Demographics	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	GICS:35202010	RFXENDTC	Date	Y

Industry Sector Classification

Option 1

GICS: Global Industry Classification Standard

“The Industry Standard”



The **GICS** indices is an industry taxonomy for use by the global financial community as a basis to assign companies to a sub-industry, and to an industry, industry group, and sector, by its principal business activity.

- 11 Sectors
- 24 Industry Groups
- 69 Industries
- 158 Sub-Industries

Schema Base: "Classification" Meta Tag

```
{
  "@context": "https://odca.tech/v1",
  "name": "Demographics",
  "type": "spec/schema_base/1.0",
  "description": "The Demographics domain includes a set of essential standard variables that describe each sub
  classification": "GICS:35202010",
  issued_by": " ",
  "attributes": {
    "STUDYID": "Text",
    "DOMAIN": "Text",
    "USUBJID": "Text",
    "SUBJID": "Text",
    "RFSTDTC": "Date",
    "RFENDTC": "Text",
    "RFXSTDTC": "Text",
    "RFXENDTC": "Text"
  },
  "attr_blinding": [
    "STUDYID",
    "USUBJID",
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    "RFSTDTC",
    "RFENDTC",
    "RFXSTDTC",
    "RFXENDTC"
  ]
}
```

Global Industry Classification Standard Code

GICS:35202010

Sector code:
35 - Health Care

Industry group code:
3520 - Pharmaceuticals,
Biotechnology & Life Sciences

Industry code:
352020 - Pharmaceuticals

Sub-industry code:
35202010 - Pharmaceuticals

Description:
Companies engaged in the
research, development or
production of pharmaceuticals.
Includes veterinary drugs.

Spreadsheet (Human-readable)

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Schema Base [SB]	SB: Description	SB: Classification	SB: Attribute Name	SB: Attribute Type	SB: Blinding Identity
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  },
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Demographics	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	GICS:35202010	RFXTDTCT	Date	Y
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  "attributes": {
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    "DOMAIN": "Text",
    "USUBJID": "Text",
    "SUBJID": "Text",
    "RFSTDTC": "Date",
    "RFENDTC": "Text",
    "RFXSTDTC": "Text",
    "RFXENDTC": "Text"
  },
  "attr_blinding": [
    "STUDYID",
    "USUBJID",
    "SUBJID",
    "RFSTDTC",
    "RFENDTC",
    "RFXSTDTC",
    "RFXENDTC"
  ]
}
```

Check: *Blinding Identity Taxonomy (BIT)*

Ref.:
<https://docs.kantarinitiative.org/Blinding-Identity-Taxonomy-Report-Version-1.0.pdf>

Blinding Identity Taxonomy (BIT)



- Names (incl. First Names, Last Names, Full Names, Entity Names)
- Physical Addresses
- E-mail Addresses
- Telephone Numbers
- Postal Codes
- Personal Software Application Handles (e.g. Skype, Slack, Hyperledger Chat, etc.)
- Profile Pages
- Passport Numbers
- Social Security Numbers
- National Insurance Numbers
- Driving License Numbers
- Vehicle Registration Numbers
- Bank Account Numbers
- Credit (or Debit) Card Numbers
- Personal Identification Numbers (PIN)
- Private Keys / Master Keys
- Symmetric Keys
- Public Keys
- Link Secrets
- Employee Identifiers
- Account Identifiers
- Governmental Identifiers
- Membership Identifiers (e.g. Trade Union Membership, etc.)
- Institutional Identifiers (e.g. Private Health Care Identifiers, etc.)
- Case Identifiers (e.g. Case ID Numbers, Benefit Plan Participation Identifiers, etc.)
- User Identifiers (e.g. User IDs, Logins, etc.)
- Passwords
- Signatures
- Digital Certificates
- Photos
- Videos
- Images
- Vocal Sound Bites
- Dates and timestamps (e.g. Date of Birth, transaction dates, etc.)*
- Genetic Identifiers (incl. chromosomal, deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) data)
- Biometric Identifiers (incl. voiceprints, iris scans, facial imaging and dactyloscopic (fingerprint) data)
- Internet Protocol (IP) Addresses
- Media Access Control (MAC) Addresses
- Service Set Identifiers (SSID) (incl. local WiFi SSIDs)
- Bluetooth Device Addresses (BD_ADDR)
- Locational Information (incl. Global Positioning System (GPS), 3 word address, etc.)
- Cookie Browser Identifiers
- Radio Frequency Identifiers
- IoT Identifiers (incl. smart meter data)
- International Mobile Equipment Identity (IMEI)
- International Mobile Subscriber Identity (IMSI)
- Social media interactive elements, posts and comments (incl. likes, emojis and polling results)
- Free-Form Text Fields / Unstructured Data**

* Note: Not all captured dates will reveal identity but some will so, if in doubt, encrypt.

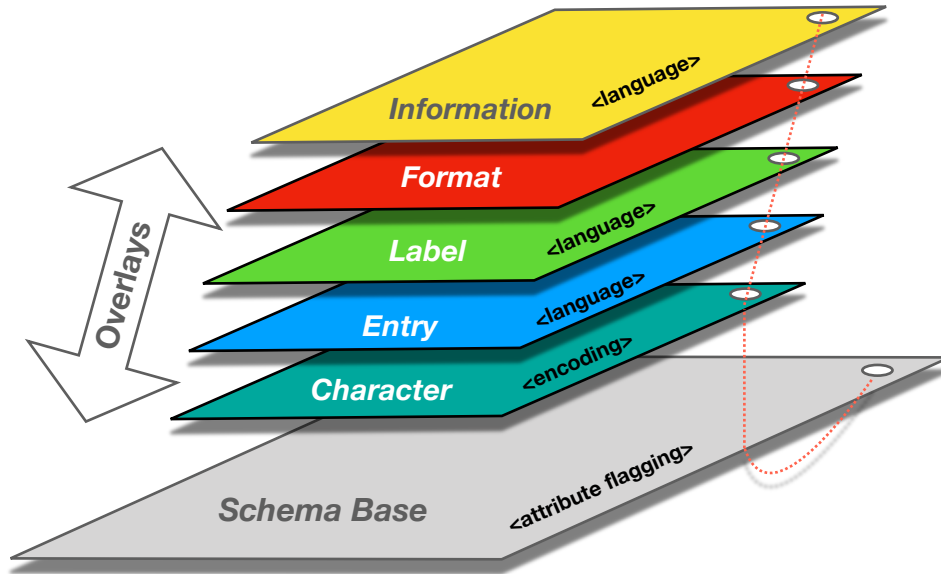
** Defn.: Text which does not have a given structure, nor which is entered in any specific format. Note: All free-form text fields should be encrypted.

Spreadsheet - (Human-readable)

- Schema Base [Part 1]

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Schema Base [SB]	SB: Description	SB: Classification	SB: Attribute Name	SB: Attribute Type	SB: Blinding Identity
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Demographics	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	GICS:35202010	DOMAIN	Text	
Demographics	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	GICS:35202010	USUBJID	Text	Y
Demographics	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	GICS:35202010	SUBJID	Text	Y
Demographics	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	GICS:35202010	RFSTDTC	Date	Y
Demographics	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	GICS:35202010	RFENDTC	Date	Y
Demographics	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	GICS:35202010	RFXSTDTC	Date	Y
Demographics	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	GICS:35202010	RFXENDTC	Date	Y

Overlays



Format Overlay

```
{
  "@context": "https://odca.tech/overlays/v1",
  "type": "spec/overlay/format/1.0",
  "issued_by": "",
  "role": "",
  "purpose": "",
  "schema_base": "h1:b6MPrSsq35AxiNSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK",
  "attr_formats": {
    "RFSTDTC": "ISO 8601",
    "RFENDTC": "ISO 8601",
    "RFXSTDTC": "ISO 8601",
    "RFXENDTC": "ISO 8601"
  }
}
```

Spreadsheet (Human-readable)

- Format Overlay [Part 2]

G	H	I	J	K	L
			Investigator	Investigator	Reviewer
			Trial Data	Entry Instructions	CDISC Notes
Format Overlay	Label Overlay	Character Encoding Overlay	Entry Overlay	Information Overlay	Information Overlay
	en_US		en_US	en_US	en_US
	Study Identifier	utf-8			Unique identifier for a study.
	Domain Abbreviation	utf-8	DM		Two-character abbreviation for the domain.
	Unique Subject Identifier	utf-8			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-
	Subject Identifier for the Study	utf-8			Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.
ISO 8601	Subject Reference Start Date/Time	utf-8			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.
ISO 8601	Subject Reference End Date/Time	utf-8			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.
ISO 8601	Date/Time of First Study Treatment	utf-8			First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.
ISO 8601	Date/Time of Last Study Treatment	utf-8			Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTDC (or the latest value of EXSTDTC if EXENDTDC was not collected or is missing).

Label Overlay

```
{  
  "@context": "https://odca.tech/overlays/v1",  
  "type": "spec/overlay/label/1.0",  
  "issued_by": "",  
  "role": "",  
  "purpose": "",  
  "schema_base": "hl:b6MPrSsq35AxiNSYzv8f0GkRBqv1tNoPx9XveXfUSQcK",  
  "language": "en_US",  
  "attr_labels": {  
    "STUDYID": "Study Identifier",  
    "DOMAIN": "Domain Abbreviation",  
    "USUBJID": "Unique Subject Identifier",  
    "SUBJID": "Subject Identifier for the Study",  
    "RFSTDTC": "Subject Reference Start Date/Time",  
    "RFENDTC": "Subject Reference End Date/Time",  
    "RFXSTDTC": "Date/Time of First Study Treatment",  
    "RFXENDTC": "Date/Time of Last Study Treatment"  
  },  
  "attr_categories": [  
  ],  
  "cat_labels": {  
  },  
  "cat_attributes": {  
  }  
}
```


Spreadsheet (Human-readable)

- Label Overlay [Part 2]

	G	H	I	J	K	L
				Investigator	Investigator	Reviewer
				Trial Data	Entry Instructions	CDISC Notes
Format Overlay	Label Overlay	Character Encoding Overlay	Entry Overlay	Information Overlay	Information Overlay	Information Overlay
	en_US		en_US	en_US	en_US	en_US
	Study Identifier	Jtf-8				Unique identifier for a study.
	Domain Abbreviation	Jtf-8	DM			Two-character abbreviation for the domain.
	Unique Subject Identifier	Jtf-8				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-
	Subject Identifier for the Study	Jtf-8				Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.
ISO 8601	Subject Reference Start Date/Time	Jtf-8				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.
ISO 8601	Subject Reference End Date/Time	Jtf-8				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.
ISO 8601	Date/Time of First Study Treatment	Jtf-8				First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.
ISO 8601	Date/Time of Last Study Treatment	Jtf-8				Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTDC (or the latest value of EXSTDTC if EXENDTDC was not collected or is missing).

Character Encoding Overlay

```
{
  "@context": "https://odca.tech/overlays/v1",
  "type": "spec/overlay/character_encoding/1.0",
  "issued_by": "",
  "role": "",
  "purpose": "",
  "schema_base": "hl:b6MPrSsq35AxiNSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK",
  "default_character_encoding": "utf-8",
  "attr_character_encoding": {
    "STUDYID": "utf-8",
    "DOMAIN": "utf-8",
    "USUBJID": "utf-8",
    "SUBJID": "utf-8",
    "RFSTDTC": "utf-8",
    "RFENDTC": "utf-8",
    "RFXSTDTC": "utf-8",
    "RFXENDTC": "utf-8"
  }
}
```

Spreadsheet (Human-readable)

- Character Encoding Overlay [Part 2]

	G	H	I	J	K	L
				Investigator Trial Data	Investigator Entry Instructions	Reviewer CDISC Notes
Format Overlay	Label Overlay	Character Encoding Overlay	Entry Overlay	Information Overlay	Information Overlay	Information Overlay
	en_US		en_US	en_US	en_US	en_US
	Study Identifier	utf-8				Unique identifier for a study.
	Domain Abbreviation	utf-8	DM			Two-character abbreviation for the domain.
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ISO 8601	Date/Time of Last Study Treatment	utf-8				Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).

Entry Overlay

```
{  
  "@context": "https://odca.tech/overlays/v1",  
  "type": "spec/overlay/entry/1.0",  
  "issued_by": "",  
  "role": "Investigator",  
  "purpose": "Trial Data",  
  "schema_base": "h1:b6MPPrSsq35AxiNSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK",  
  "language": "en_US",  
  "attr_entries": {  
    "DOMAIN": [  
      "DM"  
    ]  
  }  
}
```

Spreadsheet (Human-readable)

- Entry Overlay [Part 2]

	G	H	I	J	K	L
				Investigator	Investigator	Reviewer
				Trial Data	Entry Instructions	CDISC Notes
Format Overlay	Label Overlay	Character Encoding Overlay	Entry Overlay	Information Overlay	Information Overlay	Information Overlay
	en_US		en_US	en_US	en_US	en_US
	Study Identifier	utf-8				Unique identifier for a study.
	Domain Abbreviation	utf-8	DM			Two-character abbreviation for the domain.
	Unique Subject Identifier	utf-8				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-
	Subject Identifier for the Study	utf-8				Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.
ISO 8601	Subject Reference Start Date/Time	utf-8				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.
ISO 8601	Subject Reference End Date/Time	utf-8				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.
ISO 8601	Date/Time of First Study Treatment	utf-8				First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.
ISO 8601	Date/Time of Last Study Treatment	utf-8				Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTDC (or the latest value of EXSTDTC if EXENDTDC was not collected or is missing).

Information Overlay

```
{
  "@context": "https://odca.tech/overlays/v1",
  "type": "spec/overlay/information/1.0",
  "issued_by": "",
  "role": "Reviewer",
  "purpose": "CDISC Notes",
  "schema_base": "hl:b6MPrSsq35AxiNSYzv8fQGkRBqv1tNoPx9XyeXfUSQcK",
  "language": "en_US",
  "attr_information": {
    "STUDYID": "Unique identifier for a study.",
    "DOMAIN": "Two-character abbreviation for the domain.",
    "USUBJID": "Identifier used to uniquely identify a subject across all studies for all applicat",
    "SUBJID": "Subject identifier, which must be unique within the study. Often the ID of the subj",
    "RFSTDTC": "Reference Start Date/time for the subject in ISO 8601 character format. Usually eq",
    "RFENDTC": "Reference End Date/time for the subject in ISO 8601 character format. Usually equi",
    "RFXSTDTC": "First date of exposure to any protocol-specified treatment or therapy, equal to t",
    "RFXENDTC": "Last date of exposure to any protocol-specified treatment or therapy, equal to th"
  }
}
```

Spreadsheet (Human-readable)

- Information Overlay [Part 2]

	G	H	I	J	K	L
				Investigator	Investigator	Reviewer
				Trial Data	Entry Instructions	CDISC Notes
Format Overlay	Label Overlay	Character Encoding Overlay	Entry Overlay	Information Overlay	Information Overlay	Information Overlay
	en_US		en_US	en_US	en_US	en_US
	Study Identifier	utf-8				Unique identifier for a study.
	Domain Abbreviation	utf-8	DM			Two-character abbreviation for the domain.
	Unique Subject Identifier	utf-8				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-
	Subject Identifier for the Study	utf-8				Subject identifier, which must be unique within the study. Often the ID of the subject as recorded on a CRF.
ISO 8601	Subject Reference Start Date/Time	utf-8				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.
ISO 8601	Subject Reference End Date/Time	utf-8				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.
ISO 8601	Date/Time of First Study Treatment	utf-8				First date of exposure to any protocol-specified treatment or therapy, equal to the earliest value of EXSTDTC.
ISO 8601	Date/Time of Last Study Treatment	utf-8				Last date of exposure to any protocol-specified treatment or therapy, equal to the latest value of EXENDTC (or the latest value of EXSTDTC if EXENDTC was not collected or is missing).

.XLS file (Human-readable)

AutoSave OFF | SDTM_DM

Home | Insert | Draw | Page Layout | Formulas | Data | Review | View | Tell me

Font: Helvetica Neue, 10 | Text | Conditional Formatting | Format as Table | Cell Styles | Insert | Delete | Format | Sort & Filter | Find & Select | Ideas

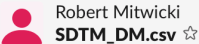
A1

	A	B	C	D	E	F	G	H	I	J
1										Investigator
2										Trial Data
3	Schema Base [SB]	SB: Description	SB: Classification	SB: Attribute Name	SB: Attribute Type	SB: Blinding Identity	Format Overlay	Label Overlay	Character Encoding Overlay	Entry Overlay
4								en_US		en_US
5	Demographics	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	GICS:35202010	STUDYID	Text	Y		Study Identifier	utf-8	
6	Demographics	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	GICS:35202010	DOMAIN	Text			Domain Abbreviation	utf-8	DM
7	Demographics	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	GICS:35202010	USUBJID	Text	Y		Unique Subject Identifier	utf-8	
8	Demographics	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	GICS:35202010	SUBJID	Text	Y		Subject Identifier for the Study	utf-8	
9	Demographics	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	GICS:35202010	RFSTDTTC	Date	Y	ISO 8601	Subject Reference Start Date/Time	utf-8	
10	Demographics	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	GICS:35202010	RFENDTTC	Date	Y	ISO 8601	Subject Reference End Date/Time	utf-8	
11	Demographics	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	GICS:35202010	RFXSTDTTC	Date	Y	ISO 8601	Date/Time of First Study Treatment	utf-8	
	Demographics	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	GICS:35202010	RFXENDTTC	Date	Y	ISO 8601	Date/Time of Last Study Treatment	utf-8	

Sheet 1

100%

Convert to .CSV file (Machine-readable)



16KB CSV snippet created on August 25, 2020. This file is private.

ACTIONS ⚙

```
1 ;;;;Investigator;Investigator;Reviewer
2 ;;;;Trial Data;Entry Instructions;CDISC Notes
3 Schema Base [SB];SB: Description;SB: Classification;SB: Attribute Name;SB: Attribute Type;SB: Blinding Identity;Format Overlay;Label Overlay;Character Encoding
  Overlay;Entry Overlay;Information Overlay;Information Overlay
4 ;;;;en_US;en_US;en_US;en_US
5 Demographics;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;GICS:35202010;STUDYID;Text;Y;;Study Identifier;utf-8;;Unique identifier for a study.
6 Demographics;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;GICS:35202010;DOMAIN;Text;;Domain Abbreviation;utf-8;DM;;Two-character abbreviation for the domain.
7 Demographics;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;GICS:35202010;USUBJID;Text;Y;;Unique Subject Identifier;utf-8;;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.
8 Demographics;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;GICS:35202010;SUBJID;Text;Y;;Subject Identifier for the Study;utf-8;;Subject identifier, which must be unique
  within the study. Often the ID of the subject as recorded on a CRF.
9 Demographics;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;GICS:35202010;RFSTDTCT;Date;Y;ISO 8601;Subject Reference Start Date/Time;utf-8;;"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."
10 Demographics;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;GICS:35202010;RFENDTCT;Date;Y;ISO 8601;Subject Reference End Date/Time;utf-8;;"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."
11 Demographics;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;GICS:35202010;RFXSTDTCT;Date;Y;ISO 8601;Date/Time of First Study Treatment;utf-8;;First date of exposure to any
  protocol-specified treatment or therapy, equal to the earliest value of EXSTDTCT.
12 Demographics;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;GICS:35202010;RFXENDTCT;Date;Y;ISO 8601;Date/Time of Last Study Treatment;utf-8;;Last date of exposure to any
  protocol-specified treatment or therapy, equal to the latest value of EXENDTCT (or the latest value of EXSTDTCT if EXENDTCT was not collected or is missing).
13 Demographics;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;GICS:35202010;RFICDTC;Date;Y;ISO 8601;Date/Time of Informed Consent;utf-8;;Date/time of informed consent in
  ISO 8601 character format. This will be the same as the date of informed consent in the Disposition domain, if that protocol milestone is documented. Would be
  null only in studies not collecting the date of informed consent.
14 Demographics;The Demographics domain includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for
```

Create OCA

Enter name

Name of the schema base which you are creating. E.g. Driving licence

Enter description

Provide description for schema. E.g. Official driving licence schema issued by Gov

Create

Calculate hashlink

No file chosen

Browse

Upload OCA

Search in OCA Repository

or choose zip file

No file chosen

Browse

Don't have one yet? Try [demo](#)

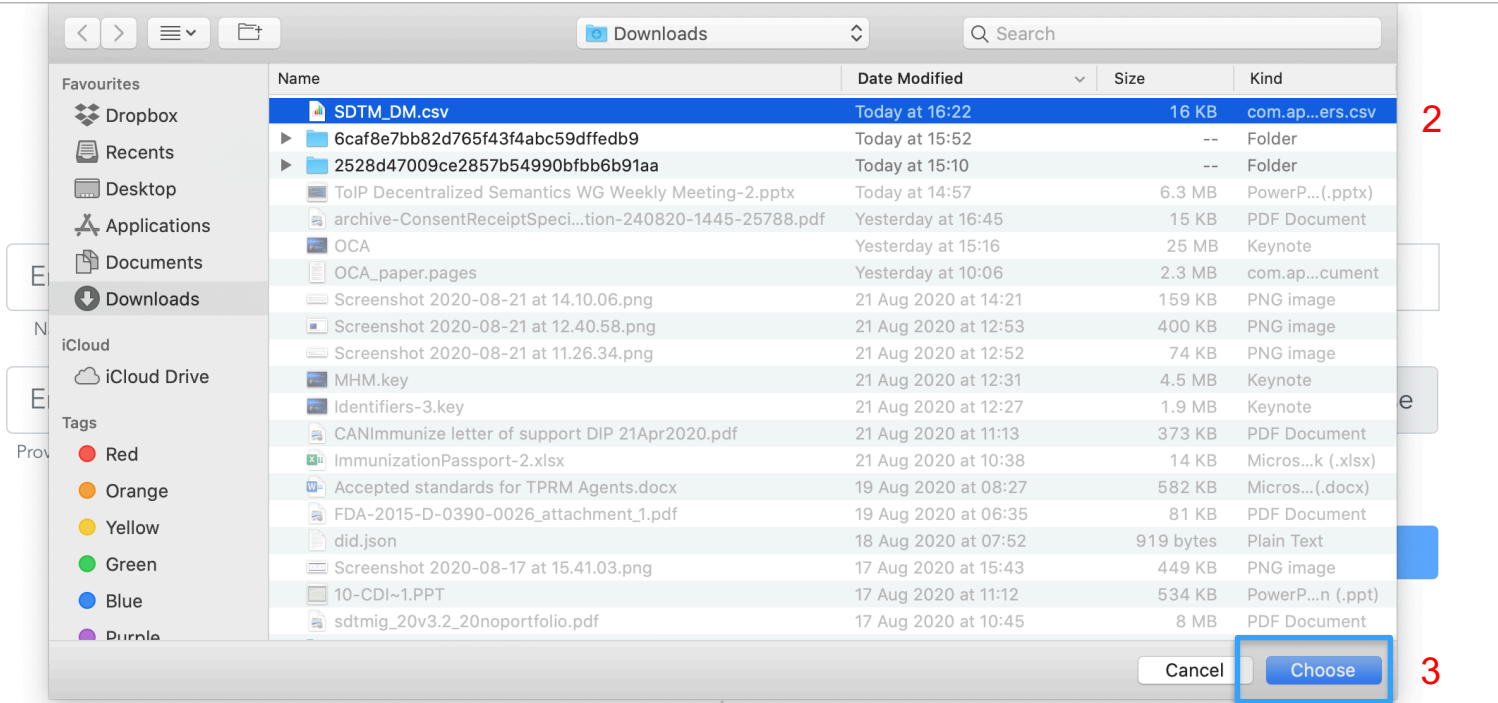
Upload

Convert **CSV file** to OCA

No file chosen

Browse

Click on Browse button and select .CSV file



Calculate hashlink

No file chosen

Convert CSV file to OCA

No file chosen

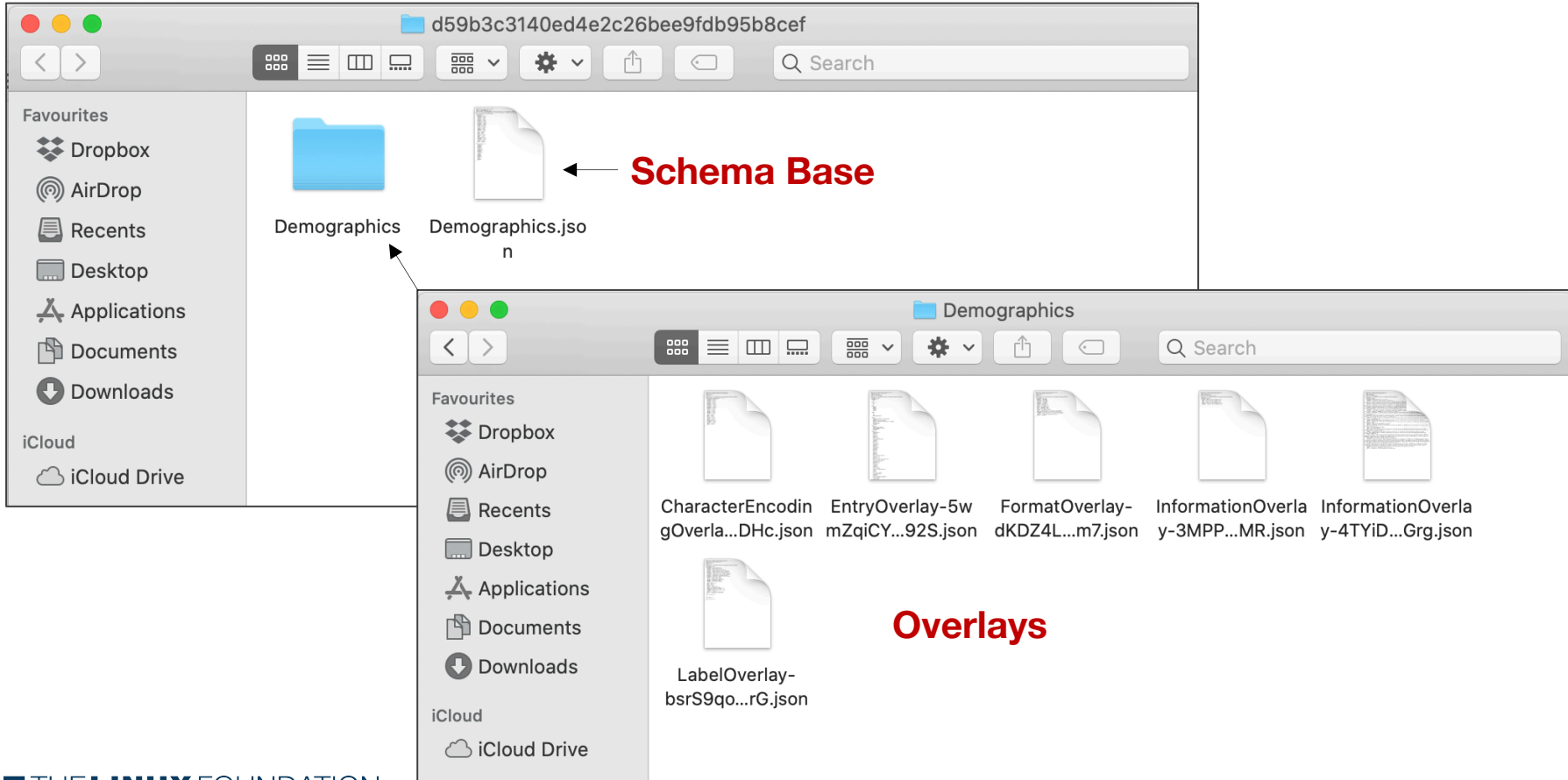
Check Downloads folder

The screenshot displays the website editor.oca.argo.colossi.network with four main sections:

- Create OCA:** Includes a form with "Enter name" (with subtext "Name of the schema base which you are creating. E.g. Driving licence") and "Enter description" (with subtext "Provide description for schema. E.g. Official driving licence schema issued by Gov"). A blue "Create" button is at the bottom.
- Upload OCA:** Includes a search bar "Search in OCA Repository", a file selection area with "No file chosen" and a "Browse" button, and a blue "Upload" button. Subtext reads "or choose zip file" and "Don't have one yet? Try [demo](#)".
- Calculate hashlink:** Includes a file selection area with "No file chosen" and a "Browse" button.
- Convert CSV file to OCA:** Includes a file selection area with "SDTM_DM.csv" and a "Browse" button. Subtext reads "Download [output form zip file](#) which can be uploaded above".

A macOS Downloads folder window is overlaid on the top right, showing a file named "d59b3c3140ed4e...6bee9fdb95b8cef" with a size of 8 KB. The window also includes a "Clear" button and standard macOS window controls.

Retrieve JSON files



FHIR-OCA FG:

Scheduling a working call to discuss priority use cases
(10 mins)

M.Parthasarathy / J.Walker

<https://wiki.trustoverip.org/display/HOME/FHIR-OCA+Object+Transformation+FG>

FHIR-OCA FG

Sits underneath ...

MITF at DSWG

FHIR-OCA Object Transformation FG (Proposed)

Created by Paul Knowles, last modified 6 minutes ago

Overview

True interoperability of dispersed data amongst multiple healthcare providers (and across organizational or geographic boundaries) remains unattainable in the current tapestry of today's digital economy. In terms of schema design, [Overlays Capture Architecture](#) (OCA) represents a schema as a multi-dimensional object consisting of a stable schema base and interoperable overlays. Reverse engineering currently deployed single-object schemas into multiple-dimensional objects would facilitate a separation of concerns: (i.) data capture vs. exchange and (ii.) data usage.

Research into a globally standardized and decentralized approach to health data capture and exchange has birthed a powerful alternative architecture in OCA. This new architecture will enable easier and effective monitoring and assessment of outbreaks and healthcare policies whilst minimizing the possibilities of tampered, damaged or erroneous data in care delivery. OCA also has the potential to better support new developments in precision medicine, gene-based therapies, federated AI solutions and other social determinants of health (SDOH) initiatives.

In conjunction with the technical components described below, OCA provides a choice architecture to better enable patient-driven consent, privacy and compliance requirements across all use cases.

Mission and Scope

The mission of the FHIR-OCA Object Transformation FG is to create and maintain FHIR-compliant OCA schema bases and core overlays that correspond to the normative HL7 FHIR Version R4 resource model.

The scope of this FG includes:

1. Per MITF, alignment with ToIP Foundation member's relationships and partnerships with standards organizations such as HL7, IHE, and ISO TC215
2. Ensuring compatibility with FHIR Profiles, FHIR Extensibility model.
3. Ensuring alignment with key ongoing HL7 initiatives (Argonaut, USCDI, DaVinci, Carin, Gravity)
4. Proof-of-concept activities such as the creation of Open Source tools to demonstrate the principles of decentralized interactions (Use cases specified below) that can ensure:
 - a. regulatory compliance
 - b. respecting patient-centric consent & privacy policies

Intellectual Property Rights (Copyright, Patent, Source Code)

This FG uses the same IPR licensing selections as the ToIP Decentralized Semantics WG:

- Copyright mode: [Creative Commons Attribution 4.0](#).
- Patent mode: W3C Mode (based on the [W3C Patent Policy](#)).
- Source code: [Apache 2.0](#).

OCA Specification document: Contribution and RFCs (10 mins)

Presented by: R.Mitwicky

<https://the-human-colossus-foundation.github.io/oca-spec/>

<https://github.com/the-human-colossus-foundation/oca-spec>

OCA Specification

A specification template for collaborative input to enable a roadmap for OCA requirements

Unofficial Draft

TABLE OF CONTENTS

1. Introduction
 - 1.1 Overview
 - 1.2 Benefits
 - 1.3 Example of similar construct
- A. Security Considerations
- B. Privacy Considerations
- C. Resources

OCA Specification

Overlays Capture Architecture

Unofficial Draft 11 August 2020

Latest editor's draft:
<https://github.com/the-human-colossus-foundation/oca-spec>

Editor:
[Robert Mitwicky](#) (The Human Colossus Foundation)

Authors:
[Robert Mitwicky](#) (The Human Colossus Foundation)
[Paul Knowles](#) (The Human Colossus Foundation)

Participate:
[GitHub the-human-colossus-foundation/oca-spec](#)
[File a bug](#)
[Commit history](#)
[Pull requests](#)

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Abstract

The post millennial generation has witnessed an explosion of captured data points which has sparked profound possibilities in both Artificial Intelligence (AI) and Internet of Things (IoT) solutions. This has spawned the collective realization that society's current technological infrastructure is simply not equipped to fully protect personally identifiable information (PII) or to entice corporations to break down internal data silos, streamline data harmonization processes and ultimately resolve worldwide data duplication and storage resource issues.

The FAIR Data Principles are a set of guiding principles in order to make data findable, accessible, interoperable and reusable (Wilkinson et al., 2016). These principles provide guidance for scientific data management and stewardship and are relevant to all stakeholders in the current digital ecosystem.

In line with the FAIR principles, data harmonization and interoperability processes between internal departments and functions is a high priority for corporate organizations but the current cognitive framework available for data

Ref.: <https://the-human-colossus-foundation.github.io/oca-spec/>

Ref.: <https://github.com/the-human-colossus-foundation/oca-spec>

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 1st, 2020



Closing Q & A

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