Design and Implementation of an Open Clinical Trials Platform Using HL7® FHIR® Within the Orthokids-Project

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Keywords: System Design and Development, Health Informatics, HL7 FHIR, Digital Clinical Trials.

Abstract: Design and implementation of real care processes is a complex task, where the information model is central and serves as a basis for further implementation of the overall IT system. In this contribution, we describe the process of modeling study-specific structures on the base of FHIR in the OrthoKids project. The OrthoKids project is a clinical study aimed at establishing an orthopedic preventive medical examination for children. We explain how FHIR was used for modeling the data and in what form it is used, ending in summarizing our experiences we made when modeling the OrthoKids study with FHIR.

1 INTRODUCTION

Digital platforms transform clinical trials, offering numerous benefits that enhance research efficiency and effectiveness. These platforms facilitate improved enrolment, promote enhanced participant engagement and adherence to trial protocols through personalized interventions and real-time monitoring. Digital solutions provide cost-effective and scalable approaches to conducting large-scale, decentralized clinical trials. Furthermore, these platforms enable more efficient and reliable data collection, improving the quality and timeliness of clinical trial data (Inan, 2020).

In order to deliver usable and process integrated digital medical documentation platforms, the project- and study-specific management structures, data and care pathways must be modeled as closely as possible to reality in order to subsequently transfer them into the digital applications and user interfaces. Therefore the design and development of the information model is central to this process. The information model is a digital representation of reality and must include all digital data elements and process steps within a study process.

In this contribution, we want to describe the process of modeling and representing study-specific structures in the OrthoKids project, which was funded by the German Innovation Fund. The OrthoKids project is a clinical study aimed at establishing an orthopedic preventive medical examination for children and adolescents between the ages of 10 and 14. The medical care pathway within the preventive medical examination consists of several stages that include questionnaire-based assessments (in context of OrthoKids so-called *EKFB*), medical check-ups and diagnostics. The OrthoKids study is conducted outside of existing medical care structures, so in addition to patients and doctors, study coordinators are also involved in the process. Currently, around 12,500 study participants and approximately 200 doctors are using the Orthokids platform within the context of the OrthoKids study (Scheckel, 2023).

Since a fundamental requirement of the funding was to develop reusable and extensible technological solutions, the HL7 FHIR standard was chosen as the basis for modeling the project presented here. The FHIR standard supports data exchange between software systems in healthcare and describes data formats and elements as so-called "resources". Beyond the mere representation of data, FHIR also offers standardized interfaces for data exchange, allowing information-processing services to build upon it.

The following chapters describe the OrthoKids study design and the technical elements, the information model and how the data is processed. Chapter 5 refers to the related work in the area of standardized clinical trials platforms and Chapter 6 ends with a conclusion and summarizes experiences we made when modeling the OrthoKids study using HL 7 FHIR.

Grohnert, A., John, M., Häusler, B., Giertz, C., Kraufmann, B., Klose, S. and Klaus, C.
Design and Implementation of an Open Clinical Trials Platform Using HL7® FHIR® Within the Orthokids-Project.
DOI: 10.5220/0013378600003911

In *Proceedings of the 18th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2025) - Volume 2: HEALTHINF*, pages 936-943
ISBN: 978-989-758-731-3; ISSN: 2184-4305

2 ORTHOKIDS STUDY DESIGN

The pediatric musculoskeletal system of young people goes through several developmental phases. It is in a sensitive growth and transformation phase between the ages of 10 and 14. Orthopedic deformities are often difficult to recognize during this phase. As part of the preventive medical examinations for children and adolescents, the musculoskeletal system so far is only checked by pediatricians. Up to now a specialized preventive medical examination (screening) by an orthopaedist is not typically included in standard care in Germany. However, this could be beneficial for the healthy growth of children and adolescents.

The OrthoKids project introduces an additional orthopedic preventive medical examination for children and adolescents for early detection and early treatment of skeletal deformities in the foot and leg axes, hip and spine. For this purpose, patients aged between 10 and 14 are screened (preventive medical examination) and, if abnormalities are detected, the treatment progress is checked after one year (follow-up examination). During this year, therapy recommendations are made by the doctor to the parents. The implementation of these therapies will also be inquired about during the follow-up examination.

To systematize the study process, different phases and activities have been defined that a participant goes through over a period of 12 to 14 months. Firstly, this includes the study enrollment, which involves consent to participate in the study, user registration, signature of the treatment contract and the initial medical assessment (EKFB t0). At the beginning of the study, a specialized orthopedic assessment and the preventive medical examination are carried out by the treating orthopaedist. In case of a medically positive result the follow-up examination takes place after 12 months. During this 12-month observation period, the patient can access standard care services if there are notable findings and will also receive two more questionnaire-based assessments (EKFB t1, t2) to collect additional health-related study data. The regular study ends after the completion of the follow-up examination. In case of study withdrawal, the patient is treated as a drop-out.

During study enrollment and study participation, many documents such as consent forms, treatment contracts, various surveys and assessments are created and stored in the participant's master data sheet and study record. At the end of the study, these data are exported for further analyzation by an evaluating institute.

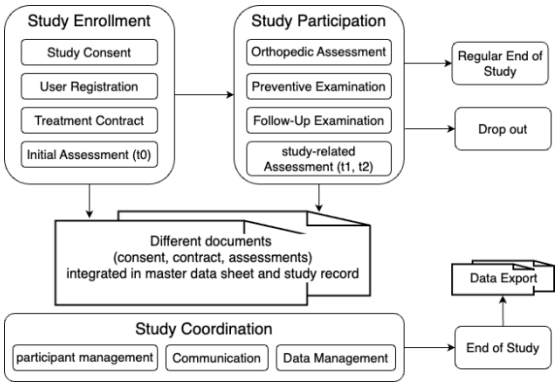

Figure 1: Central processes supported by the OrthoKids platform.

The study coordination is a parallel process that includes participant management, communication with doctors and participants, as well as data management. Various support functions have been developed for this purpose, allowing the study coordinators to manage the study process digitally using the OrthoKids platform. All these process steps in the study's workflow were modelled first before digital applications and data elements have been designed, developed and implemented.

2.1 Digital Support in Study Execution

The conduct of the study and the data processing are realized through the OrthoKids platform. Thus, it supports children, parents, specialists and study coordinators in the OrthoKids preventive process.

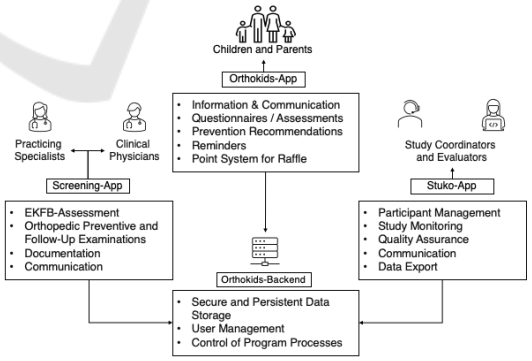

Figure 2: Overview of the digital applications on the OrthoKids platform.

The children participating in the study receive a *smartphone app* that accompanies them throughout the study process. Informational materials and participating doctors can be queried, and surveys can be completed even before the doctor's visit. After the preventive medical examination (screening) took

place, the app serves as a guide for accompanying prevention programs.

With the *Screening-web-app* for orthopedic specialists, the examination process and results can be documented with minimal effort. Established pathways for preventive and follow-up examinations, as well as therapy recommendations, standardize the usage auf the interface during examination and minimize documentation efforts.

The *Stuko-app* supports the study coordinators in managing the study process. Here, study participants can be managed, current data statuses can be viewed, and communication with participants can be documented. A reminder management system alerts to upcoming or outstanding actions in the study process.

All examination data is collected and processed within the OrthoKids IT-platform. At the same time, it serves as a central communication and information medium among the involved parties and provides not only information about the preventive medical examination but also accompanying informational materials on health-promoting preventive offerings. Additionally, questionnaires can be integrated into the platform, simplifying the documentation for the accompanying scientific study. All collected data is transmitted via secure communication channels to the OrthoKids project server (backend) and stored persistently there.

3 INFORMATION MODEL

The abstraction of reality occurs through an information model, which represents both the data and states of the examinations as well as the underlying processes. Hence, the information model is the representation of the semantic and procedural relationships in the study data. It follows the principles of interoperability, simplicity and flexibility to facilitate integration and communication between different healthcare systems. In the OrthoKids project it was created based on the data that are necessary for the conduct of the study from a medical perspective and the perspective of study management.

For the modeling of the study process presented in the OrthoKids project, FHIR® was chosen as the basis. FHIR (Fast Healthcare Interoperability Resources) is a standard developed by HL7® (Health Level Seven International) [1], which is gaining increasing importance worldwide and is also attracting growing interest in Germany, particularly in the context of the digitalization of healthcare and initiatives such as the electronic health record (ePA).

With FHIR, both actors (e.g. patient, doctor) and activities (e.g. study enrollment, examinations with appointment scheduling, doctor changes) can be represented. FHIR provides corresponding resources that can also abstract entire processes by linking the resources accordingly. For instance, the Appointment resource represents the agreement for an examination appointment or a consultation. The Encounter then represents the actual occurrence of the appointment, and the Condition, possibly in combination with an Observation, represents the result of the examination. If these FHIR resources are linked appropriately, the process of carrying out an examination or screening can be represented.

To define the information model for OrthoKids, the study process was analyzed and divided into phases (study enrollment, study participation, study completion) and within these phases into activities (see following Chapter 3.1). Based on the modeled activities of the study process, the FHIR resources were identified. One of these activities is the conduct of the preventive medical examination, and another is the doctor change, which will exemplarily demonstrate how the modeling process was carried out.

3.1 Preventive Medical Examination

For clarification of the necessary process steps first the routine of a preventive medical examination was modelled using BPMN (see figure 3).

Parents and children present themselves at the doctor's office for the examination and pass through the screening. At the beginning of the examination, the doctor logs into the Screening-web-app and accesses the participant's study record. If the child has not yet been registered as a study participant, the study record can also be created immediately before the examination. The actual examination is documented by first stating a preliminary diagnosis and then conducting and documenting the corresponding diagnostics (e.g. imaging). Depending on the results of the diagnostics, the preliminary diagnosis is either confirmed or rejected. In the case of a confirmed diagnosis, the ICD-10 code is documented. Additionally, any therapy recommendations issued by the doctor can also be documented. Upon completion of the preventive

[1] HL7 International. See therefore https://www.hl7.org/fhir/overview.html. Retrieved 16.12.2024

medical examination, the date for the upcoming follow-up examination 12 months later is automatically set by the OrthoKids system.

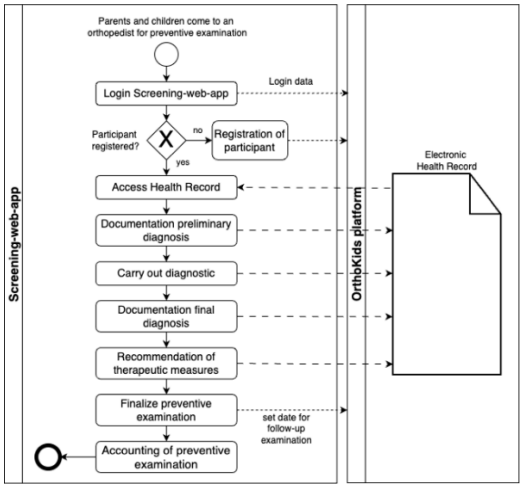

Figure 3: Individual steps of the preventive medical examination as BPMN diagram.

3.2 Change of Doctor by Patients

Another process related requirement of the OrthoKids platform was the change of practitioners during the clinical study, e.g. if they wish to undergo the final follow-up examination with a different doctor. For this, the new orthopaedist must obtain a renewed consent from the participant. Based on the participants personal data the OrthoKids platform recognizes that a study record already exists and provides access for the new orthopaedist to the existing study record (see figure 4). The existing participant ID remains unchanged. The previous specialist receives a visual notification regarding the change of doctor and the altered access permissions when accessing the study record. Due to the new permission after the change of doctor the previous specialist can only read the data he previously entered. Data entered after the change of the new specialist is generally not accessible to the previous doctor.

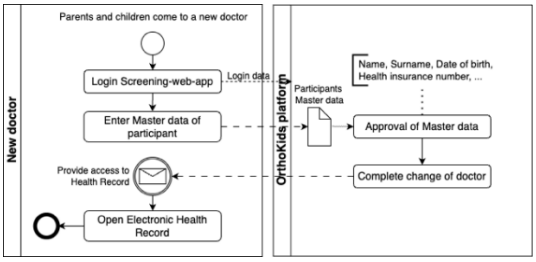

Figure 4: Procedure for changing doctors as BPMN diagram.

3.3 Mapping to FHIR® Resources

The following table shows the concrete transformation of the real data generated in the OrthoKids study into the corresponding FHIR resources of the information model.

Table 1: Transformation of the real data to the corresponding FHIR resources of the information model.

Data (Reality)	Representation (FHIR Resource)
OrthoKids Study	ResearchStudy
Study Participation	ResearchSubject
Study Consent	Consent
Study Participant	Patient
Parent	RelatedPerson
Health Insurance, Trust Office	Organization
Participating Doctor, Study Coordinator	Practitioner
Result of an Examination (Diagnosis)	Condition
Observation of an Examination	Observation
Note on an Examination	Condition (Condition.note)
Questionnaires Orthopedic Medical History EKFB T0-T2 Preventive, Follow-up Examination(s)	Questionnaire
Questionnaire Response Orthopedic Medical History EKFB T0-T2 Preventive, Follow-up Examination(s)	QuestionnaireResponse
(Doctor's) Appointment	Appointment
Doctor's Visit	Encounter
Treatment Period	EpisodeOfCare
(Chat) Message	Communication
Medical Recommendation, Filling Periods EKFB T0-T2	Task
Collection of Recommendations	CarePlan
Informational Documents	DocumentReference Attachment
Collection of Information (Textual)	Composition
Request for Termination of Participation in the Study	ServiceRequest
Grouping of Participants + Participating Doctors	Group

Each study participation is modeled as a ResearchSubject, which refers to the OrthoKids study (ResearchStudy). For each study participation, there exists a study participant in form of a Patient resource, which represents master data such as first and last name, gender, date of birth, health insurance number and affiliation with a health insurance provider. For each study participant, a study consent and a parent as RelatedPerson for contact purposes are created and linked to the Patient resource through corresponding references.

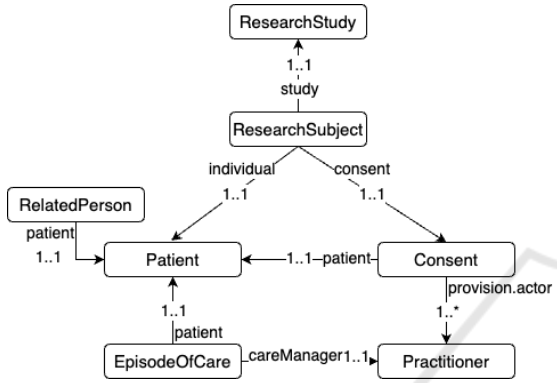

Figure 5: Modeling of a study participant and their practitioner association.

The affiliation of a study participant with a treating Practitioner is established both through the study consent and the treatment period as EpisodeOfCare. In the case of a change of doctor, the new treating doctor, if not already present, is added to the study consent, the treatment period of the previous doctor is closed, and a new EpisodeOfCare is created for the new treating doctor.

For the modeling of the doctor's appointment or the doctor's visit in the context of a preventive and follow-up examination, the resources Appointment and Encounter are used. The assessments to be conducted, such as the EKFBs (parent-child-questionnaires), orthopedic medical history or the preventive and follow-up examinations, are represented by questionnaires and the corresponding questionnaire responses.

A more detailed description of the representation of the preventive and follow-up examinations, as well as the extraction of medically relevant data from the questionnaire responses, is provided in the following section (see Chapter 3.4).

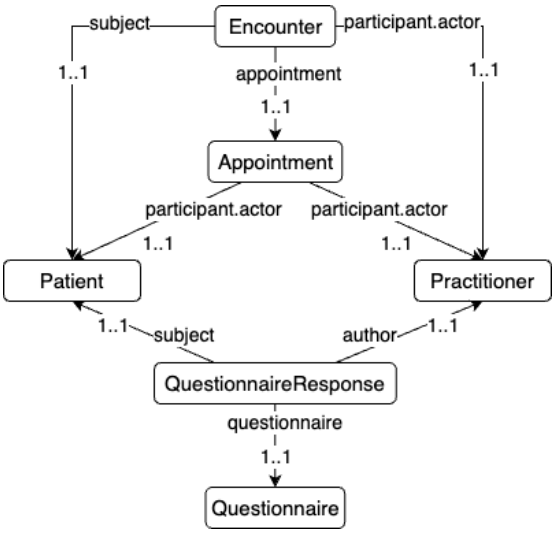

Figure 6: Modeling practitioner's appointment, doctor visit and assessments.

3.4 Examination Pathways

The medical procedure during a preventive or follow-up examination within the OrthoKids study follows a defined path with decision routes that lead to an examination result and diagnosis. These decision paths can be well represented with the FHIR® resource Questionnaire, allowing to model the concrete course of the examination, including possible alternative pathways to be reflected. While there is also the FHIR resource PlanDefinition, which could represent the workflow of a treatment pathway consisting of appointment, examination, diagnostics and results, the preventive and follow-up examinations in the context of OrthoKids also involved decisions during the examination that needed to be mapped and resulted in different subsequent activities during the examination. For example, the doctor needs the option to choose the type of diagnostics (X-ray / no X-ray), and depending on the decision, the represented treatment path provides specific diagnoses (e.g. hip disease M93.0 ECF cannot be diagnosed without X-ray or in the context of the spine, entering an angle after the X-ray is necessary, but not if no X-ray is performed). Therefore, the Questionnaire resource was suitable for modeling the decision tree in the treatment pathway. It allows diversions of the path providing if-then functionality.

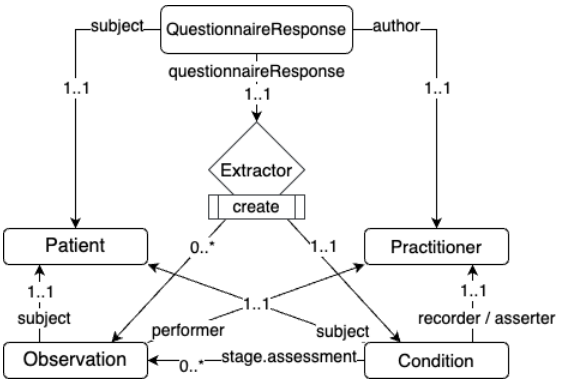

Figure 7: Extraction of relevant data from the questionnaire response and transfer to resources.

For each relevant body region (spine, hip, leg axes and feet), a corresponding representation of the region-specific examination was created on a Questionnaire resource. Thus, there are a total of 2x4=8 questionnaires (for spine, hip, leg axes and feet; each for preventive and follow-up examinations) that represent the entire treatment process of the orthopedic examination in the OrthoKids study. Relevant data from the questionnaire responses are extracted (such as angles for the spine, diagnosed ICD-10 codes) and transferred to corresponding resources (Observation, Condition) and subsequently linked with other entities.

At the beginning of the follow-up examination, the questionnaire response is pre-populated with the results of the preventive medical examination, so that the corresponding start of treatment path is already selected. The questionnaire for the follow-up examination then includes only the answer options that are designated for this path. The study participation ends with the doctor's visit for the follow-up examination. For this, the status of the study participation for a ResearchSubject is changed to off-study and the period end to the current timestamp is set. The treatment period (EpisodeOfCare) for the treating doctor is closed. The data in the participant's study record cannot be modified from this point onward.

4 FHIR® STORE: USE OF DATA

All data are persisted in the FHIR store. In OrthoKids, the HAPI-FHIR open-source[2] libraries were used for the implementation. To enable complex data queries and operations (so-called Custom Operations - COPs) for filters, key figures and statistics, the basic HAPI-FHIR-store was extended. In the context of study management, participating doctors as well as study coordinators need various filters and statistics like lists or key performance indicators (e.g. an overview of patients with open examinations). Such complex data queries for different values of the attributes of various resources can be implemented using COPs in the FHIR store. This way, the application (like the OrthoKids Stuko-app) only needs to make one call instead of many to the FHIR store to obtain the required values. The data is aggregated in the backend and delivered back to the application.

For example, if patients with a completed preventive medical examination from a certain Health Insurance Provider (HIP) and a positive finding from January 2024 are to be filtered, the following resources and their attributes with the following values for the filter are considered:

- Encounter.status = finished
- Encounter.period = 01.01.24 – 01.31.24
- Appointment.appointmentType = CHECKUP
- Condition.code != Z01.- (no findings)
- Patient.managingOrganization = HIP

For each COP, both the filtered patient list and the number of patients can be retrieved. Several filter options and attribute configurations were implemented. Patients with started examinations are filtered by type (preventive or follow-up) and period, in which the examination began. Patients with completed examinations are filtered by type, period, result (positive or negative diagnosis) and in combination with completed questionnaires (medical history, EKFB). Also, COPs for alerts and reminders for activities (follow-up examination or questionnaires EKFB t0-t2) exist. COPs are also used for handling processes like the change of practice for all patients from one practice to another, deleting patients or doctors and sending specific messages to participant groups (reminders, announcements, individual messages).

Within the framework of the OrthoKids study, data export is also necessary, e.g. for supporting the study coordinators during the study, for analysing the data at the end of the study and for billing purposes. The export is implemented through a client, based on HAPI. For example, to obtain an overview of the

[2] HAPI FHIR. See therefore https://www.hl7.org/fhir/overview.html. Retrieved 16.12.2024

patients undergoing follow-up examinations by each doctor, the export client only considers positively diagnosed patients who have not yet completed the follow-up examination by pre-filtration performed before the export. This pre-filtration is realized solely through the modeling of the follow-up appointment on the FHIR® Appointment resource. Based on the type of appointment (=FOLLOWUP) and the status (=PENDING || BOOKED || PROPOSED), the records of positively diagnosed patients with an open follow-up examination are exported.

5 RELATED WORK

While the use of standards may be appropriate for clearly defined and established care structures, most health-related research projects have their own specific framework conditions and processes. Their processes are often compared with complex interventions (Abraham, 2023).

Nevertheless, there are individual structures that recur throughout the study process (Kirchner 2024): After the study design and the conceptual phase, the care-relevant phases are carried out in the form of a clinical study. Participants must be recruited, and health data will be collected to evaluate the effect of the new therapy. Jain et. al systematize interrelated sub-processes of a clinical trial from the different perspectives of service providers, patients, organisations and sponsors (Jain, 2019).

IT-based frameworks for conducting clinical trials can be categorised as project-specific in-house developments, commercial or open-source solutions. While project-specific developments are very cost-intensive but highly customised to the respective process, commercial standard solutions may lack access to the programme code and thus a necessary degree of flexibility. Although open-source solutions offer access to the programme code and therefore the possibility of adapting the solution to the project-specific study process, they often lack the support structure that is necessary for clinical studies (TMF, 2024).

Leroux (2019) present the activities of the HL7® Biomedical Research and Regulations FHIR working group in developing FHIR-based models and solutions for designing and conducting clinical research. They develop a first model for the description of a clinical study design in FHIR, which is based exclusively on the semantics of the already defined FHIR resources.

The Clinical Data Interchange Standards Consortium (CDISC) is also working on harmonising its defined processes and standards with the HL7 FHIR standard (CDISC, 2021). On the part of the HL7 community, these activities were taken up by the VULCAN project and led to the creation of the FHIR Implementation Guidelines for Retrieval of Real-World Data for Clinical Research (HL 7 International, 2023).

In summary, it can be said that previous work in the field of standardising clinical trial processes using HL 7 FHIR has focused strongly on integrating existing structures and well-defined organisational processes (e.g. applying for a trial and the provision and subsequent use of trial results). In the OrthoKids project, an HL 7 FHIR-based IT solution was also developed that covers the entire management process of a study in addition to its implementation. To the best of our current knowledge, such a standards-based study platform is novel.

6 CONCLUSION AND OUTLOOK

As conclusion we present our findings by modelling and implementing the OrthoKids IT-platform using the FHIR standard and the HAPI implementation of that standard. We recognized that the study process and all involved roles, data and activities could be well represented using FHIR, as FHIR accurately reflects the modeling needs of the medical domain, as it provides an accurate representation of reality, such as resources for actors (patient, doctor) or activities within a treatment process (e.g. encounter, appointment). Interestingly, Leroux (2019) model the general study process in a very similar way, assuming that the general study process is already very well covered by the existing FHIR resources.

Nevertheless, there remains some leeway, especially in the representation of study and project specific processes. For example, for modelling the different paths in the context of examinations, the Questionnaire resource was used (see Chapter 3.4), as the examinations necessitate decisions and consequently result in different subsequent activities during the examination. Depending on the specific use case, it is essential to find the appropriate representation.

A significant advantage of FHIR® is its user-defined extensibility for resources and data types to meet the often complex and diverse requirements for health data and use cases. For example, in the context of OrthoKids, the Questionnaire resource was extended to provide "commands" (so-called

Structured Data Capture[3]) for visualization and to pre-fill other resources from the Questionnaire (see Chapter 3.4). By setting the *questionnaire-choiceOrientation* to the value *vertical*, the answer options are rendered not side by side, as usual, but one below the other, or when *questionnaire-itemControl* is set to the value *radio-button*, the options are presented as circular selection options instead of dropdown menus. Conveniently, external libraries can be used for visualizations in the user interfaces. We used the Faiadashu library[4] which is optimized for displaying FHIR Questionnaire resources. This library can also process and interpret the extensions explained before for the Questionnaire resources, thus influencing the visual representation accordingly.

In the future, we want to successively generalize and make the study platform configurable in the context of additional medical studies, so that other use cases can also be represented with the platform. This also includes the extension (e.g. for vital parameters) and generalization of the information model, as fundamental tasks in a study process are recurring. There will always be participant management, medical data will be collected (e.g. in the form of examinations and questionnaires), and different actors need access to the data in the medical context.

ACKNOWLEDGEMENTS

The OrthoKids-project is a project of the German innovation fund (01NVF20022). We thank all the stakeholders and users who participated in the process of design, implementation and operation of the OrthoKids-platform. Especially we thank our project partners Kassenärztliche Vereinigung Baden-Württemberg (KVBW), Klinikum Stuttgart and Institut für Gesundheitsökonomie und Klinische Epidemiologie der Universität zu Köln (IGKE) who intensively discussed with us the requirements of the OrthoKids-platform and helped us to optimize it by constantly providing feedback to the current state of its implementation.

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