

CDISC Focus Group

Industry sector: [Health Care](#)

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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. ToIP architecture principles addresses the issue of breaking down silos across trust boundaries, whether across entities (organizations, nations etc) based on existing social, legal and business processes.

The FDA mandates that clinical trial data used to support approval of drugs and devices is submitted using CDISC standards. However, much of today's research is conducted using clinical systems where data is typically exposed and shared as FHIR. This opens the door for addressing the hurdles in data interoperability due application specific/process complexities. 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 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

To address the challenge of communicating between different standards across sub-industries of the health care sector, the OCA-CDISC Focus Group will use OCA to harmonise the CDISC database models, providing a solution to semantic harmonisation between health care-specific data models and related data representation formats. This approach to semantic harmonisation will enable stakeholders to continue working with their own ontology-driven database models without the burden of being forced to produce standard transformation mappings to other standards.

The mission of the OCA-CDISC FG is to create and maintain CDISC-compliant OCA schema bases and core overlays that correspond to ... FROM HERE ... 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 Semantic Domain WG:

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

Conveners

- [John Walker](#) (SemanticClarity)
- [Mukundan Parthasarathy](#) (SemanticClarity)

Interested Members (add your name and organization if you may be interested in joining this FG)

- [Paul Knowles](#)
- [Robert Mitwicki](#)
- [Jim St.Clair](#)
- [Steven Milstein](#)
- [Chris Raczowski](#)
- [Scott Whitmire](#)

Objectives

The objectives of the OCA-FHIR FG are to:

- Demonstrate the use of [OCA](#) to advance the semantic interoperability of [HL7 FHIR](#) data
- Align with existing [FHIR EHR](#) ecosystem initiatives and standards
- Align with existing data privacy vocabularies, including [Data Privacy Vocabulary v0.1](#)
- Design schema object transformations from FHIR to OCA for maximum interoperability across healthcare platforms and processes
- Facilitate the automated generation of FHIR-compliant OCA schema objects
- Maintain all documentation and resources for FHIR-compliant OCA schemas by design

Technical components

The OCA-FHIR FG architecture will build upon the core components of the [Semantic domain](#).

Other candidate technologies include

- Flexible and expressive data modeling provided by [Overlays Capture Architecture](#) (OCA)
- Object transformations from [HL7 FHIR](#) to [OCA](#) will have maximum interoperability across healthcare platforms and processes as design priority
- Advances in digital identity and verification – such as [Decentralized Identifiers](#) (DIDs) and [Verifiable Credentials](#) (VCs)
- Blockchains and [Smart Contracts](#) – with strong auditing properties

Example use case (to be prioritized based)

- Remotely Accessible Patient EHR - patient expressly requests creation of a FHIR based EHR representation to be used by different Health Care providers in different (same country) locale. (This use case can evolve to support crossing national boundaries thus adding complexity)
- Consent to participate in Clinical Research (FHIR data)
- Consent to participate in a Clinical Trial. ([CDISC:SDTM](#) data (see SDTM Implementation Guide v.3.2 [here](#)))
- Specify the data and credential requirements for Patient Identity and Matching (e.g. ER visit)

Scope

Use case	Minimal mapping of FHIR r4 resources (include transitive dependencies via <i>Referencetype</i> properties/slots).	Comments (FHIR Profile to be identified)
Remotely accessible patient EHR	There are multiple use cases here, expect to start with <i>Immunization and ImagingStudy</i>	CDA not in scope.
Consent to participate in clinical research	<i>Consent, Contract</i>	Handling instructions: Medical treatment and Research consent directives are not explicitly modeled in R4, might require use of <i>Contract</i> etc.
Consent to participate in clinical trials	<i>Consent, Contract</i>	Handling instructions: Medical treatment and Research consent directives are not explicitly modeled in R4, might require use of <i>Contract</i> etc.
ER Visit/specify data and credential requirements for patient identity and matching	<i>Consent, Contract</i>	Handling instructions: Privacy Consent directive.

Deliverables

- Identity and specify the base FHIR resources required to support the FG use cases above.
- OCA FHIR schema bases representing a core set of base FHIR resources to support the FG use cases.
- Specify core overlays necessary to support the FHIR-compliant OCA schema bases
- Demonstrate the correctness of structure and version between the base FHIR resource and the corresponding FHIR-compliant OCA schema base.
- Demonstrate the complete and correct mapping of data values between the base FHIR resource and the corresponding populated FHIR-compliant OCA schema base.
- Create a FHIR extensibility example, create a FHIR payload to support a selected FHIR-compliant OCA schema base.

- Specification for FHIR-compliant OCA schema base and overlay processing rules.

Proposed schedule

- To be determined by FG members, this scope will be a priority of the team formed.
- Weekly FG Working Meetings, to be held as required

Shared documents and links

Related work

1. Rich Schema Objects
 - a. Interop with an Order Overlay
 - b. Interop with Verifiable Credentials (VCs)
2. Interoperability with the Ecosystem Foundry WG
3. ToIP: Federated access model/SSI interop issues as identified
4. Harmonization with general consent (e.g. Notice and Consent WG deliverables) and Domain specific (FHIR Consent model from this TF)
5. W3C Data Privacy Vocabulary & Personal Data Category (ontology)

Issues and resolution

1. FHIR R4 support for json-ld (resolution: tbd, workaround approach needs to be finalized)