

Gastroenterology (GI): Hepatitis C Harmonize and Integrate Member KNARTs White Paper

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Hepatitis C Harmonization and Integration White Paper

by Knowledge Based Systems (KBS), Office of Informatics and Information Governance (OIIG), and Clinical Decision Support (CDS)

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Chapter 1. General Process

In integrating and harmonizing the individual components of a composite knowledge artifact (KNART), the general process has been to rely on the inherent encapsulation properties envisioned in the new composite structure. Each individual knowledge artifact is presumed to be able to run in a stand-alone and independent manner. The composite artifact acts as a central orchestration agent, activating individual knowledge artifacts using an event-driven model. Intercommunication between artifacts is handled solely through global shared state external to the composite and through the process of event payloads. Individual KNARTs only communicate with the composite container.

During the creation of the individual KNARTs used in the formation of the composite, their design and implementation explicitly envisioned their further integration into a composite structure. As such, minimal harmonization or communication is generally required. All composite KNARTs use references to the individual component knowledge artifacts rather than direct inclusion. The general design principles used should ensure that the overall composite does not alter the essential information contained in the components.

The emerging composite KNART standard envisions that the parent composite will not restate the metadata included in its component parts unless there is a clinical or technical need to override or supplement the information contained in the components. This includes elements such as supporting evidence, intended use, etc. Analysis of the components of this KNART did not find the need to make any overrides or supplements to the essential metadata.

In developing the Version 2.0 KNART standard, the work group has updated the essential file structure to support composites. The design approach of the workgroup was to define the composite mechanism to support composition that includes both literal inclusion and references to other KNARTs. The emerging standard explicitly envisions that composites may be of a heterogeneous nature and supports artifacts authoring in other forms. The creation of the Version 2 schema explicitly maintains backward compatibility. The Version 1 knowledge document schema was structured such that the introduction of composite feature could not be made without breaking backward compatibility. As a result, internal organization of the schema was refactored to isolate the concept of a knowledge document and create two potential root references, which could be used depending on whether the KNART was a singleton or a composite. The Version 2 schema supports the composite structures, references, and direct inclusion of multiple knowledge documents. All the elements of the original document type are still supported.

Overview of Integration Scenario

This composite uses a simple integration scenario whereby the documentation template is first projected and the order set is then activated. All orchestration is accomplished through embedded Event-Condition-Action (ECA) rules in the composite.

General Limitations

The composite KNART is a machine-readable artifact comprised of independently validated components. The goal of the composition is not to add additional content but rather to orchestrate the individual components. The composite is not expected to be machine executable. The schema and functional environment in which the composite is created is based on an emerging standard and is not guaranteed to be compatible with the final balloted standard.

Format Limitation

The proposed Health Level Seven International (HL7) KNART format for composites is based on the original Knowledge Artifact Specification (KAS) schema. The composite extension is specifically developed to allow the composition of these singleton KAS artifacts into an organizing structure to provide greater meaning. The composite KNART format is an emerging standard at HL7 that allows heterogeneous artifacts to be grouped into one common organizing document. In creating the composite knowledge artifacts, the individual components of the composite have been limited to the existing KAS-derived artifact types. As such, the abstraction of more advanced orchestration behavior has been limited to the capabilities of that model.

Chapter 2. Process of Harmonization

General Process

- Detailed review of composite components
- Map components to conceptual white paper

Organization

At an organizational level, this composite is comprised of four major entities. The first of these entities is the documentation template named CDSK_KRprt_CRDT_B43HepC.xml. The other are three order sets: CDSK_KRprt_OS_B29HepCLediSofo.xml (Ledipasvir/Sofosbuvir), CDSK_KRprt_OS_B28HepCElbGraz.xml (Elbasvir/Grazoprevir), CDSK_KRprt_OS_B30HepC-GlecPib.xml (Glecaprevir/Pibrentasvir). For the purposes of orchestration, the composite initially triggers an event that causes the documentation template to be activated. Upon the completion of the documentation template, the completion triggers all three order set KNARTs to be activated via an ECA rule.

Data

Orchestration Data Elements

All orchestration for this composite is handled by the examination and assertion of named events. The following table lists the events are used to drive the key behavior in this composite.

Event Name	Event Type	Relevant Payload
FireDocTemplate	Named event	None
DocumentationCompleteEvent	Named event	None
FireLedipasvirOrderSet	Named event	None
FireElbasvirOrderSet	Named event	None
FireGlecaprevirPibrentasvirOrderSet	Named event	None

Redundant Data Elements Within KNARTs

N/A

Near-Duplicates Within KNARTs

N/A

Redundant References, Supporting Evidence, and Expressions Within KNARTs

N/A

Data Elements That Are to be Hidden From the User Within KNARTs

N/A

Questions Being Asked of the Documenter

General

All questions being asked of the documenter are delegated to the specific component parts. Readers are asked to refer to the details of the composite parts. No additional questions are asked by the composite itself.

Specific to the Composite

N/A

Organization of Order Sets

There are three order sets present in this composite. Each order set is presented since the composite white paper did not present any organizational or orchestrational behaviors.

Chapter 3. Integration

Process

The general process integration is based upon the detailed reading of the composite clinical white paper and the individual constituent components. Functional analysis of the expected data flow and event flow between the created entities was used to construct this composite.

Concerns

In reviewing the structure and questions asked of the documentation template, it is not clear that all the elements required to fully create a referral are being asked. It is suggested that either a standardized referral documentation template be created and used for composites or that a detailed review of the documentation template for the additional required information is conducted prior to proceeding to an implementation phase. The core logic of the white paper did not specify any manner to choose the correct order set, as a result all three order sets are activated. The clinical use case should be revisited and orchestration logic included.

Assets

The following table lists the assets that make up this composite.

Asset Filename	Description
CDSK_KRprt_CRCK_B64HepC.xml	The main composite controller
CDSK_KRprt_CRDT_B43HepC.xml	The documentation template
CDSK_KRprt_OS_B29HepCLediSofo.xml	The ledipasvir/sofosbuvir order set
CDSK_KRprt_OS_B28HepCElbGraz.xml	The elbasvir/grazoprevir order set
CDSK_KRprt_OS_B30HepCGlecPib.xml	The glecaprevir/pibrentasvir order set