Bridging the Gap Between (AI-) Services and Their Application in Research and Clinical Settings Through Interoperability: the OMI-Protocol

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Abstract

Artificial Intelligence (AI) in research and clinical contexts is transforming the areas of medical and life sciences permanently. Aspects like findability, accessibility, interoperability, and reusability are often neglected for AI-based inference services. The Open Medical Inference (OMI) protocol aims to support remote inference by addressing the aforementioned aspects. Key component of the proposed protocol is an interoperable registry for remote inference services, which addresses the issue of findability for algorithms. It is complemented by information on how to invoke services remotely. Together, these components lay the basis for the implementation of distributed inference services beyond organizational borders. The OMI protocol considers prior work for aspects like data representation and transmission standards wherever possible. Based on Business Process Modeling of prototypical use cases for the service registry and common inference processes, a generic information model for remote services was inferred. Based on this model, FHIR resources were identified to represent AI-based services. The OMI protocol is first introduced using AI-services in radiology but is designed to be generalizable to other application domains as well. It provides an accessible, open specification as blueprint for the introduction and implementation of remote inference services.

Zusammenfassung

Anwendungen der Künstliche Intelligenz (KI) im Forschungs- und klinischen Bereich werden die Medizin- und Biowissenschaften nachhaltig verändern. Aspekte wie Auffindbarkeit, Zugänglichkeit, Interoperabilität und Wiederverwendbarkeit werden bei KI-basierten Inferenzdiensten derzeit jedoch oft vernachlässigt. Das Open Medical Inference (OMI) Protokoll zielt darauf ab KI-Algorithmen als Service über institutionelle Grenzen hinweg verfügbar zu machen, indem es die o.g. Aspekte adressiert. Schlüsselkomponente des Protokolls ist ein interoperables Register für Inferenzdienste, welches die Auffindbarkeit von Algorithmen erleichtert. Enthalten sind Informationen, wie Dienste aus der Ferne aufgerufen werden können. Zusammen bilden diese Komponenten die Grundlage für den Aufbau und die Umsetzung von verteilten Inferenzdiensten. Das OMI-Protokoll berücksichtigt aktive Initiativen und Standards für Aspekte wie Datentransport und Datendarstellung. Basierend auf Geschäftsprozessmodellen für Anwendungsfälle innerhalb der Service Registry und Inferenzprozessen wurde ein generisches Informationsmodell abgeleitet. Auf der Grundlage des Informationsmodells wurden FHIR-Ressourcen identifiziert, um KI-Dienste zu repräsentieren. Diese Ressourcen werden profiliert, um erwartete Ein- und Ausgabedatentypen und -formate zu definieren. Das OMI-Protokoll wird zunächst anhand von Anwendungsfällen in der Radiologie beispielhaft abgebildet, ist aber generisch ausgelegt, sodass auch andere Anwendungsdomänen unterstützt werden. Es bietet eine zugängliche, offene Spezifikation als Grundgerüst für die Einführung und Umsetzung von Fern-Inferenz.

Introduction and background

The Open Medical Inference (OMI) project aims to support clinical- and research use cases where remote inference can be applied. OMI, as a methodological platform, is embedded within the German Medical Informatics Initiative (MII) [1]. It is closely interlinked and interacts with the Radiological Cooperative Network (RACOON) [2] as well as the Network University Medicine (NUM) [3]. Initially, the primary focus lies on radiological use cases. However, future use cases are not limited to radiological applications as OMI wants to be use case agnostic and integrate various digital ecosystems. For this purpose, the OMI protocol is being developed. It lays the groundwork for inter-institutional remote invocation of inference services by providing a repository of suitable algorithms in combination with machine processable information about services and access to the remote inference infrastructure. The proposed protocol is designed as open-source specification, and this whitepaper is intended to lay the basis for discussion between stakeholders.

Artificial Intelligence in medical sciences

Artificial Intelligence (AI) and machine learning are on the verge of revolutionizing medical and life-sciences. Medical imaging is considered the most important field for AI applications [4], [5]. Specialized AI applications already outperform experts at certain tasks like skin lesion assessment [6] and surgical audits [7] in a research context. Clinical adoption is still limited due to regulatory and technical hurdles but also human reservations towards the technology [8]. While development of new AI algorithms is happening fast, regulation and questions about data quality and model validation are often deferred [9]. Currently most AI algorithms are developed in a research context, but maturity levels can indicate readiness for usage outside of the research context [10].

Description of the problem

For radiological use cases, AI-based algorithms typically operate on one or more images or series of images acquired through different modalities like x-ray, computed tomography (CT), magnetic resonance imaging (MRI) amongst others. There are several use cases for AI algorithms described across various medical fields [11], [12]. Conceptually, algorithms within radiological use cases can be broadly categorized into four domains, as shown in Table 1.

Table 1 – Overview of categories for AI based algorithms in medical imaging, following classification of Litjens et al. *[11].*

Category	**Generalized goal**	**Examples**
Segmentation	Predict the segmentation of structures, like organs or pathologies.	• Segmentator [13], • nnUnet [14],
Classification	Predict a certain classification(s) related to an image.	• classification of a lung lesion as metastases or benign nodule [15], • classification of tumor type or malignancy, • classification of primary tumor from metastases appearance [16].

Detection	Localization of organs or landmarks as well as detection of lesions.	• (Brain) Tumor segmentation algorithms [17].
Generation	Create a new image based on existing images.	• Using Generative Adversarial Networks (GANs) or a denoised image [18].

Currently, there is no harmonization and common data model how to represent and interact with algorithms. These circumstances hinder interoperability and put a barrier on anyone that wants to publish or find algorithms. This fact stands in direct contrast to the FAIR principles promoted by the scientific community since 2016 to improve Findability, Accessibility, Interoperability, and Reuse of digital assets [19].

As AI-based services mature and their accuracy improves, more confident results are being achieved. However, the application of these algorithms within a clinical setting is often not considered or thought about by the developers initially, which consequently leads to difficulties when transitioning these services from research to clinical care setting. Moreover, every research institution tends to have their own catalogue(s) of algorithms, which may lead to scientists and clinicians not being aware of which kind of algorithms are available to answer a given research- or clinical question. When stepping outside of the borders of a single organization, this challenge is worsened, such that it becomes a necessity to find suitable, applicable algorithms to answer a research- or clinical question.

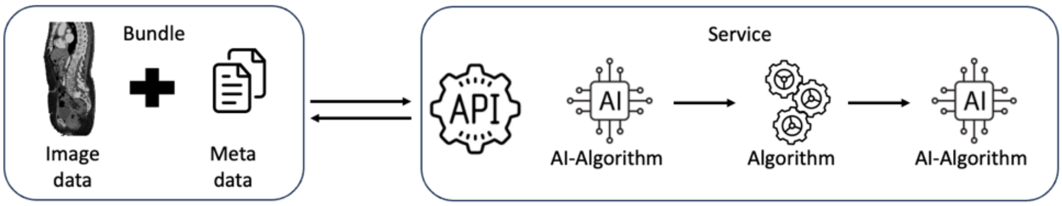

Figure 1 – Requirements for the OMI Protocol: data bundles consisting of image- and metadata (left) are transferred via an API to a service which consists of ai- or non-ai algorithms that act in a pipeline (right). The result is received by the recipient asynchronously.

With the progressive development of algorithms and services, the topic of orchestration and workflow integration becomes increasingly relevant for pipelines consisting of one or more AI-based services as shown in Figure 1. These developments and requirements are to be considered while elaborating the OMI protocol.

Established system and imaging formats in radiology

Hospitals already have established infrastructure for healthcare delivery and research in radiology: Picture Archiving and Communication Systems (PACS), which store medical images, e.g. in the common Digital Imaging and Communications in Medicine (DICOM) format, after they have been acquired using different modalities like x-ray, CT, MRI and more. These systems may operate only within a care delivery context. Additionally, there might be a separate PACS system which enables research and the application of AI-Algorithms on images within the research context.

Transitioning from pipelines and models to inhouse- and distributed services

Currently, a lot of AI related development and inference provision is happening within a single organization or department, sometimes even only on a single workstation computer. Given the increasing requirements for AI training data, computing power and inference response times, it becomes clear that no single institution can handle all these requirements alone. Collaborations and networks must be formed where resources and knowledge are shared among stakeholders. We must transition from AI-based models to AI-based services, which can be accessed safely and securely from within any organization that is part of the network. This implies a fundamental change in the way we develop AI-based services as we must define interfaces and parameters that support the operation of a given algorithm. The subsequent challenge is findability of services within the network beyond text-based lists, in particular as machine processable semantically interoperable entities. As developments progress and new fields are going to be covered by AI-based services, we need to make sure that users can find the right service for the desired task. To overcome the challenges outlined, we need new architectures, new standards, and new coherent workflows. We outline a possible solution in the following chapters.

Current state of the art

The problems outlined above are not unique and efforts such as registries for AI-based algorithms to enhance accessibility, reproducibility and usability of models for biomedical research were already described in the literature [20], [21]. While using an open specification for the description of AI models, platforms such as the AIMe registry[1] do not consider the use of widespread interoperability standards or any semantic machine processing approaches. Additionally, the aspect of how to access inference services is not covered, users must set up their own environment and pipeline integrations. The data model employed for the register's database does not support finding algorithms and models based on their in- and output parameters.

Standardization entities like Integrating the Healthcare Enterprise (IHE) and Digital Imaging and Communications in Medicine (DICOM) already published proposals on how to handle certain workflows of AI based services, by designing the use-case of remote inference in existing standards and definitions [22], [23], [24]. However, to date there has been no proposal on how to handle searchability and discoverability for AI-based algorithms between institutions.

Existing solutions and specifications only address a subset of use cases, and none of them manages to provide a comprehensive approach to the issue of providing a structured and semantically interoperable way to describe and apply AI-based services, especially providing methods to I) register, II) find, III) request inference and IV) train AI-based algorithms.

The Fast Healthcare Interoperability Resources (FHIR) communication standard released by Health Level 7 (HL7) enables interoperable data representation supported by a well-documented, open Application Programming Interface (API). It also enables efficient querying and discovering of services through standardization. It joins established standards like DICOM

[1] https://aime-registry.org/, last accessed on 15.10.2023

and enriches them with semantically interoperable, non-image data. On an international level, there are initiatives that evaluated the level of *FAIRness* for FHIR Implementations which can serve as a guideline for the proposed OMI protocol [25].

Proposed solution

After reviewing the literature and to achieve the goals outlined by the FAIR principles, we follow a workflow-driven multi-step process including Business Process Modeling (BPM) combined with the usage of FHIR as interoperable communication standard. A FHIR Implementation Guide (IG) is being created giving guidance and addressing challenges that arise when trying to find and to apply algorithms to datasets beyond institutional boundaries, independently if they are based on AI or not. As a communication standard, FHIR supports and encourages the use of state-of-the-art web and transport layer security technologies. Dikici et al. [10] proposes the integration of AI into the radiology workflow based on maturity levels. Based on this description, we derived an architectural overview, as shown in Figure 2.

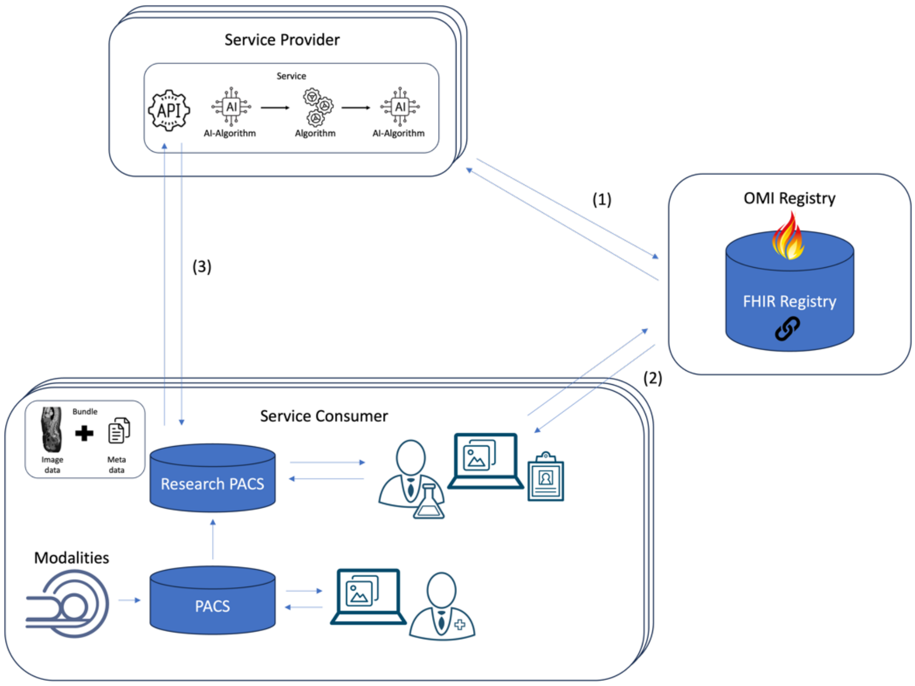

Figure 2 – Architectural overview of activities: (1) registration: the service provider (upper) has an algorithm and hardware to process requests from external sources as a service. He provides information about his algorithm in the registry, adds information on how to access this service and gets approved by the registry. The service is now part of the registry and can be found by any user. (2) search and request: a service consumer (e.g. a hospital, but also a medical specialist in private practice) has pictures and additional information in his research Picture Archiving and Communication System (PACS) and wants to request a service outside of his institution. He searches for a service within the OMI registry. A service suitable for his data is provided by Hospital 1. He then sends a data bundle to the service provider and receives an asynchronous answer. (3) training an algorithm: a service consumer sends the links on where to access images to the API of Hospital 1. After a certain time, he receives an asynchronous answer provided by the service provider containing the results.

In order to share data for the remote inference in a secure and efficient manner between organizations, developments like the MII Data Sharing Framework (DSF) [26] will be evaluated to handle any generic workflow or pipeline, even in distributed architectures [27]. DSF supports feasibility queries [28] as well as record linkage for more advanced use cases [29] this will be especially important for the use-case of training image-based inference models but may introduce unneeded overhead for the service consumer of inference services in a care setting for a patient.

Managing workflows using business process models

This section outlines the workflows supported by the first version of the OMI protocol and registry: in addition to basic methods to create (register), read (search), update (modify), delete and deactivate services, more workflows like invoking remote inference and request training data shall be supported. This paper shows only a selection of workflows, and we refer the interested reader to the more complete and up-to-date material that is provided on Github[2]. Outlined processes currently represent an ideal case without deeper error handling. Generally, there are three main actors involved in the workflows I) the registry itself – which holds information about which (potentially AI-based) services are available and which input parameters are required for inference, II) service providers (SP) – which offer the aforementioned services, and III) service consumers – such as researchers/clinicians, which want to trigger remote services on their datasets. Modularity of proposed processes allows for an easier integration into more complex use cases such as scientific data usage or potential clinical therapy planning.

Register a new service in the registry

For a service to be discoverable, it needs to be properly documented within the registry. In addition to name and metadata like service maturity levels, responsible organization as well as the endpoint itself, it is key to also represent in- and output parameters and technical preconditions for services. This enables us of finding suitable services by filtering them by their technical preconditions and their input parameters. Figure 3 shows the process of registering a new service.

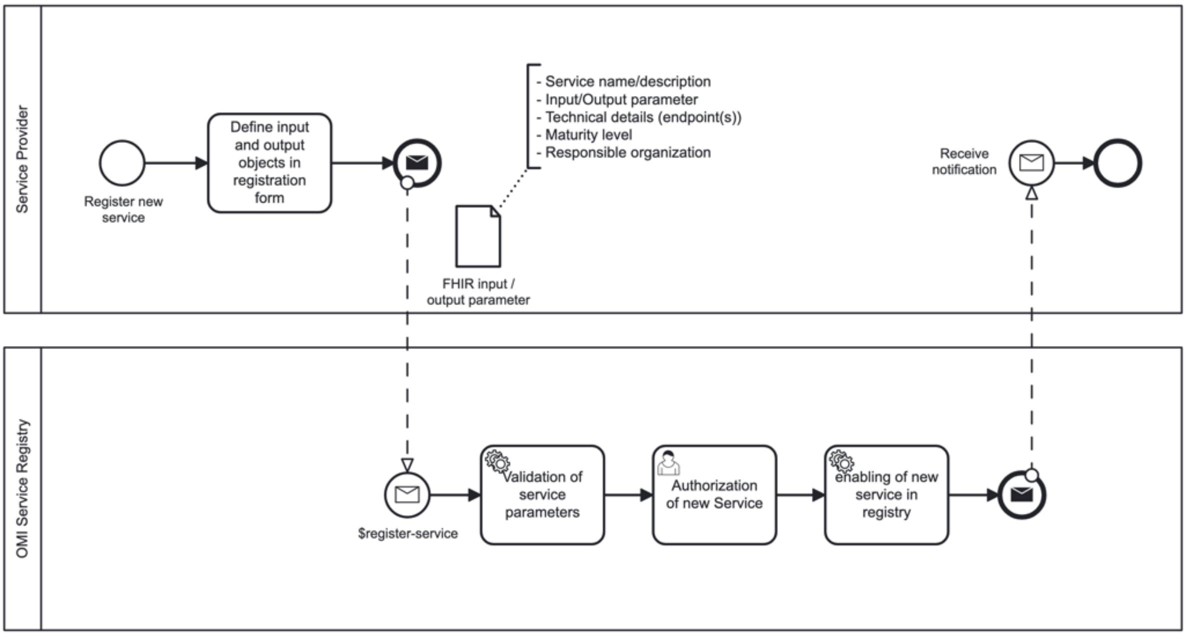

Figure 3 - Registration of a new service: a Service Provider (upper pool) registers his service by stating data characterizing the algorithm and its in- and output parameters. The Service Registry (lower pool) receives the registration, validates it technically but then waits for the approval of a human user. Once this activity is completed the Service Provider receives a notification that the registration process is complete.

The main actors of this process are the registry itself and the service provider. After defining metadata as well as the in- and output parameters and technical preconditions, the service

[2] https://github.com/medizininformatik-initiative/OMI-Protokoll-WP1, last accessed on 22.11.2023

registry receives the request. Parameters are automatically validated, and the new service is initially approved in a manual process accordingly. The service will then be activated and can be found by the search function. Additionally, a notification is sent to the service provider to finish the registration process.

Modify and update information related to an inference service within the registry

Services are under constant development and new versions of algorithms might be released frequently. The registry needs to support changes for algorithms metadata to reflect these developments. The envisioned process includes a two-step change/update process (see Figure 4): firstly, the service provider needs to select the service he wants to modify. After manually providing the service details, he triggers an automated validation as well as manual re-authorization. If both steps are successful, the modified version is enabled within the service registry.

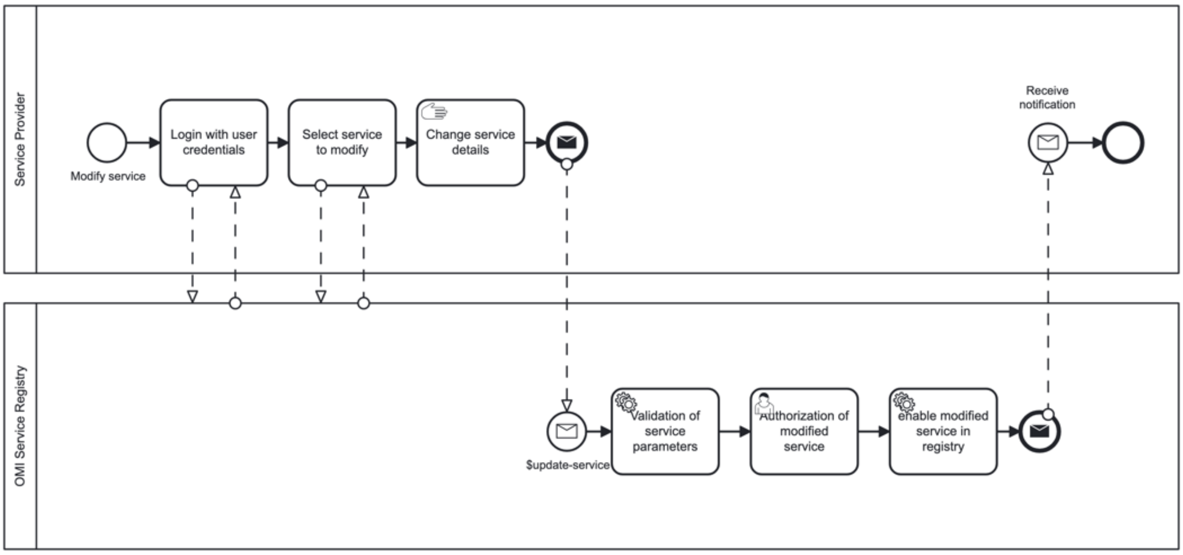

Figure 4 – Updating information regarding a service e.g. due to a new version it can be necessary to change the required input parameters. Service Providers (upper) can do this by logging into their registry account and selecting their service to modify. After finishing modifications, the request to change is sent towards the registry (lower) where it is validated, authorized (manual process) and finally enabled within the registry. A notification is sent towards the Service Provider when the process terminates.

Finally, the service provider is notified about the accepted changes, which terminates the process.

Find and use services in the OMI Registry

After registering, one might want to request remote inference provided by a service, which is registered in the service registry. For this reason, we established a process model which accommodates this use case (see Figure 5). We differentiate between an already known service versus one that must be found by the researcher first. If the service is already known, the service consumer can go on to request the service over the known endpoint. If not, the service consumer has to look up a suitable service in the registry. After selecting a service, he then requests the execution of this service with his data, in direct communication with the service provider and independent from the registry itself.

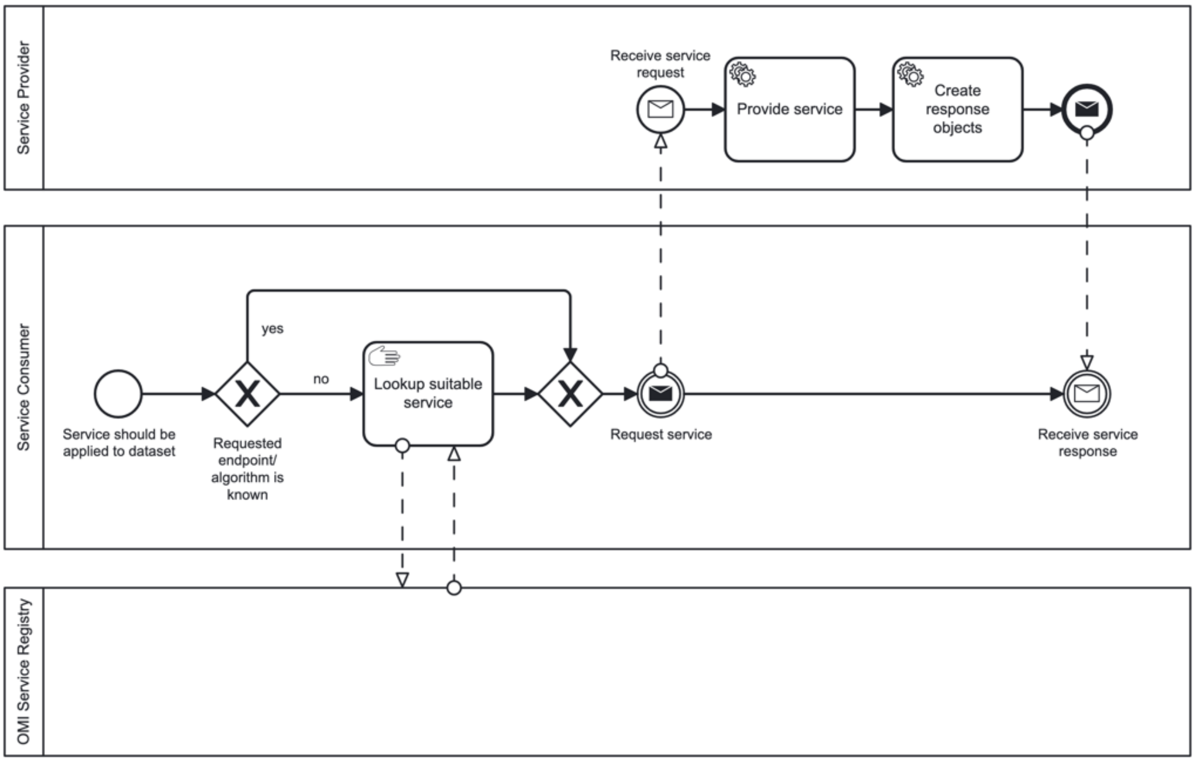

Figure 5 - Request remote inference services: a Service Consumer (middle pool) decides whether he already knows where the service he wants to request is located. If the endpoint is not known he does a lookup within the Service Registry (lower pool). After triggering the service the Service Provider (upper pool) receives the request, executes the service remotely and creates the defined response objects asynchronously. The service response is then sent to the Service Consumer.

After receiving the service request, the service provider can process the request in his pipeline and create the corresponding response object whenever the inference service finishes. Lastly the service response is sent back to the service consumer.

Train a service with annotated images from data providers

The necessity for acquiring site-specific training data to enhance algorithm accuracy depends on the maturity level of a service. The registry plays a crucial role in facilitating dataset querying by connecting (image) data providers with service providers (see Figure 6). Upon establishing the requirements for the necessary training datasets, a request is submitted to the OMI Service Registry. Authorization for the training data request is subsequently granted by the responsible personnel at the OMI registry. Once authorization is granted, a query for datasets is initiated with the data providers. Subsequently, links to datasets or relevant information about these datasets are consolidated and transmitted to the service provider.

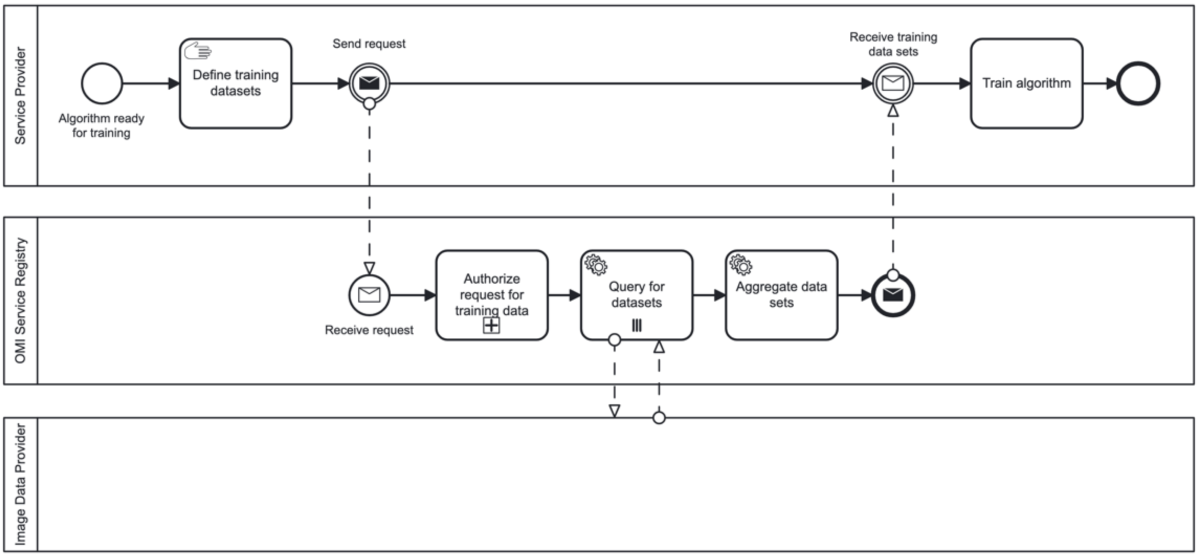

Figure 6 - Train Algorithm: A Service Provider (upper pool) wants to train an algorithm, so he manually defines training datasets that support his use case. He then sends this request towards the OMI Service Registry (middle pool), which receives the request, authorizes it, and queries Image Data Providers (lower pool) for datasets. Once the activity concludes data sets are aggregated and sent back to the Service Provider, who goes on to train his algorithm and concludes the process.

If successful, the service provider receives one or more data sets, trains his service, and terminates the process if a desired accuracy for the service is reached.

Deriving a generalized information model

To narrow down a functional specification and operationalize a service registry and communication protocol, a generic information model was derived (see Figure 7). It contains a minimal dataset to represent the information needed by processes outlined before.

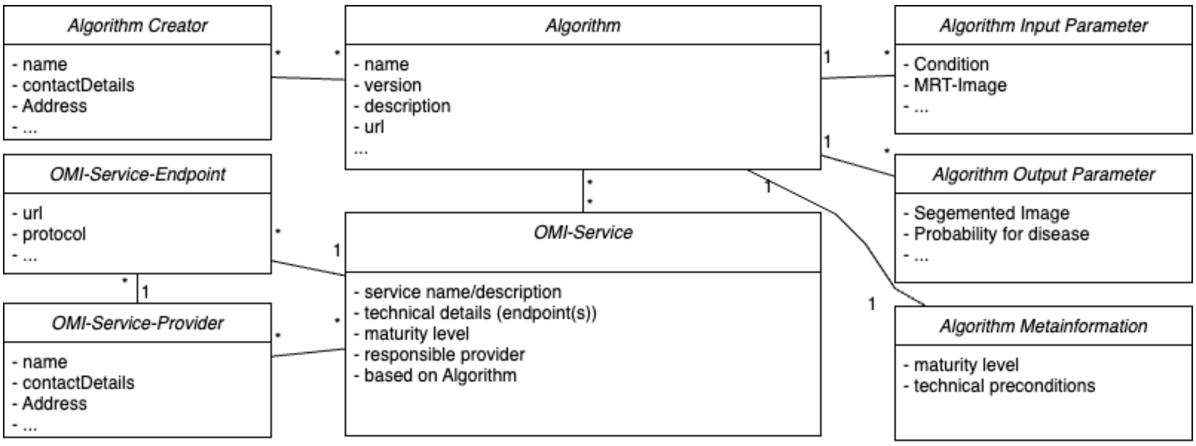

Figure 7 – UML like generic information model for inference services and related information. It consists of algorithm creator, his algorithm(s) and their in- and output parameters as well as available services, their endpoints and service providers. Services are characterized by maturity levels, which indicate if they can be used in an experimental, research or clinical context.

The main component of this information model is the *algorithm*, which is characterized through a name, description amongst other information like its version. An *algorithm* has one or more authors as well as many *in- and output parameters*. It can be part of one or more *services*. Attributes of the service include the name, maturity level of the service, which provides an overview of the service's development status and indicates in which context the service can be used. A *service* has one or more *endpoints*, which are characterized through information about the specific URL and used protocol. A *service* has one or more *service* *providers*. A *service provider* points to the organization primarily responsible for developing and managing this *service*. It includes attributes like the name and other relevant information such as contact information and address. An *endpoint* is linked to a *service* and describes an access point in the form of an API or other web service. Its attributes include things like name, specific URL where the *endpoint* is located and the communication protocol that the *endpoint* uses.

When thinking about scalability, we must design the protocol such that *services* are agnostic about where they are running physically. Eventually multiple *endpoints* of the same *service* are made available by different *providers*. When executing inference requests, the *service* should provide information about the specific version from which the results were derived, including information like the versions of the *algorithms* that were run.

Outlining in- and output parameter patterns

Based on the example use-cases within scope of the OMI project, we can broadly categorize diverse types of input parameters: 1) images – acquired by different modalities, 2) segmentation layers, 3) image metadata and clinical metadata, such as laboratory results, histology, age, sex, time of survival amongst others. Outputs are heterogeneous and differ between algorithms: from numerical values for predictions like survival time over segmented images, diagnosis codes and more. We can establish abstract patterns that represent these parameters as shown in Table 2.

Table 2 - Overview of in- and output patterns for image related Services within the OMI protocol. Services can ingest images (#1), images and segmentation data (#2) as well as metainformation (#3) e.g. in textual form. Brackets indicate optional parameters.

Pattern	Description	Image Data	Segmentation Data	Meta-information
#1	Images are provided/produced	✓	✗	✗
#2	Image- and or segmentation data are provided/produced	(✓)	✓	✗
#3	Image-, segmentation- and metadata are provided/produced	(✓)	(✓)	✓

Parameter patterns are agnostic if they are utilized as in-put or output parameters, so e.g. an AI-based service that consumes pattern #1 can produce a pattern #2 and vice versa. Segmentation data can be stored e.g. in DICOM SEG or NIFTI image format. Image data is hereby independent of the acquisition modality (e.g. MRI sequence). Segmentation data always needs a point of reference, i.e. an image or coordinate points of the contour. Metainformation about pictures or the patient also needs references to where it belongs to. Some parameters for AI-based algorithms may require temporal information as an input like follow-up values over time (e.g. bodyweight) as an input. Therefore, the protocol should be able to represent requested parameters, for instance the last five measurements of bodyweight over a period not longer than 3 weeks in total.

FHIR profiles ensuring conformance and interoperability

From the abstract process and data model definitions above, we derived a FHIR specification (see Figure 8 and Table 3). An algorithm is represented as *Device* resource which is remote inference calling entity. A service is represented as a *HealthcareService* Resource which links to a device resource. The resource's capability to represent virtual services is a crucial factor for its applicability for the OMI registry. It holds information on how to access the service via the *Endpoint* resource. In addition, services represented as *HealthcareService* resources, can be part of referral networks and service directories. An extension for maturity level of the *HealthcareService* resource provides the ability to evaluate the development stage of a service.

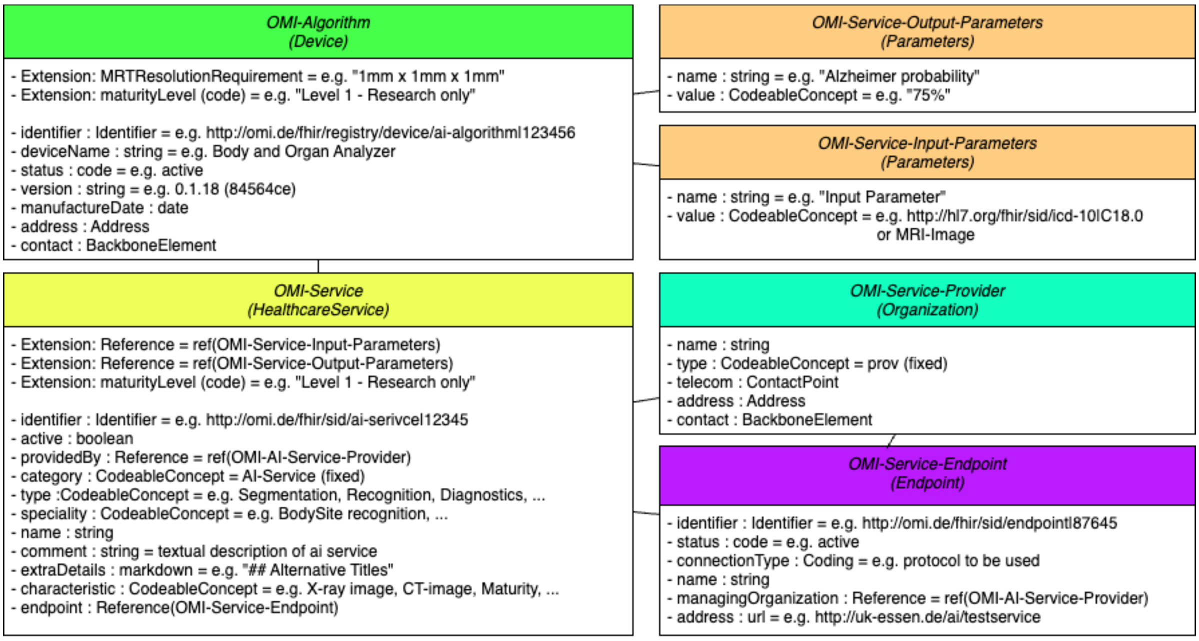

Figure 8 – FHIR R4 model for the representation of OMI-Services and their characterizing aspects like Organization, Endpoint as well as In- and Output Parameter.

A *Service-Provider* is represented by an *Organization* resource and can be used to support other resources that need to reference organizations. In this case, each AI Service has a reference to the managing organization of the Service. The *Organization* resource has all the necessary attributes to identify the responsible *Organization* for an AI Service and does not require further extensions to represent the *Service-Provider*.

For the *Service-Endpoint*, the *Endpoint* resource is chosen for its capability to describe the technical details of connection points and their usage for delivery or retrieval of information. Each service will have to have some sort of interface like an API or a web service. Each *Endpoint* will contain the technical details of these interfaces, such as the used protocol and the location of the endpoint in the form of a URL.

In- and Output-Parameters are defined by *Parameters* resources. Its flexibility allows it to handle different types of data. The *Parameters* resource does not need to be extended to represent the necessary attributes for this use case. It is versatile enough, enabling the usage of both raw FHIR data types and FHIR resources. While generating profiles for resources adds an additional layer of workload, it significantly enhances semantic interoperability.

Table 3 - FHIR base resources overview: their derived profiles, and a description of their purpose.

Base Resource	Profile name	Description
Device	OMI-Algorithm	Represents an algorithm itself, including information about name and version as well as responsible organization, maturity, and technical preconditions.
HealthcareService	OMI-Service	Holds information about a service offered by an organization, including met information such as status, type, specialty, maturity, and available endpoints. It also references in- and output parameters.
Endpoint	OMI-Service-Endpoint	Holds information about an endpoint and how to interact with it.
Parameters	OMI-Service Input/Output Parameter	Holds the in- and output parameters of the algorithm which is provided as a service.

Conclusions, limitations, and further actions

This whitepaper aims to provide a basis for discussion connecting stakeholders like (AI) service providers and potential users. The OMI framework aims to empower people who are looking for an inference service for their data, but who do not have the capacity to overcome the infrastructural challenges of setting up AI services in their own institution. The outlined methodology for the OMI protocol specification covers processes of registering, finding, and applying inference services for biomedical research questions based on open interoperability standards beyond the scope of a single organization. Leveraging the FHIR standard enables machine processable interoperability without losing semantic context when traversing between different services and institutions.

The methodology outlines the representation of services as well as the process of finding suitable services in a machine processable way. Additionally, a process on how to find data for algorithm training was presented. However, the protocol does not establish a way for data transport itself. Here, established open standards are employed. Mechanisms for data transfer like the usage of the DSF [26], [30] as part of the MII [1] will be used.

Currently, the protocol definition is missing procedures on how services are billed and how the infrastructure for the provisioning of services is organized. Requesting remote inference is associated with costs and latency times when receiving the results from a service call, which must be considered by both the requester and the service provider in their technical implementation. As adoption gets more widespread, queues for inference will get longer and upgrading computing infrastructure will likely become a necessity for service providers. Some steering of traffic could be achieved via status attributes within the registry. However, it cannot replace efforts and management solutions to actively manage the remote infrastructure and endpoints in regards of traffic and computation load. These are aspects for the future development and revision of the OMI framework.

Concerns regarding data and privacy protection emerge, particularly in healthcare settings but also within research scenarios. It must be carefully thought about what kind of data is shared or accessed to provide inference. It also must be guaranteed that data is reliably managed after usage for inference on the remote location. Other aspects like re-identification of individuals based on images of different modalities is also a possible risk. Current defacing algorithms, which are available for some imaging modalities [31] mitigate this problem, but they may interfere with the application of AI based algorithms [32]. We plan to collaborate with the broader scientific community in order to integrate new methodologic developments in this domain into the OMI framework.

Declarations and Conflicts of interest

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