# Software Implementation of the EU Patient Summary with Archetype Concepts

Evgeniy Krastev
Faculty of Mathematics and Informatics
Sofia University St. Kliment Ohridsky
Sofia, Bulgaria
e-mail: eck@fmi.uni-sofia.bg

Dimitar Tcharaktchiev
Department of Medical Informatics
Medical University
Sofia, Bulgaria
e-mail: dimitardt@gmail.com

Lyubomir Kirov
Faculty of Medicine
Sofia University St. Kliment Ohridsky
Sofia, Bulgaria
e-mail: kirov.lyubomir@gmail.com

Petko Kovatchev
Faculty of Mathematics and Informatics
Sofia University St. Kliment Ohridsky
Sofia, Bulgaria
e-mail: az@petko.info

Simeon Abanos
Faculty of Mathematics and Informatics
Sofia University St. Kliment Ohridsky
Sofia, Bulgaria
e-mail: simeonabanos@gmail.com

Alexandrina Lambova
Faculty of Mathematics and Informatics
Sofia University St. Kliment Ohridsky
Sofia, Bulgaria
e-mail: sanilambova@gmail.com

*Abstract*— **The design and software implementation of the International Patient Summary (IPS) is recently in the focus of several updates of major eHealth standards and technical specifications in European Union (EU) countries. These updates are built exclusively on Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) and HL7 Clinical Document Architecture (CDA) technologies. The purpose is to develop a single, common specification of the minimal and non- exhaustive set of clinical data that can be used by all clinicians for cross- border, unscheduled care of a patient. It requires reusability and semantic interoperability of such data segments that are delivered essentially in terms of Archetype concepts. At the same time, the relation of the Archetype paradigm to patient summary standards and specifications is not well investigated in the current draft versions of these documents. This research investigates the application of the CEN 13606 and openEHR archetypes in the design and software application of IPS sections. The objective of the numerical experiments is to identify the level of compatibility between technologies, related to Archetype paradigms, and the software technologies employed in the current draft versions of standards and specifications of the IPS. The obtained results are novel because the Archetype paradigm is not considered in these draft versions. They serve to extend the practical experience in cross-border sharing of clinical data represented in terms of semantic interoperability of archetype concepts.**

*Keywords-semantic interoperability; software for health; international patient summary; medication summary; archetype concept.*

## I. INTRODUCTION

The research work for the development of a standard for an International Patient Summary (IPS) has a long history. It has started with the European Patients – Smart Open Services (epSOS) project having as a main objective to enable a service infrastructure for cross-border interoperability between EHR systems in Europe [1]. This pilot infrastructure has been planned to allow a citizen from one EU country to receive relevant treatment for unscheduled health need in another country. The outcomes of this project have laid the foundations for sharing and exchanging patient summary and electronic prescription records. Research work has continued in several other EU projects like the Joint Action to support the eHealth Network project (JAseHN [2]) and the obtained results have been implemented in the eHealth Digital Service Infrastructure (eHDSI [3]) or adopted by the eHealth Network (eHN [4]).

The European Commission for Standardization (CEN) in a collaboration with HL7 [5] [6] produced this year draft versions correspondingly of a standard (prEN 17269 [7]) and a technical specification (FprCEN/TS 17288 [8]) for an IPS. These two documents provide a detailed abstract specification of an IPS model from which concrete models can be derived and implemented. Therefore, the IPS model is described in terms of clinical relevant data set that is "*minimal*", "*specialty-agnostic and condition- independent*".

The objective of this paper is to investigate these newly published documents from the point of view of the software implementation of the proposed domain information model and the data set specifications. For example, it is important to learn how well this IPS model can be expressed with CEN 13606 and openEHR, where CEN 13606 [9] is the EU approved standard for semantic interoperability. The reason to explore this subject in prEN 17269 is that the collaboration of CEN with HL7 has led to a rather unbalanced interpretation of the use cases in terms of software technologies exclusively related to HL7 FHIR [10] and HL7 CDA [11]. Indeed the data set references to ISO 21090 [12] make this model compatible with the data sets used in information models based on American Standards HL7 v3, HL7 FHIR or an EU standard like CEN 13606. On the other side, the IPS draft standard prEN 17269 does not provide guidance for implementing semantic interoperability in the exchange of IPS records. In fact the draft version of FprCEN/TS 17288 provides just a short informative reference to CEN 13606 and openEHR archetypes, while semantic interoperability appears to be out of the scope of this IPS model. Moreover, the evaluation of the IPS model is presented only in terms of the Messages Paradigm of HL7 CDA and HL7 FHIR making use of a specific ART-DECOR template exchange format with Native XML databases (NXD) [13]. Besides, practical experience shows that the support for semantic interoperability of the Messages paradigm is problematic and it is difficult to scale it at National levels [14].

Our approach to evaluate the IPS model is based on designing and implementing the IPS document with archetype concepts satisfying the Archetype Object Models of CEN: 13606 [15] [16] and openEHR [17]. It is a novel research work because it aims to evaluate newly published draft versions of a standard and the accompanying it technical specification for IPS, where the Archetype paradigm is superficially taken in consideration. Note that the ART-DÉCOR template format is not directly compatible with the Archetype Description Language (ADL) [15] [17]. The above formulated issues are currently poorly explored in the existing literature especially regarding their software implementation. In this paper, we take one of the required sections of the IPS as a case study to validate the application of our approach for introducing semantic interoperability support in the scenarios for managing IPS extracts. The details of our approach are as follows:

- Implement the IPS Medication section in prEN 17269 both in terms of CEN 13606 Archetype Object Model (AOM)and in terms of the openEHR AOM.
- Explore the compatibility of the obtained CEN 13606 Archetype conceptual design with respect to the requirements of an openEHR engine for running openEHR Operational templates.
- Explore the W3C XML Schemas of IPS archetype conceptual models with respect to potential practical implementations of the proposed standard.
- Develop a client- server application for testing the openEHR Operational template on an openEHR engine in a local and cloud environment.
- Propose a methodology for transforming a CEN 13606 or openEHR archetype conceptual models into a format that enables the creation of archetype instances compatible with NXD.

This paper is divided into sections as follows. In the following section, we present the IPS archetype conceptual design; where we adopt a well-structured archetype modeling methodology [18] and explore the compatibility between different AOM. In Section III, we present our software implementation details. In Section IV, we summarize the obtained results and on this basis a methodology for implementing the Archetype paradigm with the IPS standard

is proposed. Section V makes a conclusion and provides remarks on future work.

## II.    IPS DESIGN WITH ARCHETYPE CONCEPTS

The draft standard prEN 17269 represents the IPS as a set of reusable data blocks integrated with ontologies such as SNOMED-CT [19]. The data blocks are organized in four groups- *Header*, *Required*, *Recommended* and *Optional* sections. Without loss of generality, we consider the *Medication Summary* section, which is one of the three *Required* sections.

The data structure and the data types used in section are described in full details in Table 26 of the prEN 17269 standard. The draft version of this standard describes the same way the rest of the sections of the IPS, where the data set borrows data types from ISO 21090.The detailed description of the IPS contains all the information necessary for building a conceptual model in terms of archetypes. In our research work, we explored the design of this model with CEN 13606 and openEHR archetypes. For this purpose, we follow a five-stage methodology for archetype design [18]. It allows us to transform correctly a clinical document like the IPS into an archetype conceptual model. We have also compared the application of different software tools in obtaining the desired conceptual model. For example we have found that LinkEHR Studio [20] is more suitable for creating a CEN 13606 AOM, while the Template Designer and Archetype Editor [21] are more specialized and appropriate to employ with the openEHR AOM.

These tools allow us to bind semantic context to the archetype conceptual model from terminology servers and this way map terms to national standards like LOINC, SNOMED-CT, and ICD-10. It allows the IPS conceptual model to deliver meaningful, reliable, semantical clinical information at the point of care. The obtained conceptual models are displayed in Figure 1. We have preserved the names for the concepts, the semantics of the data types from ISO 21090 and the constraints on occurrences as they are specified by the draft standard for the IPS. The AOM of CEN 13606 allows to represent the conceptual model of the IPS in the *Medication Summary* section as a single archetype (Figure 1.).
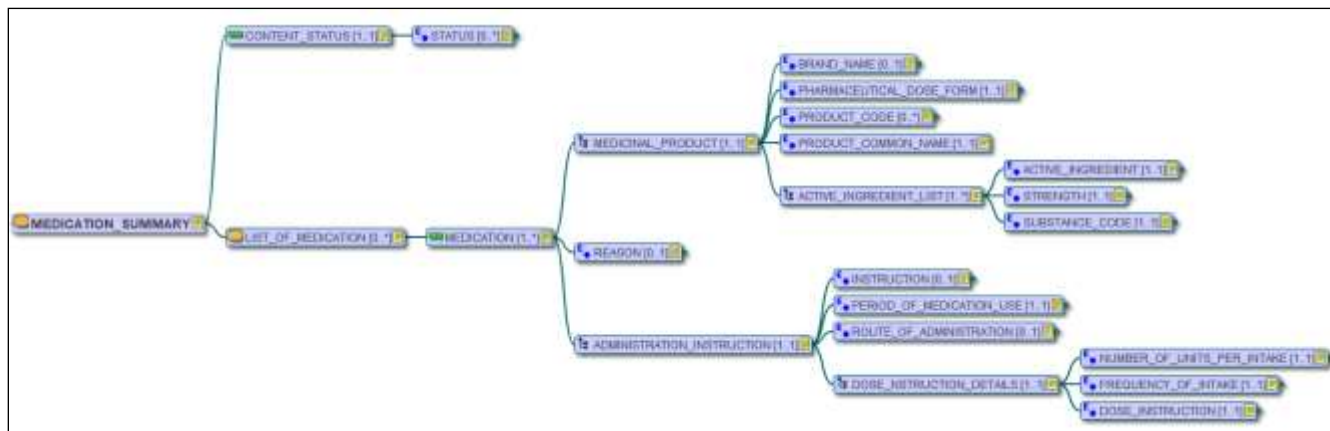


Figure 1.   Mind map design of the IPS Medication Summary Section in prEN 17269:2018 with a CEN 13606 archetype.

On the other side, the AOM of openEHR requires to design separate archetype models for COMPOSITION archetype (representing the whole IPS) with slots for SECTION archetypes (representing slots for each of the sections of the IPS) and specialized ENTRY archetypes (representing the CONTENT_ITEM in each one of the IPS sections). For example, the *Medication Summary* section has been created an INSTRUCTION specialization of the ENTRY archetype. Finally, all the COMPOSITION, SECTION and INSTRUCTION archetypes have been assembled in a single template, shown on the right side in Figure 2.

Both conceptual models can be exported to valid openEHR Operational templates no matter the structural differences in the explored conceptual model. Moreover, it has allowed us to execute the obtained openEHR conceptual model in a client- server application making use of an openEHR engine for processing instances of the *Medication Summary* section Operational template. The conceptual design of the IPS section of the archetype models can be explored in W3C XML Schema format. This approach to investigate the IPS conceptual model is a novelty in the existing literature because a W3C XML Schema Definition Language (XSD) model of the IPS is not presented in the proposed prEN 17269 standard. At the same time, its practical implementation implies the use of web services, where the XSD model specification is important.

The XSD model of the *Medication Summary* section is shown in Figure 3 in CEN 13606 concepts. This model is suitable for implementations in NXD, where XQuery can serve as a good replacement for the absence of an Archetype Query Language in the AOM of CEN 13606.
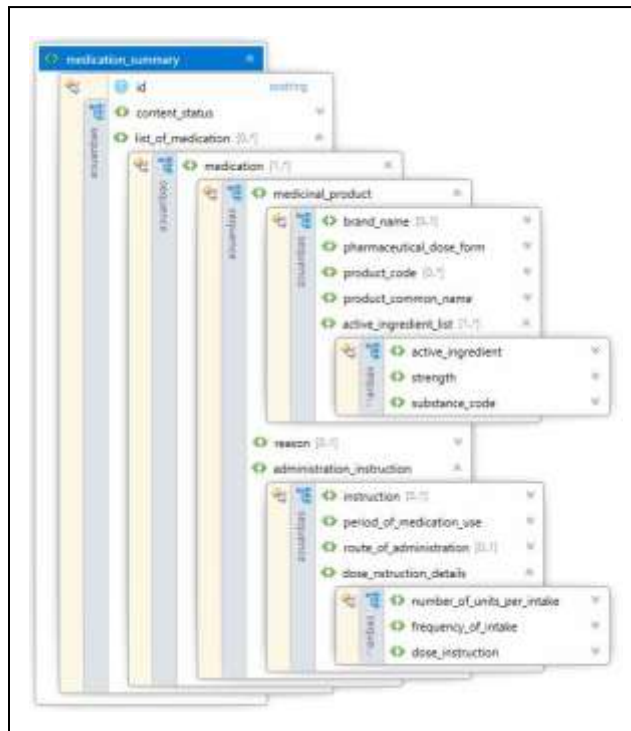


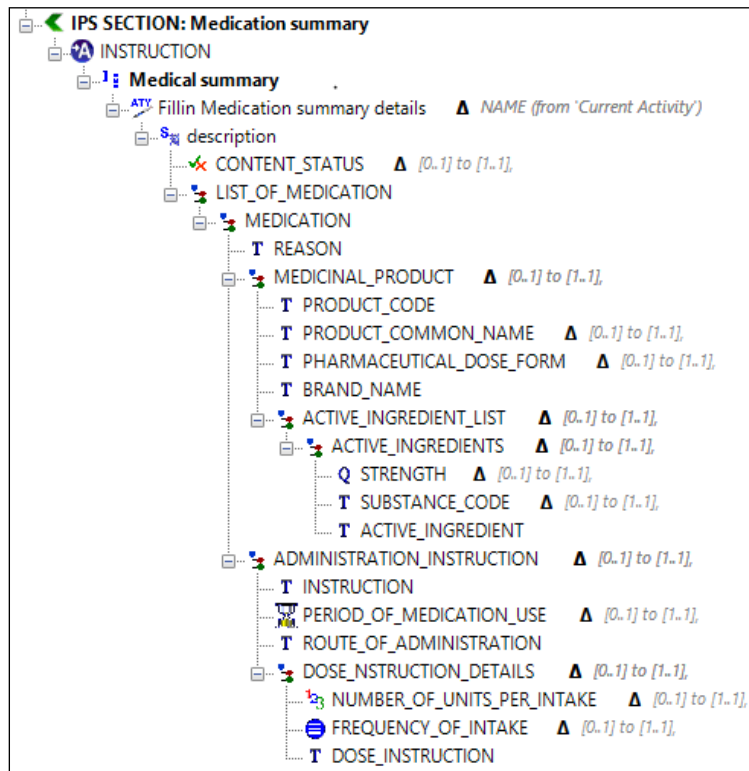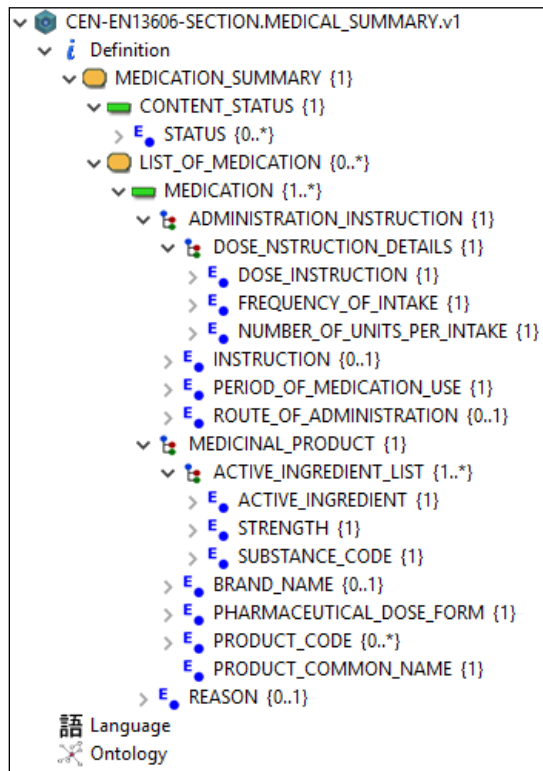Figure 3.   W3C XML Schema of an IPS Section in CEN 13606 AOM.



Figure 2.   IPS Medication Summary design as a CEN 13606 archetype (left side) and as a template of openEHR archetypes (right side).

For comparison, the XSD model of openEHR concepts includes a lot of metadata payload. Real- life IPS applications process large numbers of openEHR XSD model instances. Therefore, it is not practicable to employ NXD for storage and the management of such instances.

### III. SOFTWARE IMPLEMENTATION

The software implementation of the IPS conceptual models in a client server application has been developed with the objective to evaluate the applicability of the Archetype paradigm in implementing the proposed IPS standard. For this purpose, the openEHR Operational template of the *Medication Summary* section has been installed and run on both a local CaboLabs openEHR engine [21] and a cloud-based Code4Health platform [22]. A client PHP application has been developed to store and read instances of the Operational template from the openEHR server by means of RESTful API. A snapshot of the client application is shown in Figure 5.

The user interface of the client can be auto generated from the archetype conceptual model. A client application can use a custom defined graphical user interface as well. This application links each instance of the Operational template to a unique Patient ID that is displayed in the query string of the HTTP GET request. The sample client application makes use of SNOMED-CT codes (see fields *Route of Administration* and *Substance code* in Figure 5) and real *Medicinal Product Details* to prove that the semantic context embedded in the archetype conceptual model can be interpreted correctly by any client that manages instances of that model. By selecting an archetype conceptual model, the client agrees to follow the mapping of terms to standards provided by the terminology servers linked to the selected model.



Figure 4.   Methodology for semantic interoperability of the IPS.

### IV. DISCUSSION

In this paper, we have evaluated the applicability of the Archetype paradigm in software applications that implement the draft version of the IPS standard. Although the Archetype paradigm is not in the focus of this standard, we have demonstrated that it can be successfully employed in software applications apply this standard.

The practical experience in producing the here reported results allow us to propose a methodology for applying the proposed IPS standard in use cases where semantic interoperability is a requirement (Figure 4). The first stage in this methodology is to create a correct conceptual model on the IPS document. The archetypes in this model serve as "*plug-and-play*" building blocks for semantic interoperability that can be imported from a repository known a Clinical Knowledge Manager. It is important to note at this stage the requirement for binding of the archetype model to Terminology servers. Therefore, it would be useful the final version of the IPS standard to provide public access not only to a promised standard set of SNOMED-CT code set, but also to publish a set of standard CEN 13606 archetypes together with their XSD representations. The obtained archetype conceptual model is ready for reuse in software applications. Clients select an archetype conceptual model and manage instances of that model in terms of semantic interoperability. Unlike the Messaging Paradigm the implementation of the Archetype paradigm with the proposed IPS standard makes possible all data, information and knowledge in each system to be available in a uniform and standard way.

Finally, we note that in the existing literature there is evidence that openEHR archetypes can be transformed to CEN 13606 archetypes making use of the common ISO 21090 data set [23] The mapping from CEN 13606 to openEHR is not explored so far. As a side result, we have established that it is not possible to convert CEN 13606 archetypes directly into openEHR archetypes. The reason is that the concrete class ENTRY from the Reference model of CEN 13606 is mapped to the abstract class ENTRY in the Reference model of openEHR. Therefore, we can export a CEN 13606 archetype into a valid openEHR Operational template. However, it is not possible to create instances of that template. In openEHR there are concrete specializations of class ENTRY like OBSERVATION, EVALUATION, INSTRUCTION and ACTION. Hence, it is very difficult to map a concrete ENTRY class in CEN 13606 to some of these specializations of the openEHR class ENTRY.

### V. CONCLUSION AND FUTURE WORK

This paper has investigated the design and software implementation of the International Patient Summary according to the current draft versions of prEN 17269 and FprCEN/TS 17288. These versions make use exclusively of HL7 FHIR and HL7 CDA technologies with the purpose to develop a single, common specification of the minimal and non- exhaustive set of clinical data that can be used by all clinicians for cross- border, unscheduled care of a patient. Our analysis of these documents shows that they are built exclusively on top of the Message paradigm information
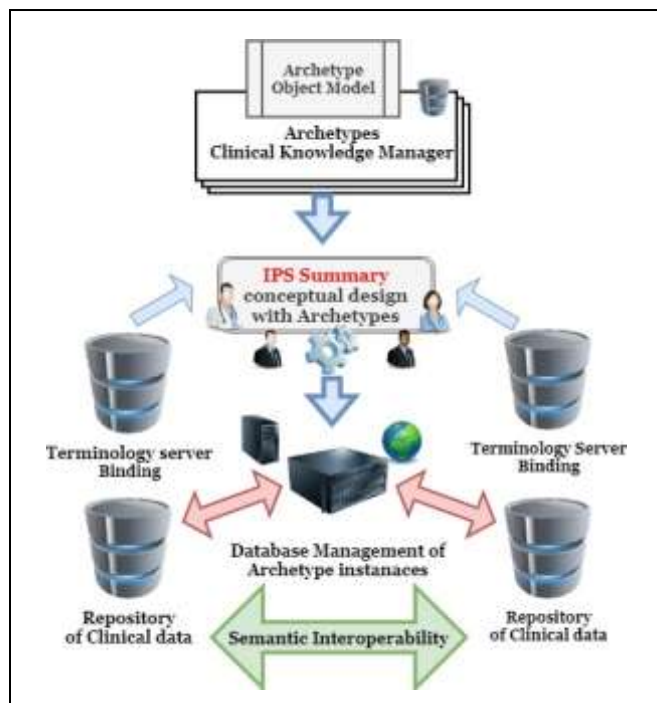
model and data set. Therefore, in this paper, we explore how the objectives of this standard can be achieved by applying the Archetype paradigm approach. In the literature it is recognized that reusability and semantic interoperability of clinical data like the IPS segments can are delivered essentially in terms of Archetype concepts. The obtained results provide evidence that the IPS can be designed in terms of CEN 13606 and openEHR archetype concepts. Both archetype models support binding to semantic context provided by terminology servers like SNOMED-CT.

We have established that the CEN 13606 AOM cannot be used to create instances compatible with the openEHR AOM. It is an important conclusion because the compatibility of transformation from CEN 13606 to openEHR has not been explored in the existing literature. The numerical experiments demonstrate that both archetype models can be exported in W3C Schema definitions, where the XSD of openEHR AOM contains considerably larger payload of metadata. Therefore, it is preferable to manage instances of openEHR archetype models by means of operational templates on native openEHR engines.

It is noteworthy, that the draft versions of both the IPS standard and its technical specification do not consider a XSD model of the IPS. At the same time, practical implementations of this standard rely on web services where the specification of the XSD models is important. We have demonstrated this approach in a client server application with real medicinal data and terminology codes, where the same operational template of the IPS section can run both on a local and on a cloud-based openEHR engine. Accordingly, instances of CEN 13606 archetypes can be managed in NXD as it is demonstrated in the use cases of FprCEN/TS 17288 with HL7 concepts.

We plan to explore the feasibility of this different approach for enabling IPS semantic interoperability in our future work.

In summary, the obtained results are presented in a uniform methodology for implementing the IPS in terms of the Archetype paradigm. These results are novel because the Archetype paradigm is not considered in the draft version of the IPS standard. They serve to extend the practical experience in cross-border sharing of clinical data represented in terms of semantic interoperability of archetype concepts.

REFERENCES

[1] European Patients Smart Open Services (epSOS) , "D3.2.2 Final definition of functional service requirements- Patient Summary," 29 October 2012. [Online]. Available: https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved. [retrieved: August, 2019].

[2] European Commission, "Joint Action to support the eHealth Network [JAseHN][677102] - Joint Actions," 30 June 2018. [Online]. Available: https://webgate.ec.europa.eu/chafea_pdb/health/projects/677102/summary. [retrieved: August, 2019].

[3] eHealth DSI, "PS Use Case," 30 April 2019. [Online]. Available: https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/PS+Use+Case. [retrieved: August, 2019].

[4] eHealth Network, "Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU.," Brussels, 2016.

[5] HL7 International, "International Patient Summary," 2018. [Online]. Available: http://international-patient-summary.net/mediawiki/index.php?title=IPS_implementationguide_1 [retrieved: August, 2019].

[6] HL7 International, "HL7 Version 3 Standard: Pharmacy; Medication Order, Release 2," 2019. [Online]. Available: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=65. [retrieved: August, 2019].

[7] CEN/TC 251, "prEN 17269. Health informatics - The Patient Summary for Unscheduled, Cross- border Care," European Committee for Standardization, Brussels, 2018.

[8] CEN/TC 251, "FprCEN/TS 17288. Health informatics - The International Patient Summary: Guidance for European Implementation," European Committee for Standardization, Brussels, 2018.

[9] CEN/TC 215, "ISO 13606-1:2008 Health informatics -- Electronic health record communication -- Part 1: Reference model," 2 2008. [Online]. Available: https://www.iso.org/standard/40784.html. [retrieved: August, 2019].

[10] HL7 FHIR, "FHIR Release 4. International Patient Summary Implementation Guide," 27 December 2019. [Online]. Available: https://build.fhir.org/ig/HL7/fhir-ips/. [retrieved: August, 2019].

[11] HL7 International, "HL7 Version 3 Clinical Document Architecture," 2019. [Online]. Available: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7. [retrieved: August, 2019].

[12] ISO/TC 215 Health informatics, "ISO 21090:2011 Health informatics -- Harmonized data types for information interchange," Feb 2011. [Online]. Available: https://www.iso.org/standard/35646.html. [retrieved: August, 2019].

[13] ART-DECOR, "ART-DECOR Open Tools," 2019. [Online]. Available: http://art-decor.org/art-decor/decor-project--hl7ips. [retrieved: August, 2019].

[14] G. Freriks, G. de Moor and D. Kalra, "White paper: Archetype paradigm: an ICT revolution is needed," 13 March 2007. [Online]. Available: http://www.eurorec.org/files/filesPublic/ArchetypeParadigmFeb2007.pdf. [retrieved: August, 2019].

[15] ISO/TC 215, "ISO 13606-2:2019. Health informatics -- Electronic health record communication -- Part 2: Archetype interchange specification," ISO, 2019. [Online]. Available: https://www.iso.org/standard/62305.html [retrieved: August, 2019].

[16] ISO/TC 215, "ISO 13606-1:2019 Health informatics -- Electronic health record communication -- Part 1: Reference model," ISO, 2019. [Online]. Available: https://www.iso.org/standard/67868.html. [retrieved: August, 2019].

[17] openEHR Foundation, "10. Archetypes and Templates," openEHR, December 2018. [Online]. Available: https://specifications.openehr.org/releases/BASE/latest/architecture_overview.html#_archetypes_and_templates. [retrieved: August, 2019].

[18] D. Moner, J. A. Maldonado and M. Robles, "Archetype modeling methodology," Journal of Biomedical Informatics, vol. 79, pp. 71-81, 2018.

[19] SNOMED International, "SNOMED CT," 2019. [Online]. Available: http://www.snomed.org/snomed-ct/get-snomed-ct. [retrieved: August, 2019].

[20] VeraTech for Health, "LinkEHR Ineroperability Platform," 2019.

[21] P. P. Gutiérrez, "Towards the Implementation of an openEHR-based Open Source EHR Platform (a vision paper)," in MEDINFO 2015: EHealth-enabled Health: Proceedings of the 15th World Congress on Health and Biomedical Informatics, São Paulo, Brazil, 2015, pp.45–49.

[22] Code4Health, "Code4Health Platform," 2019. [Online]. Available: https://github.com/code4health-platform. [retrieved: August, 2019].

[23] T. Beale, "openEHR to ISO 13606-1, ISO 21090 mapping," 15 May 2015. [Online]. Available: https://openehr.atlassian.net/wiki/spaces/stds/pages/5373954/openEHR+to+ISO+13606-1+ISO+21090+mapping. [retrieved: August, 2019].
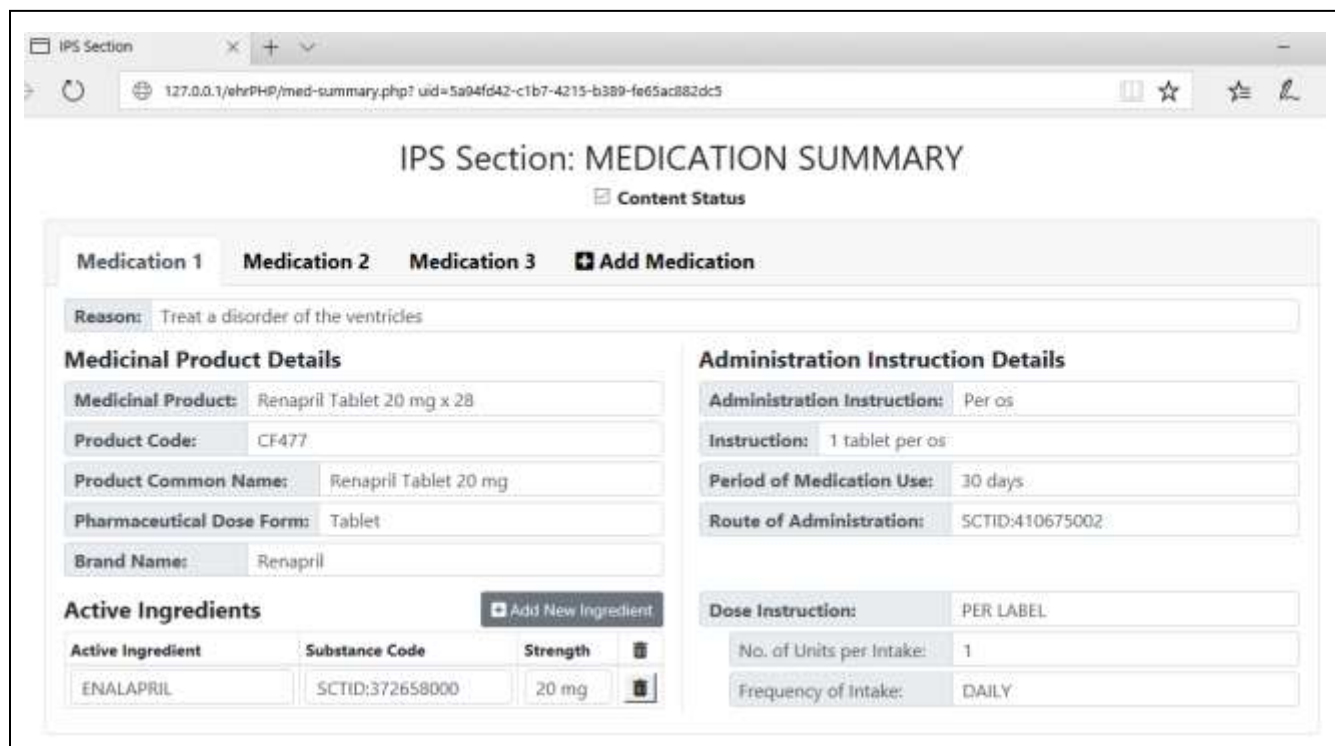


Figure 5.   Snapshot of a client application creating an openEHR archetype instance of the IPS Medication Summary Section.