Streamlining Clinical Research:

Enhancing FHIR Interoperability Beyond DICOM Constraints

CitiusTech

Typically, in Radiology and Life Sciences, clinicians and researchers rely on DICOM (Digital Imaging and Communications in Medicine) standard for management of metadata to drive downstream clinical and research workflow.

However, DICOM standard alone is insufficient in clinical and research environment (CARE) and thus, there is an evolving need for integrating order, encounter, and other consumer-based imaging with corresponding clinical data. Unlike DICOM, Non-DICOM imaging formats ingested in the Imaging repositories do not have metadata attached to it.

To preserve the proprietary nature of encounter or consumer based non-DICOM images, there is need to explore other standards to ingest images into imaging repository with associated metadata. Fast Healthcare Interoperability Resources (FHIR) standard is one such way of enabling the non-DICOM imaging workflow and medical image data management.

The Importance of FHIR in Metadata Management in CARE

In the realm of medical image data management, metadata plays a pivotal role in organizing and understanding of imaging data. Properly managed metadata enhances the efficiency of data retrieval, storage, and analysis for research processes. This whitepaper delves into the significance of metadata in medical image data management and explores relevant use cases. Additionally, it highlights how FHIR can provide crucial solutions to effectively address these use cases.

Building Cohorts for Research and Annotation:

The process of constructing a cohort of imaging data for research and annotation, necessitates the execution of precise searches or queries. Leveraging FHIR data elements allows for efficient labeling and cataloging of imaging data using structured codes, anatomical regions and therapeutic areas. By using FHIR data, researchers can streamline the organization of imaging data, enabling more accurate and targeted analysis.

Integrating Imaging Data with Clinical Information:

FHIR data associated with images can be exposed using API to other healthcare information systems to integrate with clinical information for the patient for which FHIR data is exposed. Through API integration FHIR data elements facilitate the seamless integration of imaging findings with relevant clinical information.

In the coming time FHIR, interoperability framework, will play a crucial role in providing solutions for the aforementioned use cases. Its adoption offers the following advantages:

- Structured Data Labeling: FHIR data elements enable structured coding of imaging data, creating a uniform and standardized way to categorize and organize information. This enhances data consistency and facilitates efficient data retrieval, promoting effective research and analysis.
- API-driven Interoperability: FHIR's reliance on APIs enables seamless data exchange between different systems and devices. The integration of imaging data with clinical data ensures a comprehensive view of patients' health, empowering healthcare professionals to make well-informed decisions.
- Data Security and Privacy: With the sensitive nature of medical imaging data, maintaining data security and privacy is of paramount importance. FHIR incorporates security measures and user access controls through APIs, allowing data repositories to flag data sensitivity. This ensures that only authorized individuals have access to the required information while safeguarding patient privacy.

Interventions in the FHIR Framework

CitiusTech developed a FHIR framework for clinical trial workflow for indexing non-DICOM and DICOM imaging metadata in FHIR database. The selection of FHIR resources within this framework was based on the associated metadata of the medical images and requirements of the clinical trial workflow.

A mapping process was employed to map metadata received with imaging data to equivalent FHIR data elements. Mandatory elements required by FHIR resources identified for clinical trial use case were assigned logical attributes and values. Additional FHIR attributes required to obtain clinical trial workflow were carefully tagged with identifiable default values per use case e.g., study name, study description, anatomical area, therapeutic area, or disease area, etc.

To create a comprehensive end-to-end clinical trial workflow, the identified FHIR resources were interconnected using references, following the standards set forth by FHIR. These references were links between the resources, allowing for seamless navigation and retrieval of related information within the clinical trial workflow. The proper utilization of references in the FHIR framework ensured the efficient and accurate representation of the clinical trial data throughout its lifecycle.

While mapping the metadata the cardinality of each resource and their data elements was considered. To build an end-to-end clinical trial workflow, identified FHIR resources were linked using references as per FHIR standards. The FHIR framework had a futuristic view and was designed in such a way that it could be easily scaled up from FHIR R3 to R4 version with bare minimum changes which is very important to adhere to the FHIR version compatibility.

Outcome of FHIR Framework Development

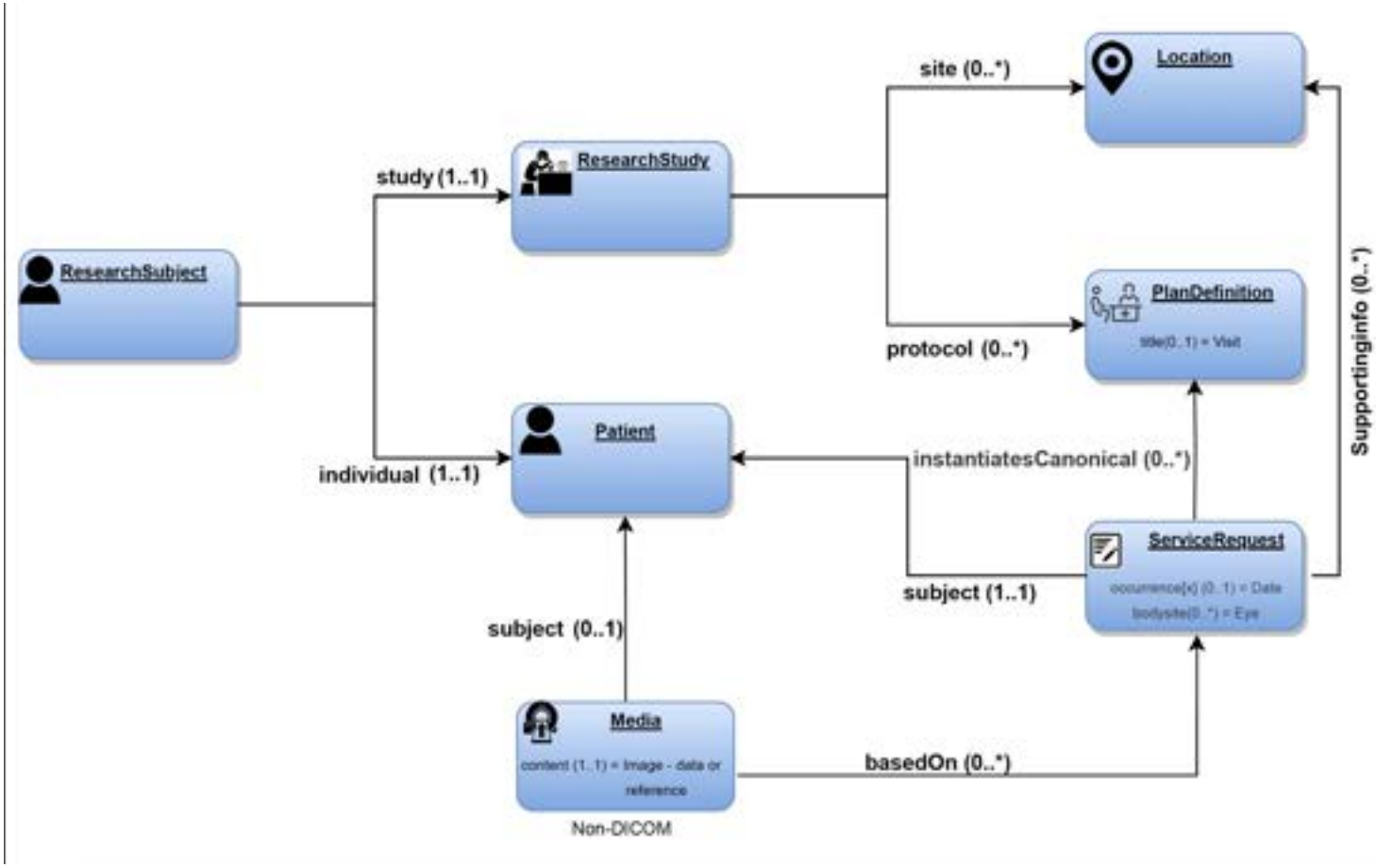

Fig 1. FHIR Framework for NON- DICOM Scenario

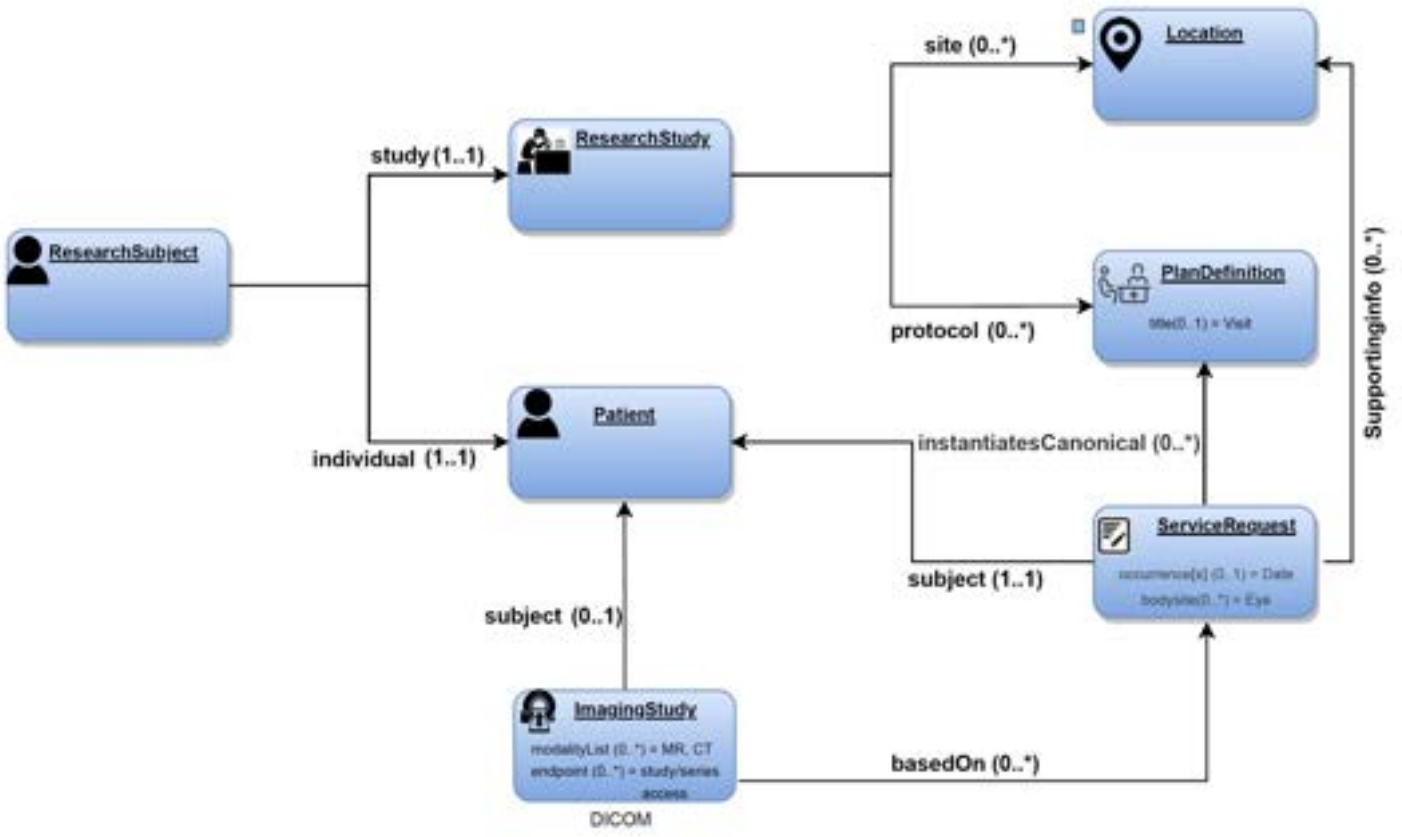

Fig 2. FHIR Framework for DICOM Scenario

The FHIR framework was designed to handle DICOM and non-DICOM data within the imaging ingestion pipeline. Its purpose is to effectively manage the metadata associated with imaging from various sources and devices. For a more comprehensive understanding, please refer to Figure 1 and 2, which provide detailed visual representations of the framework's architecture and components.

A FHIR mapping workflow framework can be created to support both DICOM and Non-DICOM scenarios for ingestion of imaging data for multiple clinical and research use cases. A custom adaptor can be built within ingestion pipeline for DICOM and non-DICOM images to map their metadata to appropriate FHIR data elements into FHIR database.

Challenges while designing FHIR framework

Capturing the clinical attributes of a subject through FHIR posed significant challenges when dealing with image and pixel data from DICOM. DICOM files contain crucial information about medical images, such as patient demographics, imaging modalities, acquisition parameters, and clinical interpretations. However, the existing FHIR specifications are needed to adequately support these image-specific attributes' inclusion.

Extensions were introduced to the FHIR framework to overcome this challenge and accommodate DICOM's image and pixel data. These extensions allow for the capture and organization of essential attributes related to the images within the FHIR data model. By leveraging these extensions, clinical researchers can integrate image-specific data into the clinical data lake using the FHIR framework.

DICOM files may contain private tags, which are non-standardized tags used by certain vendors or organizations to store proprietary information. These personal tags often contain valuable clinical data that should be considered during integration. However, the default mapping of DICOM files to the imaging study resource in FHIR did not account for private tags.

To ensure the comprehensive integration of DICOM files, CitiusTech FHIR framework addressed the mapping of private tags to the imaging study resource. This ensured that the valuable clinical information stored within private tags were included correctly in the FHIR representation. The framework incorporating private tags will enable holistic and accurate representation of the imaging data within the clinical data lake.

About the Author

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Sheetal Joshi is an experienced Healthcare IT (Information Technology) professional and have worked directly with large Healthcare Systems, Imaging IT vendors and Pharmaceuticals. She has 17 years of experience supporting, architecting, and leading implementations for Imaging IT solutions and initiatives across global teams. She has led enterprise-wide implementations for Advanced 3D Visualization, Enterprise Imaging, Image Sharing, PACS and RCM (Revenue Cycle Management) IT solutions.
Sheetal has an MS in Biomedical Engineering and is PMP and CPHIMS certified. At CitiusTech Sheetal Joshi leads delivery for Image exchange professional services and is instrumental in training and grooming teams in Imaging domain across all the markets.

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Harshali is a Senior Healthcare Business Analyst with CitiusTech for last 3+ years; with an overall 6+ years of experience and worked across Scheduling, Registration, HIM and RCM. She has completed her Bachelor's degree in Biomedical engineering. She has Masters in Hospital and Healthcare Management and Post-graduation Diploma in Medico Legal systems. She is a certified Scrum Master (CSM) and has worked within CitiusTech majorly in Life Science market. Recently, she in collaboration with CitiusTech Imaging SME designed the framework to capture DICOM and Non-DICOM clinical data using FHIR, this poster was listed on SIIM 2022 website.

About CitiusTech

Our vision is to Inspire new possibilities for the health ecosystem with technology and human ingenuity. At CitiusTech, we constantly strive to solve the industry's greatest challenges with technology, creativity, and agility. Together with the world's leading Healthcare and Lifesciences organizations and our partners, we aim to accelerate the transition to a human-first, sustainable, and digital healthcare ecosystem.

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