Streamlining Clinical Research:

Enhancing FHIR Interoperability Beyond DICOM Constraints

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In Radiology and Life Sciences, the use of the DICOM (Digital Imaging and Communications in Medicine) standard has traditionally been relied upon by clinicians and researchers for effective metadata management, subsequently driving downstream workflow processes. However, it has become evident that it takes more than the DICOM standard to meet the Clinical and Research Environment (CARE) requirements.

As a result, there is an increasing demand to integrate non-DICOM imaging, encompassing orders, encounters, and other consumer-based imaging, with their corresponding metadata. Unlike DICOM imaging formats, non-DICOM formats lack inherent metadata associations when ingested into imaging repositories. This absence of metadata makes preserving the proprietary nature of encounter or consumer based non-DICOM images a challenge. Thus, it becomes crucial to explore alternative standards that can facilitate the ingestion of images into imaging repositories while preserving associated metadata.

Among the various standards available, the HL7-FHIR (Health Level Seven Fast Healthcare Interoperability Resources) standard emerges as a viable solution for enabling the workflow of non-DICOM imaging. HL7-FHIR provides a framework that integrates non-DICOM images into the imaging repository while associating them with the necessary metadata. By leveraging the capabilities of HL7-FHIR, clinicians and researchers can effectively bridge the gap between non-DICOM imaging and the broader clinical and research environment, promoting interoperability and enhancing workflow efficiency.

The Importance of FHIR in Metadata Management in CARE

The process of building a cohort of imaging data for research and annotation purposes involves executing searches or queries. Using FHIR data elements enables labelling and cataloguing imaging data using structured codes, providing valuable information about anatomical regions and therapeutic areas. Integrating FHIR data with clinical data through APIs allows for a comprehensive analysis of imaging findings concerning patients' overall health.

Conducting searches or queries can be utilized to construct a specific group of imaging data necessary for research and annotation purposes. FHIR (Fast Healthcare Interoperability Resources) data elements can be employed to effectively categorize and organize the imaging data.

These data elements allow labelling imaging data through structured codes, including anatomical regions and therapeutic areas devices through an API (Application Programming Interface). This facilitates the integration of imaging data with associated clinical data, seamlessly merging information from various sources for a study or subject. By leveraging this interoperability, researchers can better understand the relationship between imaging findings and clinical parameters.

Considering the sensitive nature of imaging data, it is crucial to implement measures to ensure appropriate user access. To address this, the repository housing the imaging data can incorporate a system for flagging the sensitivity of the data. By doing so, user accessibility can be managed based on individual user rights and permissions.

This helps to maintain data privacy and security while allowing authorized users to access the required information for their respective roles and responsibilities.

Interventions in the FHIR Framework

An FHIR framework was specifically developed to facilitate the clinical trial workflow by effectively indexing non-DICOM and DICOM imaging metadata into an FHIR database. The selection of FHIR resources within this framework was based on the associated metadata of the images and the requirements of the clinical trial workflow.

Upon receiving imaging data and their corresponding metadata, a mapping process was employed to match and assign equivalent FHIR data elements. In cases where specific values were mandatory according to the FHIR standard or the specific clinical FHIR workflow, default logical values or attributes were provided. These additional attributes were carefully identified and tagged with identifiable default values tailored to the particular use case. Such attributes include the study name, description, anatomical area, therapy or disease area, and more.

The cardinality of each resource and its data elements were considered during the mapping process. This ensured that the appropriate relationships and dependencies between the resources were adequately established. By adhering to the cardinality guidelines, the resulting FHIR resources managed to maintain integrity and completeness.

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.

Outcome of FHIR Framework Development

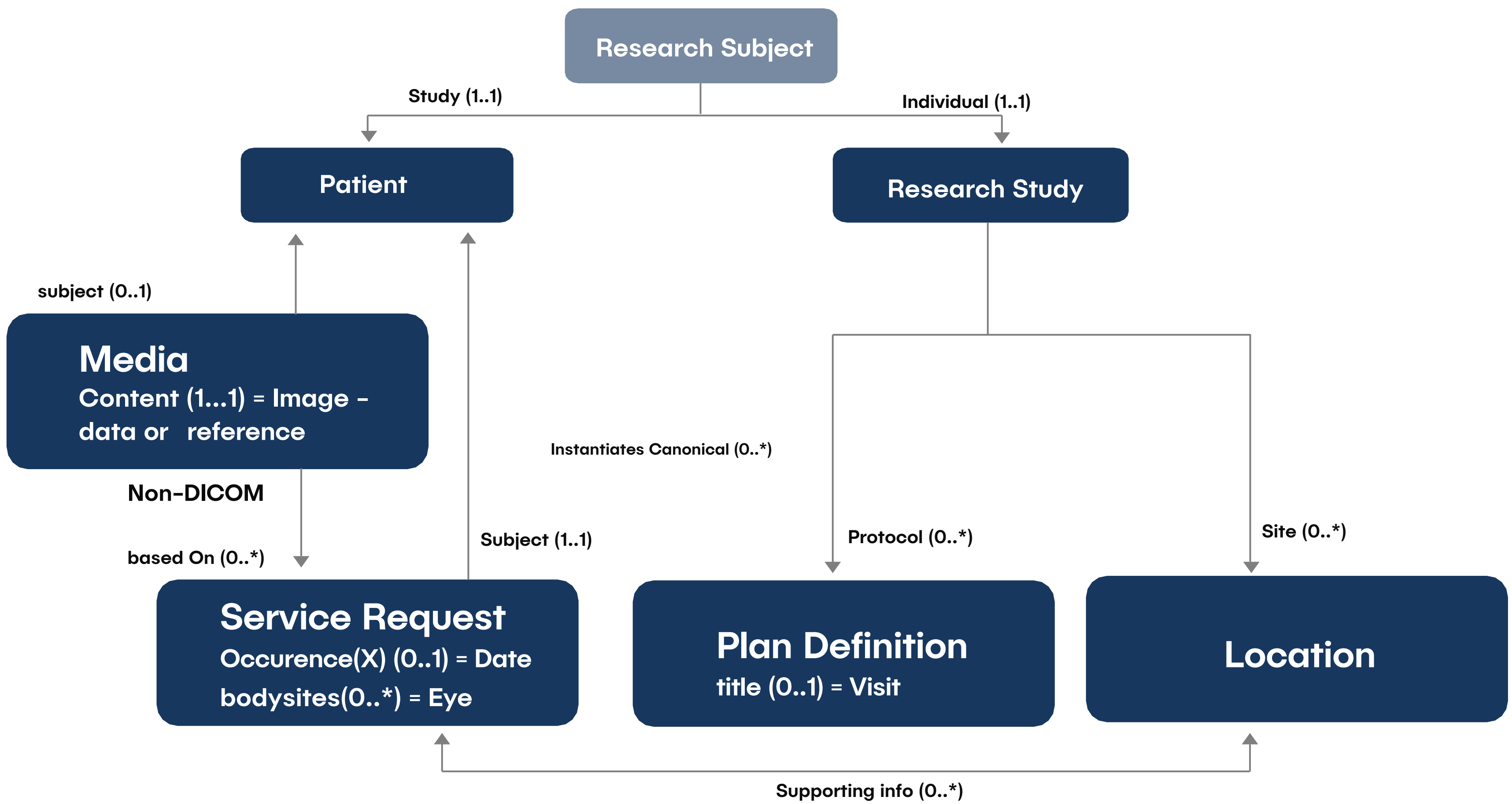

Fig 1. FHIR Framework for NON- DICOM Scenario

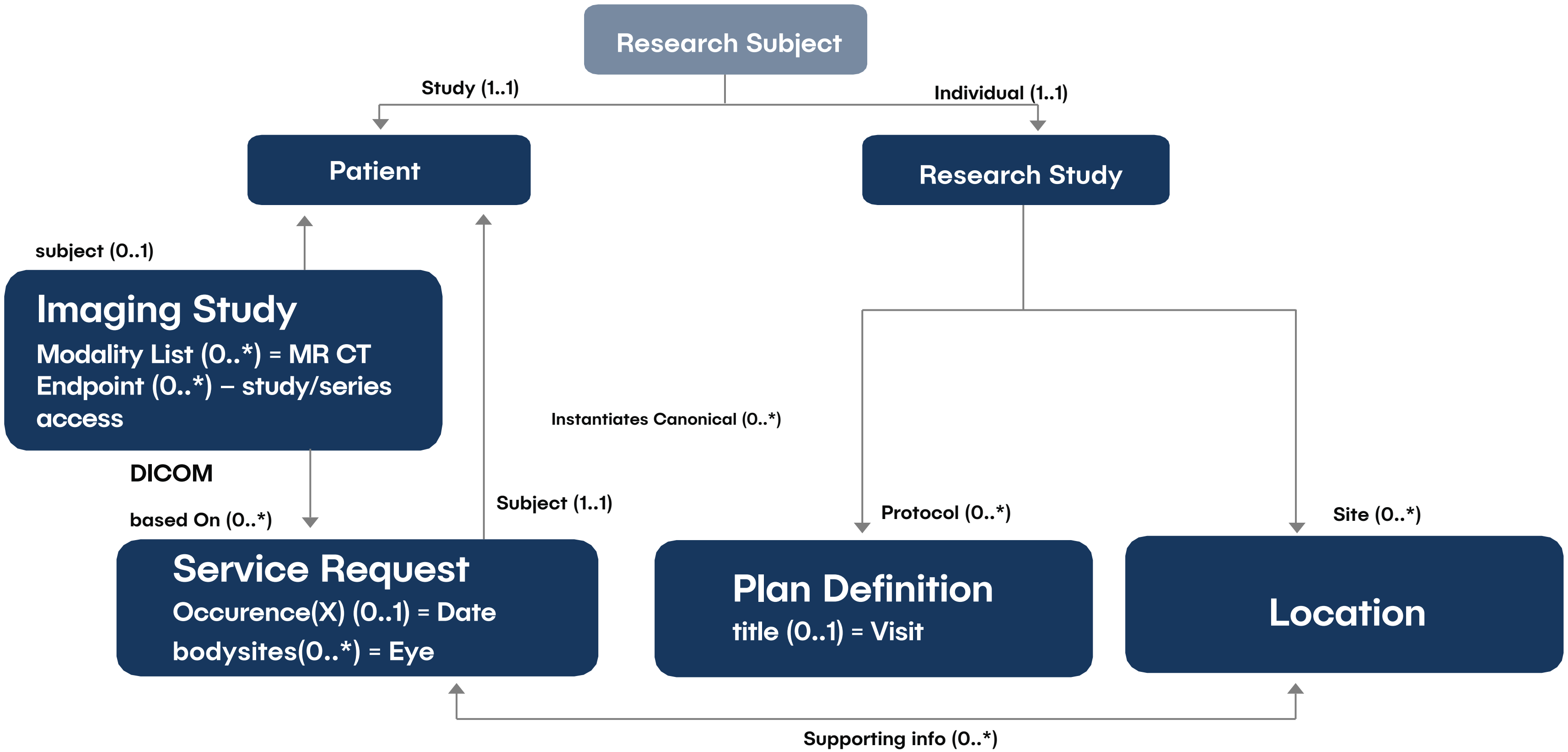

Fig 2. FHIR Framework for DICOM Scenario

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. To ensure seamless integration, an FHIR mapping framework was implemented to facilitate the development of a custom adapter for the ingestion pipeline.

This mapping framework enables the translation and transformation of data between the FHIR standard and the specific data formats utilized within the pipeline. By employing this custom adapter, the ingestion pipeline becomes capable of harmonizing and ingesting diverse imaging data from different sources, leveraging the capabilities of the FHIR framework.

Barriers to the development of the 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, the universal FHIR framework addresses the mapping of private tags to the imaging study resource. This ensures that the valuable clinical information stored within private tags is included correctly in the FHIR representation. The framework incorporating private tags enables a more holistic and accurate representation of the image data within the clinical data lake.

Summary

The utilization of a Non-DICOM Fast Healthcare Interoperability Resources (FHIR) framework presents an effective approach to mapping clinical information from encounter-based images to corresponding research studies and subjects. In addition, the FHIR framework within the Clinical Annotation Research and Exchange (CARE) platform allows for efficient management of metadata associated with these images, enabling the achievement of two primary objectives:

- Robust search functionality on the imaging repository through the execution of FHIR queries. This empowers users to conduct comprehensive searches and retrieve specific imaging data based on desired criteria.
- Cataloguing and labelling imaging studies using appropriate therapy area designations, structured codes, and operational labels such as annotations and edits. This facilitates the efficient organization and categorization of imaging studies within the repository.

However, it is essential to note that FHIR alone may not handle custom images or the acquisition of device-specific attributes. Therefore, reliance on the Digital Imaging and Communications in Medicine (DICOM) standard becomes necessary. In addition, the interoperability standards of both FHIR and DICOM can be leveraged to align clinical and imaging data more effectively, ensuring seamless integration and exchange between systems.

By integrating non-DICOM images with their associated meta-information in FHIR resources, these images can be successfully ingested into the imaging repository. Furthermore, this integration enables the initiation of downstream processes within the imaging pipeline or workflow, thereby supporting comprehensive analysis and utilisation of the images for various purposes.

Conclusion

Utilizing the non-DICOM FHIR framework with DICOM interoperability standards presents a powerful solution for managing and leveraging clinical and imaging data within healthcare systems. By effectively mapping clinical information from encounter-based images to research studies and subjects, the FHIR framework enables robust search capabilities and facilitates proper imaging studies.

In addition, integrating non-DICOM images with FHIR resources allows for successful ingestion into imaging repositories and triggers downstream processes within the imaging workflow. This promotes seamless interoperability and enhances the analysis and utilization of imaging data for a wide range of applications in healthcare.

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.

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