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Converting ODM Metadata to FHIR Questionnaire Resources

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Abstract. Interoperability between systems and data sharing between domains is becoming more and more important. The portal medical-data-models.org offers more than 5.300 UMLS annotated forms in CDISC ODM format in order to support interoperability, but several additional export formats are available. CDISC's ODM and HL7's framework FHIR Questionnaire resource were analyzed, a mapping between elements created and a converter implemented. The developed converter was integrated into the portal with FHIR Questionnaire XML or JSON download options. New FHIR applications can now use this large library of forms.

Keywords. Interoperability, HL7 FHIR, CDISC ODM, standards

1. Introduction

The advancement of health information technology lead to and increasing usage of electronic systems in health care like electronic health records (EHR) and electronic data capture (EDC) systems. These systems are nowadays not data silos anymore, but facilitate data sharing, for example in hospitals through a communication server. In such a hospital setting data rarely leaves the sphere of patient care. This means that data has oftentimes to be documented twice and transferred manually from routine care to clinical research systems when a patient participates in a clinical study.

Through increasing cost pressure in the healthcare sector this important topic of interoperability has also arrived in politics. Legislation like the 'HITECH Act' in the US in 2009 [1] and programs like the 'Förderkonzept Medizininformatik' in 2015 in Germany [2] (among others) were established to promote health data exchange and re-use.

Two systems need to be syntactically and semantically interoperable to enable data sharing. Semantic interoperability is achieved through the use of classifications like the 'International Statistical Classification of Diseases and Related Health Problems, 10. Revision' (ICD-10) or terminologies such as 'Systematized Nomenclature of Medicine - Clinical Terms' (SNOMED-CT) or Unified Medical Language System (UMLS). For syntactic interoperability general formats like Extensible Markup Language (XML) or JavaScript Object Notation (JSON) are used and in healthcare specific standards like those from Health Level-7 (HL7) or Clinical Data Interchange Standards Consortium's (CDISC) Operational Data Model (ODM).

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The Portal of Medical Data Models (MDM-Portal)[3], a registered German and European infrastructure project [4, 5], was started to foster the sharing of medical data by making UMLS annotated metadata of forms freely available to the scientific community [6]. Documents and forms or generally speaking 'data models' are stored in the ODM format, but several additional export formats such as CSV, REDCap, PDF and many more are available.

A new and popular framework for the exchange of healthcare related data is Fast Health Interoperability Resources (FHIR) from HL7 [7]. Advantages are the "combination of the best features from HL7 v2, HL7 v3 and CDA" and its focus on implementation and modern web technologies [8].

For this work our objective was to analyze this new emerging technology, evaluate whether it's possible to map from ODM to FHIR, more specifically the Questionnaire resource, and if so create converters.

2. Methods

The data models of the CDISC ODM 1.3.2 standard and FHIR Questionnaire resource, maturity level 2, were reviewed. A mapping between elements of the models was created and a converter from ODM metadata to the FHIR Questionnaire resource was implemented as a web service using the programming language Java.

3. Results

3.1. Mapping

The structure of the metadata from ODM files consists of 'StudyEvents', several 'Forms', 'ItemGroups', 'Items' and an optional 'CodeList' with 'CodeListItems'. StudyEvents don't contain actual data themselves, but describe which forms are used at a certain step in the workflow and were therefore omitted during the transformation.

A FHIR Questionnaire resource consists of 'questionnaire', 'groups', 'questions' and optional elements ('option'). A group can contain another group or a question, but not both at the same time and a question can itself contain groups as well. Questions can also contain option elements, which are permitted answers if the question type is 'choice'.

Form and ItemGroup from ODM were mapped to the group element from FHIR, Item to Question and CodeListItem to Option. Figure 1 shows the mapping of the elements and their attributes from ODM to their FHIR Questionnaire resource counterparts.



Figure 1. Mapping of ODM elements and attributes to their FHIR Questionnaire resource counterparts.

ODM supports multilingual forms by default using 'TranslatedText' elements, e.g. <TranslatedText xml:lang="en-GB">In the last two weeks...</TranslatedText>. In FHIR multilingualism can only be implemented using 'Extensions'. For this purpose the 'StructureDefinition-Extensions' 'iso21090-ST-translation' and 'iso21090-ST-language' were used in conjunction as shown in Figure 2. Figure 3 shows exemplified for one element how the mapping for different language representations was done.

```
<extension url="http://hl7.org/fhir/StructureDefinition/iso21090-ST-translation">
<valueString value="In den letzten zwei Wochen ...">
    <extension url="http://hl7.org/fhir/StructureDefinition/iso21090-ST-language">
         <valueString value="letzten zwei Wochen ...">
         <extension url="http://hl7.org/fhir/StructureDefinition/iso21090-ST-language">
         <valueString value="letzten zwei Wochen ...">
         <extension/iso21090-ST-language">
         </valueString value="letzten zwei Wochen ...">
         </extension/iso21090-ST-language">
             </extension>
            </valueString value="letzten zwei Wochen ...">
            </extension/iso21090-ST-language">
                 </extension>
            </valueString>
            </extension>
            </extension>
```

Figure 2. FHIR Extensions 'iso21090-ST-translation' and 'iso21090-ST-language' used to implement multilingualism. The iso21090-ST-translation extension expresses a translation of a string in a different language while the iso21090-ST-language extension indicates which language is expressed.



Figure 3. Example of mapping the attributes of a form name in several languages from ODM to the FHIR StructureDefinition extensions 'iso21090-ST-translation' and 'iso21090-ST-language'.

3.2. Implementation

For the implementation the programming language Java was used. The ODM classes representing the structure of the source ODM document were generated from the official XML Schema Definition (xsd) file. For the FHIR classes the HAPI-FHIR library [9] in version 1.3 was used.

The converter is realized as a web service which takes an ODM file as input and creates a FHIR Questionnaire file in XML or JSON format. The web service was then connected to the MDM-Portal in order to automatically offer the possibility to download a form in FHIR XML or JSON.

4. Discussion

We were able to create a converter which creates FHIR Questionnaire resources and takes ODM files as input. Due to the different structures of both models a converter from the FHIR Questionnaire resource to ODM was not implemented. ODM has a strict hierarchy consisting of Form, ItemGroup and Item, while the questionnaire resource is more flexible. In FHIR group and question elements can both contain group elements again and the structure of a questionnaire can therefore be more complex than the structure of an ODM form.

For our work we only regarded the metadata of ODM files and ignored the rest like the clinical data. However Leroux et. al. [10] have analyzed to which FHIR resources the different elements from ODM fit. Their analysis showed that clinical data fits several FHIR resources (Patient, ClinicalImpression, EpisodeOfCare, Encounter, QuestionnaireResponse and Observation) while ODM metadata fits to two FHIR resources, Study and StudyEvent data matches FHIR's CarePlan resource and Form, ItemGroup and Item metadata match the Questionnaire resource, which is in agreement with our implementation.

The integration of the converter into the MDM-Portal allows the FHIR community to create new applications based on this rich source with currently more than 5.300 annotated and multilingual forms. Systems that currently already use the Questionnaire resource are for example C3-PRO [11], which is employed in the C-Tracker study where the impact of hepatitis C on people's lives is evaluated [12], or the apps platform SMART-on-FHIR [13].

Currently the MDM-portal offers the possibility to download questionnaires manually. It has to be discussed whether a separate RESTful web service for

preprocessed, particular interesting questionnaires should be set up, so that these resources can be directly integrated in applications.

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