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HL7 FHIR in Health Research: A FHIR Specification for Metadata in Clinical, Epidemiological, and Public Health Studies

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Abstract. This work presents the Fast Healthcare Interoperability Resources (FHIR ®) specification of the NFDI4Health Metadata schema based on FHIR Version 4: We created 16 profiles to facilitate the integration of clinical, epidemiological, and public health study data. Despite challenges arising from the extensive MDS as well as missing concepts in semantic standards, it marks a significant advance in applying information technology standards to health research.

Keywords. FHIR, Standards, Interoperability, FAIR, Health Research, Public health

1. Introduction

The German initiative National Research Data Infrastructure for Personal Health Data (NFDI4Health) promotes collaboration between health research domains through the use of a common metadata schema (MDS) and different services. To improve data interoperability in health research, NFDI4Health'MDS aims to foster the FAIR (Findable, Accessible, Interoperable, Reusable) principles. Our goal was to map metadata from clinical, epidemiological, and public health studies to Health Level 7® Fast Healthcare Interoperability Resources® (FHIR®), a health exchange standard expanding into health research [1].

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2. Methods

We selected suitable terminologies and the health informatic standard (HL7 FHIR®), mapped the MDS to these and performed a need-gap analysis based on preliminary work [2]. Next, we focused on creating profiles for the HL7 FHIR release 4 (R4) tailored to the NFDI4Health metadata schema. These FHIR profiles are designed to facilitate the interoperability of metadata pertaining to studies, questionnaires, and documents collected in the German Central Health Study Hub. For missing elements, we reused already existing extensions, or built─whenever possible─backport extensions from FHIR Version R5.

3. Results

We developed a FHIR specification comprising 16 profiles, encompassing 67 ValueSets and 50 extensions. We used three backport extensions to utilize the elements ResearchStudy.outcomeMeasure -.comparisonGroup and -.recruitment from R5. For the creation of ValueSets, we used concepts from SNOMED CT, LOINC, NCI and ISO. In total, 193 concepts could not be mapped to international terminologies. Cardinalities with specific conditions of the MDS elements are checked by invariants. The current Implementation Guide is publicly available on the collaborative platform SIMPLIFIER.net [3].

4. Discussion and Conclusions

The implementation of numerous extensions presents a limitation, as it may complicate adaptation for other research data collection purposes. Additionally, concepts not mapped with official terminologies need to be revised. Our specification significantly advances the application of terminologies and HL7 FHIR in health research.

References

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