ISMT-599 Digital Enterprise: Capstone Project Proposal
Fall 2018 Semester

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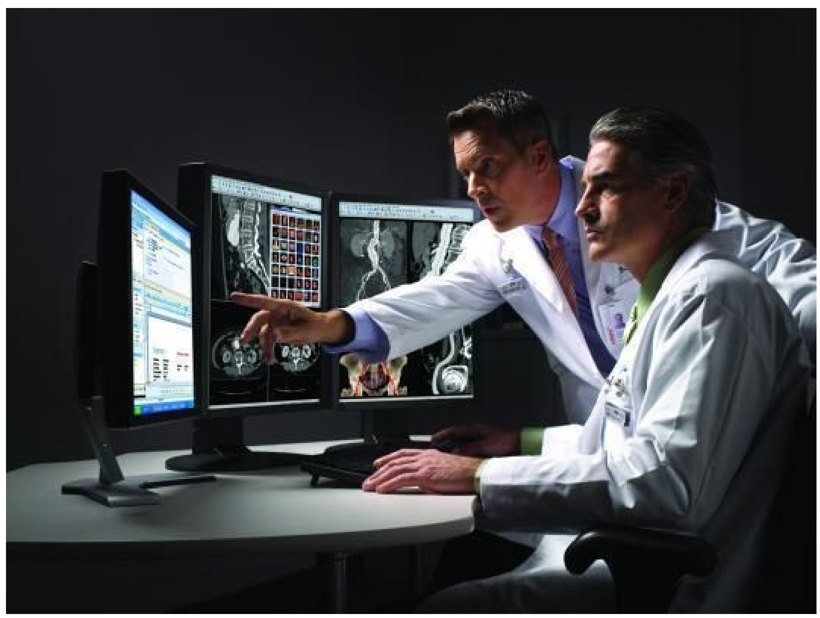
Cloud Based Machine Learning Medical Diagnosis

Innovating Gloco's PACS Product Line with DigiMed Platform and Machine Learning Analytics



Prepared for:

Executive Summary

Gloco is a well-established company in the global medical device marketplace. Its previous success is attributed to a combined focus on customer service and reliability. Gloco has been particularly successful in growing its share of the radiology sector, where its sales in 2016 grossed USD 5.1 billion - accounting for 73% of overall revenue.

Gloco's management has expressed concern over its competitors' ability to rapidly launch innovative new digital services in the medical device marketplace. By leveraging cloud-based solutions, these new services have allowed competitors to differentiate themselves with products that outperform Gloco's more traditional standalone offerings. Competitors such as GE Healthcare are posting substantial profits from analytics and cloud-based service revenue of USD 2 billion in 2016 alone (Flannery, 2017). This disruption in the marketplace is raising concerns over Gloco's ability to compete in both short and long-term sales cycles. Gloco has responded by asking its suppliers for strategies that will allow it to remain a pre-eminent purveyor of medical devices.

Team3 Consulting Ltd has helped numerous multinational firms refocus their brands on innovation. By cleverly applying cutting-edge information technology, we enable large manufacturing companies to regain their competitive advantage. We are an ideal partner in Gloco's quest to refocus on digital innovation.

We believe that advances in Computer Aided Detection (CAD) could augment existing functionality in Gloco's Picture Archiving and Communication System (PACS) products. Team3 Consulting Ltd is proposing that Gloco creates a cloud-based information technology platform – DigiMed - on which to rapidly launch new analytic and data services. Such a platform will allow Gloco to actively compete as a provider of Internet of Things (IoT) technologies. Team3 Consulting Ltd believes Gloco should immediately leverage this platform to introduce two new service offerings: "Sherlock" - a CAD service that will integrate with existing PACS products, and "MediVault" – a Cloud-based file storage solution that compliments Sherlock.

Table of Contents

1 Business Requirements

1.1 Business Context, Problems, and Objectives

The competitive landscape for MRI producers is different as can be seen by the fact, that remote services over the internet for proactive, preventive maintenance dates back almost two decades while this is a new concept to other industries. The year 2012 saw the commercialization of cloud-based PACS [Panda, R., 2012] and the advent of pure digital-players in this field such as *ResonantsPacs*.com. Again this industry is ahead: the years 2014 and 2015 marked another significant disruption with two major events paving the road what industry sources even label the "medical imaging IoT 2.0" [Daher, N.M, 2016]. In 2014 Siemens launched *teamplay* [Siemens, 2017] as the first "health cloud," enabling among others a cloud-based collaboration on imaging studies beyond organizational boundaries. Shortly followed by GE and Philips establishing their growing ecosystem for "smart health." The acquisition of *Merge* by IBM in 2015 brought together an unparalleled competence in cognitive imaging and AI. Both, the established 'smart health clouds' of competing manufacturers and future AI based analytic services are (in most cases) hardware agnostic and thus reach out to operators of any medical device. In the case of MRI scanners, this is leveraged by an industry-wide adoption of standards like *Dicom* [MITA, 2017] and *IHE Profiles for Radiology* [IHE, 2017]. Meanwhile, pure digital-players have moved away from simple cloud-based storage services towards additional cloud-based offerings for collaboration and workflow-management tool, such as TriceImaging.com. AI and ML-based analytic services, similar to Gloco's CAD, are yet not available, but again pure digital-players such as Boston based CCDS have emerged as competitors.

In this highly competitive landscape, characterized by a downturn in sales, Team3 identified the need to focus Gloco's digital strategy on the MRI scanner division (73% revenue contribution) because of its preeminent position regarding strategic threat intensity, profit contribution, and overall business impact. We base our recommendations on a SWOT Analysis (Appendix 1) for the MRI product range. The analysis shows that there are no viable strategies to avoid or convert the identified weaknesses of a missing smart health platform with shared services such as file storage and the threats imposed by competitors being ahead in digitization as depicted by the prior competitive landscape analysis. To respond to the sales decline and to catch up with the competition the objectives are to i.) move the production-ready CAD *Sherlock* to an elastic GPU cloud, ii.) implement *MediVault* - Gloco's version of a smart health ecosystem, and iii.) also offer the service for cloud-based file storage, labeled *MediVault*. An illustration of this product concept appears as a BOM in Appendix 2.

1.2 Functional Requirements

The following user stories are assembled to capture the primary functionality that will be required at launch.

1.2.1 Epic A: MRI Visit Radiology Workflow

1.2.1.1 "As-Is" State of Patient Visit Workflow

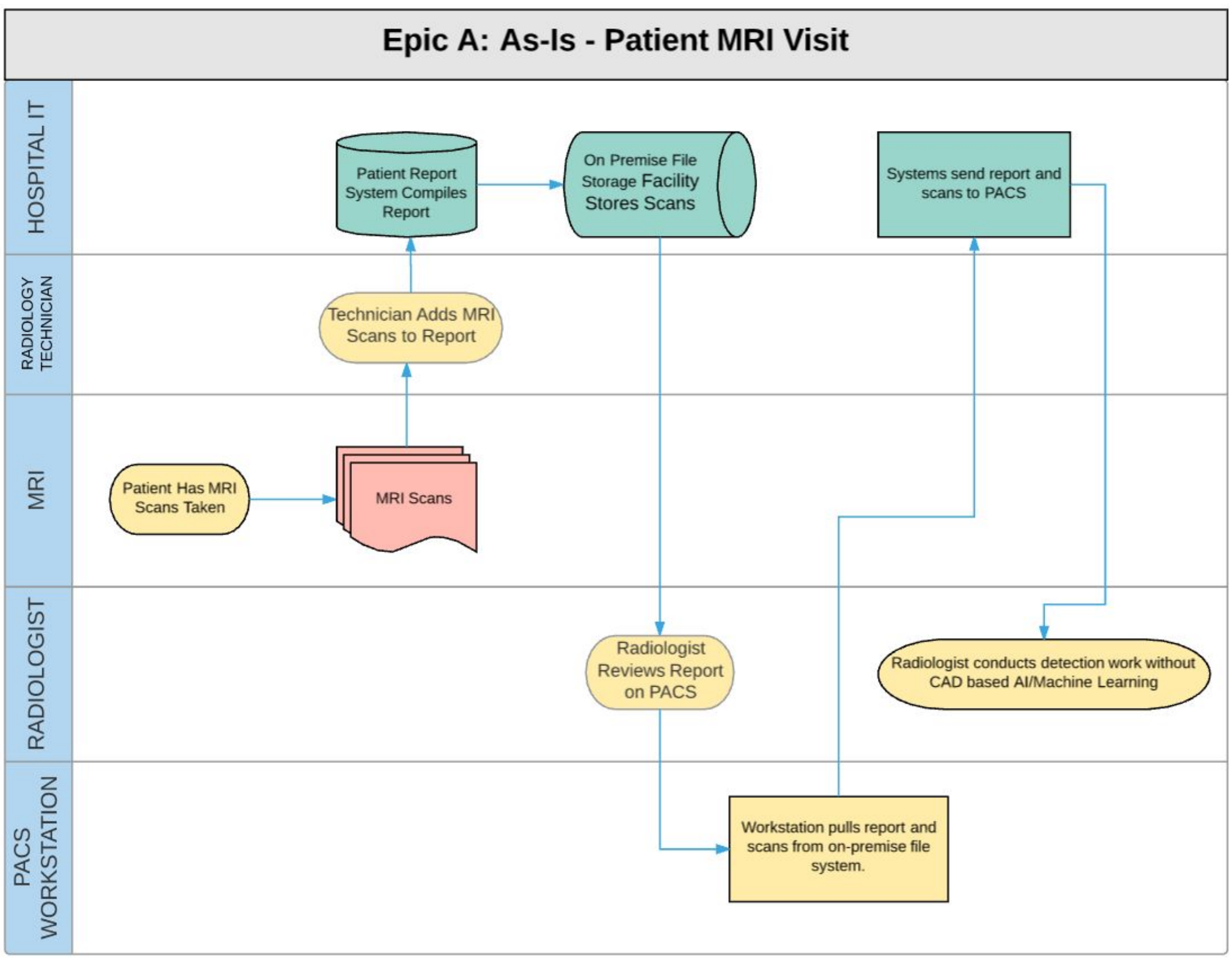


Figure 1. "As-Is" state of patient visit workflow

1.2.1.2 Future State of Patient Visit Workflow

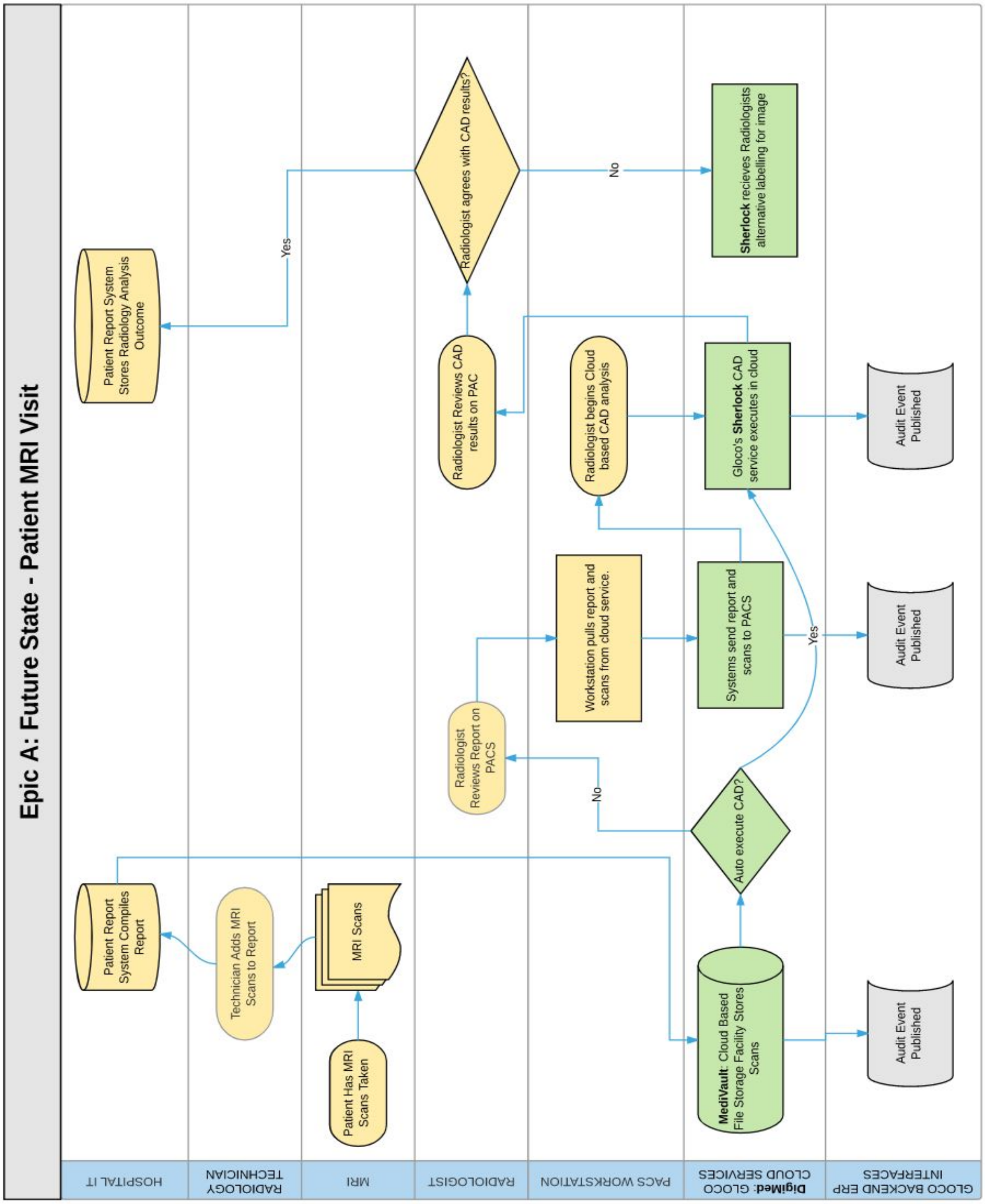


Figure 2. Future state of patient visit workflow

1.2.1.3 User stories:

1.2.1.3.1 As a Radiologist,

EA-RA-1 I need the ability to send a patient report from my Gloco PACS for real-time Computer Aided Detection (CAD) analysis. During the analysis, I require feedback as to the expected time until completion. I require the ability to specify global preferences in regards to detection certainty, as well as other parameters affecting CAD outcomes. I will also require the option of overriding these preferences on individual CAD requests. Acceptance criteria includes:

- ✓ The service runs at acceptable speeds regardless of how many patient records are being analyzed.
- ✓ The CAD service is selectable as an option from the PACS tools menu – where it appears as a sibling to other tools such as measurement.
- ✓ In the case of issues surrounding the PAC's health care provider's subscription to this service, I am given helpful error messages.
- ✓ In the case where the service is not available, or processing delays are expected – I am given helpful error messages.
- ✓ In the case of receiving incorrect CAD results, I can override them and label images with my own assessment. This allows feedback to be returned to the CAD analytic service.

EA-RA-2 I need the ability to specify that CAD should automatically be performed on all patient reports before they arrive on my PACS. Acceptance criteria includes:

- ✓ CAD results are automatically prepended to patient results when the service is configured to do so, and remain absent when not.

EA-RA-3 I need the ability to access patient reports from my Gloco PACS that have been stored in the Gloco cloud file service. Files stored in the cloud service will need to work seamlessly with all existing PACS functionality. Acceptance criteria includes:

- ✓ When files attached to a patient report reside in the Gloco cloud, the service reliably retrieves them with an acceptable level of performance.

EA-RA-4 When the CAD analytic service identifies a problem (tumor or diseased cells), I need to receive medical images with the problem areas properly labeled.

✓ A problem area within a recorded medical image is circled and labeled with a disease name (tumor, infection…etc).

EA-RA-5 I need to access the medical image profiles of patients who have been in my appointment schedules or who have transferred to me from another radiologist. The profiles are stored in the cloud file service for 90 days, after which they are automatically archived and will require a health provider manager's approval in order to retrieve the archived profile. Retrieving archived profiles results in a service fee.

✓ The PACS displays patient profiles sorted by their appointment dates.
✓ The radiologist can access corresponding patient profile folders upon searching or browsing the patient's information.
✓ Inside each patient's profile folder, their medical images display in chronological order.
✓ The cloud system periodically archives patient profiles that are older than 90 days.
✓ Radiologist can request archived folder image retrieval with a service fee application form going to a hospital manager for approval.

1.2.1.3.2 As a Radiology Technician,

EA-RT-1 I need to store images I've produced on the MRI, along with their associated patient report into the cloud, for further processing by Gloco services at a PACS. Acceptance criteria includes:

✓ Cloud storage service is always available when required.
✓ Any errors are reported in real-time with a user friendly format.
✓ The Cloud storage service does not run out of capacity when adding new files.

1.2.2 Epic B: Customer and Subscription Management

1.2.2.1 User stories

1.2.2.1.1 As a Healthcare Provider Manager,

EB-MN-1 I manage subscriptions to Gloco services on behalf of my organization. I need to be able to review the status of our subscriptions, add new subscriptions, cancel current subscriptions and browse a catalog of currently available services. Acceptance criteria includes:

- ✓ I can access a dashboard which displays all members of my hospital and their subscriptions to the analytics services.
- ✓ The dashboard displays a summary of all analytic service usage (the number of CAD service calls requested) sorted by members in the subscription.

1.2.2.1.2 As a Radiologist,

EB-RA-3 I would like to see all Gloco services that are available for my PACs to automatically display as options on the appropriate menus. Acceptance criteria includes:

- ✓ An individual user dashboard is available to display the analytic service usage on my account.
- ✓ A button on the workstation screen is available to send medical images through CAD analysis and return them with a diagnosis.

1.2.2.1.3 As a Gloco Accounts Manager,

EB-GADM-1 I require the ability to review the accounts in my sales portfolio. I need to be informed of new subscriptions, upcoming subscription expirations and any information related to the levels of service my accounts are experiencing. Acceptance criteria includes:

- ✓ A dashboard is available to display all the health provider accounts and their member subscriptions associated with my sales portfolio.
- ✓ Each health provider account has a list of subscribed members. Additions, deletions and modification can be made to the list.

1.2.3 Epic C: Gloco Product Development and Delivery

1.2.3.1 User stories

1.2.3.1.1 As a Gloco Systems Administrator,

EC-GADM-1 I require the ability to monitor the health and performance of any services running on the platform. Acceptance criteria includes:

- ✓ A dashboard displays the overall health provider account listing in the system
- ✓ Concurrent load on CAD analytic services is displayed on the dashboard
- ✓ Alerts are issued when there is continual high usage of a particular CAD service in the system

EC-GADM-2 I require the ability to monitor the health and performance of any services running on the platform. Acceptance criteria includes:

- ✓ I have the ability to run a report of individual CAD service execution volume over weekly, monthly or yearly timeframes.
- ✓ I can disable a particular CAD service in situations where it is running with abnormally high request rates (suspected DDOS attack).
- ✓ I can run a report on CAD services with highest dispute rate (analyzed result disagreed by radiologists and feed into deep learning system for reclassification of analytic service).

1.2.3.1.2 As a member of Gloco's CAD Product Delivery team,

EC-PROD-1 I require the ability to tune and reconfigure the training data used by the CAD service's machine learning functionality. Additionally I may choose between sets of training data and run tests which select a set to perform analysis with. Acceptance criteria includes:

- ✓ I can access a dashboard displaying a list of CAD services which receive radiologist feedback images for retraining.
- ✓ Individual CAD services are retrained with newly added feedback images and updated service is displayed on the dashboard.
- ✓ CAD product owners can hand-pick a set of images to feed to reclassification for updating a particular CAD analytic service.

EC-PROD-2 I require clear definitions of how my service will run within the new Gloco cloud based platform. I will need details on any APIs and standards that should be adhered to so that the CAD service I am creating is fully compatible with the platform and can take advantage of its functionality. Acceptance criteria includes:

- ✓ A dashboard displaying individual CAD analytic service functionality and example result of labelled information.
- ✓ CAD product owners can request to create a new medical image classification model with a selected list of images used for training.

1.2.4 Epic D: Gloco Enterprise Systems Integration

1.2.4.1 User stories

1.2.4.1.1 As a member of Gloco's Sales and Marketing team,

EC-ENTSALE-1 I require the ability for customers, and sales representatives to subscribe to, and cancel the digital services on Gloco's web site. Acceptance criteria includes:

- ✓ Automated provisioning of the necessary digital services for the customer. Provisioning must enable customer ability to use the service, and enterprise ability to support the service, bill for the service, and pay associated 3rd party costs incurred to provide the service.
- ✓ Automatic provisioning for customers who buy new machines without the need for customers to explicitly sign up on the Gloco web site, to include all provisioning and integration described above.
- ✓ Automated decommissioning of the digital services if the customer cancels the service. The Customer's sales representative is informed of subscription to the digital service.

1.2.4.1.2 As a member of Gloco's Product Support Team,

EC-ENTSUP-1 I require integration of the digital services support and troubleshooting information into the enterprise support knowledge base through the knowledge base APIs. Acceptance criteria includes:

- ✓ I can report, record, and resolve product issues for the digital services on all support channels in the existing enterprise support Portal.

- ✓ I know which digital service each customer subscribes to along with the information required to perform product support.

1.2.4.1.3 As a member of Gloco's Billing Team,

EC-ENTBILL-1 I require integration of the digital services billing information into the enterprise billing system through the billing system APIs. Acceptance criteria includes:

- ✓ I can bill customers for service subscriptions.
- ✓ I can stop billing customers who cancel subscriptions.

1.2.4.1.4 As a member of Gloco's Accounts Payable Team,

EC-ENTAP-1 I require integration of 3rd party resource utilization incurred providing digital services to verify bills from cloud service providers. Acceptance criteria includes:

- ✓ I can validate cloud service provider bills against 3rd party resources that were consumed while providing digital services to customers.

1.3 Non-Functional Requirements

1.3.1 DigiMed: Cloud Platform Requirements

NF-ICP-1 Platform must have 99.9 (three nines) of availability except for planned maintenance.

NF-ICP-2 Platform infrastructure must be elastic and scalable. Functions related to scalability should be invisible to end users.

NF-ICP-3 All communications must be secure, and authentication with interfacing partners non repudiable.

NF-ICP-4 Platform must provide a way to decouple services from devices – either through employing a profile type concept, or through a similar means of isolating integration requirements from implementation. In other words, a service and device with compatible profiles should be allowed to communicate with one another.

NF-ICP-5 Platform must conform to all regulatory requirements in locales where it offers services. For example, it must conform to HIPAA regulations in the USA.

NF-ICP-6 Role based security must be used wherever applicable.

NF-ICP-7 Platform must have an audit trail showing read access to medical information.

NF-ICP-8 Patient Health Information must be encrypted both when in motion, and when at rest.

NF-ICP-9 Platform must support services that can be broken down into two type of profiles. First there are those services associated with traditional IT functions – as demonstrated by the file storage system in this project. These services offer customers the benefit of reduced IT infrastructure costs. Second, there are "Mode 2" type services that are innovative and differentiate Gloco from its competitors.

NF-ICP-10 The platform must allow Gloco to deliver new products and services to the market with reduced development time and overhead.

1.3.2 MediVault: Cloud Storage for Patient Report MRI Scans Service Requirements

NF-CRS-1 Medical devices can cache at least 12 hours of data to deal with any connectivity issues and save operational data for later transmission

1.3.3 Sherlock: Cloud Service Implementation for Computer Aided Detection (CAD) Requirements

NF-CAD-1 Medical devices connected to this service can cache at least 12 hours of data to deal with any connectivity issues and save operational data for later transmission

NF-CAD-2 The Sherlock service should support and conform to IHE profiles for Radiology whenever possible.

1.4 Business Benefit Justification

In line with comparable solutions in the industry, the costs of implementing the platform include:

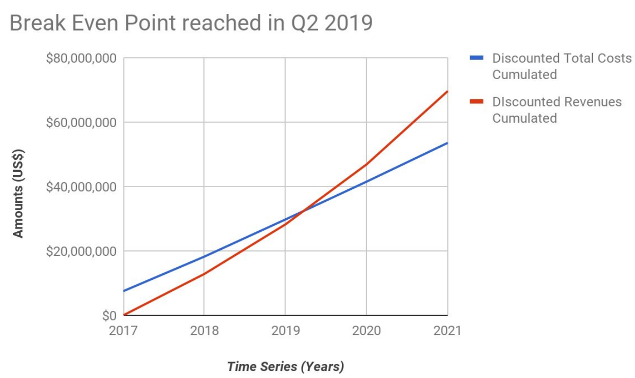
- cost of sensors on the IoT end devices
- cost of processing software and licensing fees,
- cost of bandwidth between the cloud and Gloco infrastructure
- cost of storage on the cloud
- cost of implementation
- cost of training and continuing education of support staff

It will also cost an estimated USD 7 million to integrate the software into the Gloco portfolio of product offerings and to connect the platform with Gloco's ERP system. The ICT Team will leverage

Amazon Web Service (AWS) for hosting, thus reducing costs compared to on premise hosting. Overall, we estimate a total initial cost of about USD 37.5 million to cover all expenses.

Gloco's main competitor – General Electric (GE) - has a similar initiative underway under their Predix moniker (GE, 2016). Using GE's Predix as a proxy and scaling down to Gloco's organizational size and structure, we estimate about 5% potential increase in total revenue over a five year period from the baseline of USD 6 billion we currently generate. This comes in terms of value created by productivity solutions, digitally enabled outcomes, software and professional services.

That said, we expect to break-even in the third year of the aforementioned period as shown in Figure 3, within this overall operating margin. Additional revenue should be expected if we diversify to other offerings on the same platform. Based on an even conservative scenario a break-even-point is likely to be reached in Q2 of 2019. The detailed cost-business calculations are referenced at Appendix 3.



Break Even Analysis 2017-2022						
Year	2017	2018	2019	2020	2021	2022
Total Costs Accumulated	$7,500,000	$19,150,000	$32,827,500	$48,061,356	$65,102,092	$84,261,220
Discounted Total Costs Accumulated	$7,500,000	$18,238,095	$29,775,510	$41,517,207	$53,559,652	$66,020,871
Revenues Accumulated		$13,500,000	$31,147,500	$54,273,038	$84,649,721	$124,644,644
Discounted Revenues Accumulated	$0	$12,857,143	$28,251,701	$46,883,090	$69,641,535	$97,662,340

Figure 3. Break Even point of DigiMed Platform

1.5 Key Performance Indicators and Project Success Criteria

The following Key Performance Indicators (KPI) are used to gauge success of the initiative:

Metric Category	Goal
Increase in Revenue	Increase $97M USD(2%) in revenue by providing Image storage in cloud as a service, ML analytics as a service and introducing intelligent and connected machines.
Improve Customer Experience	Proposed 20% increase in customer satisfaction through self-help resources and automation of IoT functionality, measured via CSAT surveys.
Improve Accuracy of MRI diagnosis.	30% False Positive reduction tested via radiologist verification to Sherlock service results returning from Deep Learning models.
Increase the efficiency of radiologist	30 – 50% increase in productivity of radiologists (time spent on each scan navigating and user experience).
Reduce Time to market for new services and devices	40 – 50% reduction in time since we are diversifying out of the same digitized platform. This allows the addition of imaging equipment in the future.

Table 1. KPI for DigiMed project

2 Technical Specification and Prototype

With all the business requirements identified in Part 1, we propose the technical specifications and prototype of Medivault and Sherlock services in DigiMed in this section from architecture, software solution and data design and management perspectives.

2.1 Architectural Overview

The overall DigiMed platform architecture is demonstrated in Figure 4 below. It contains Sherlock and MediVault components and DigiMed Client Portal all hosted in AWS. The details of all architecture components are listed in Appendix 4.

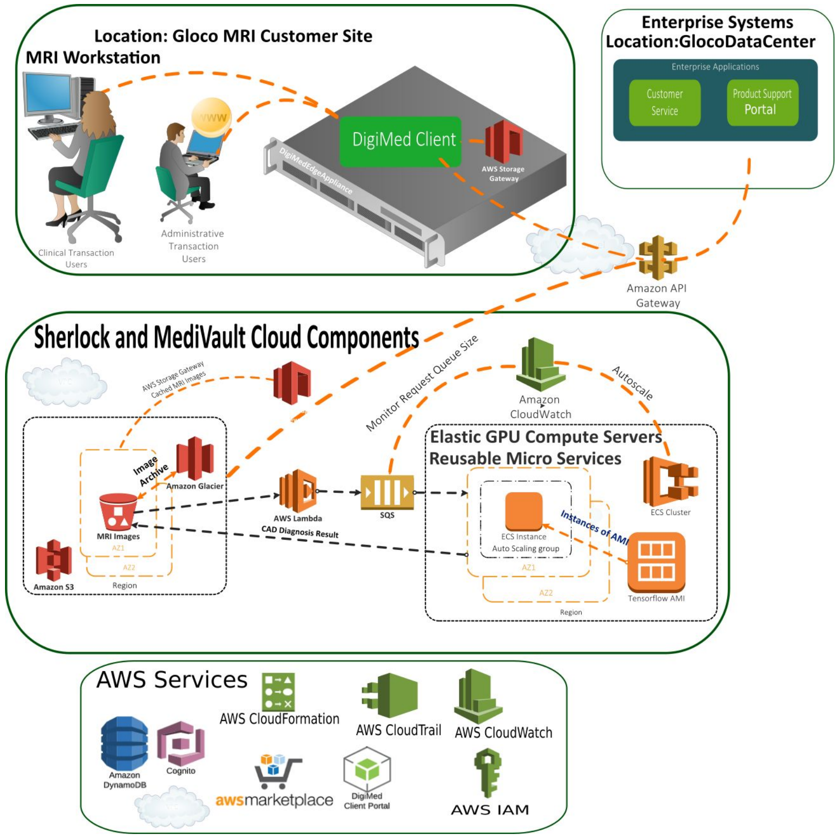


Figure 4. High Level Architecture Deployment Overview

Appendix 4 contains UML Sequence Diagrams showing how each architecture component is employed to satisfy DigiMed requirements. In general, the Architecture is:

1. Cloud based and makes maximum use of Amazon Web Services including use of those services to support operations.
2. Designed for global scale highly available deployment with transparent demand driven autoscale.
3. Enables and depends on a new sales channel and billing mechanism for GLOCO, Amazon Marketplace for sales with billing metered through the Amazon API Gateway.
4. Is highly secure, providing full auditable HIPAA Security compliance. Security is achieved through configuration. Amazon restricts which services can be used to a select subset before Amazon will sign a HIPAA Business Associate Agreement. The Architecture utilizes only services from the HIPAA select list.
5. Is event driven. All events are shown in the sequence diagrams in Appendix 4. Paragraph 4.4.3 shows the table of significant events.
6. Develops the capability to offer two new DigiMed digital products. Components employed are described in paragraphs 4.4.1.2 (MediVault Service) and 4.4.1.3 (Sherlock Service) of Appendix 4.

7. Develops significant reusable capability to accelerate GLOCO offering of new digital products. This is described in paragraph 4.4.1.4, "Reusable Components That Can Be Employed For New Digital Products" of Appendix 4.
8. Integrates GLOCO existing Product Support and Customer Service processes and platforms to provide a seamless customer service and support experience.

2.2 Software Solution

DigiMed services are implemented and delivered with AWS Lambda Serverless infrastructure at the core of the technology stack. Together with AWS Lambda, AWS API Gateway forms the app-facing part of the AWS serverless infrastructure. Lambda interacts with necessary backend AWS services, and a gateway exposes the public-facing Lambda functions. The AWS Gateway services, in turn, are marketed to customers through the AWS Marketplace.

2.2.1 AWS Marketplace

Developer and publisher portals are central to any API Full Lifecycle Management platform. These portals grant security credentials which customers can use to make API calls. They additionally manage subscriptions and billing information where required. When working with the platform, a developer portal leverages included reference documentation and resources. The publisher's portal provides analytics and health monitoring for the platform's services.

AWS offers a convenient single solution for developer portals in the form of AWS Marketplace. Here, access to DigiMed can be made available, and subscriptions to the service managed without development effort from Gloco. "Healthcare and Life Sciences" category of the Marketplace offers DigiMed API access (see Figure 5).
AWS Marketplace handles localization of DigiMed based on Amazon's many availability zones, which allows Gloco the capability of deploying DigiMed globally, without adding local resources to the various markets they participate in. Operations in all markets are controlled from a central

administrative location.

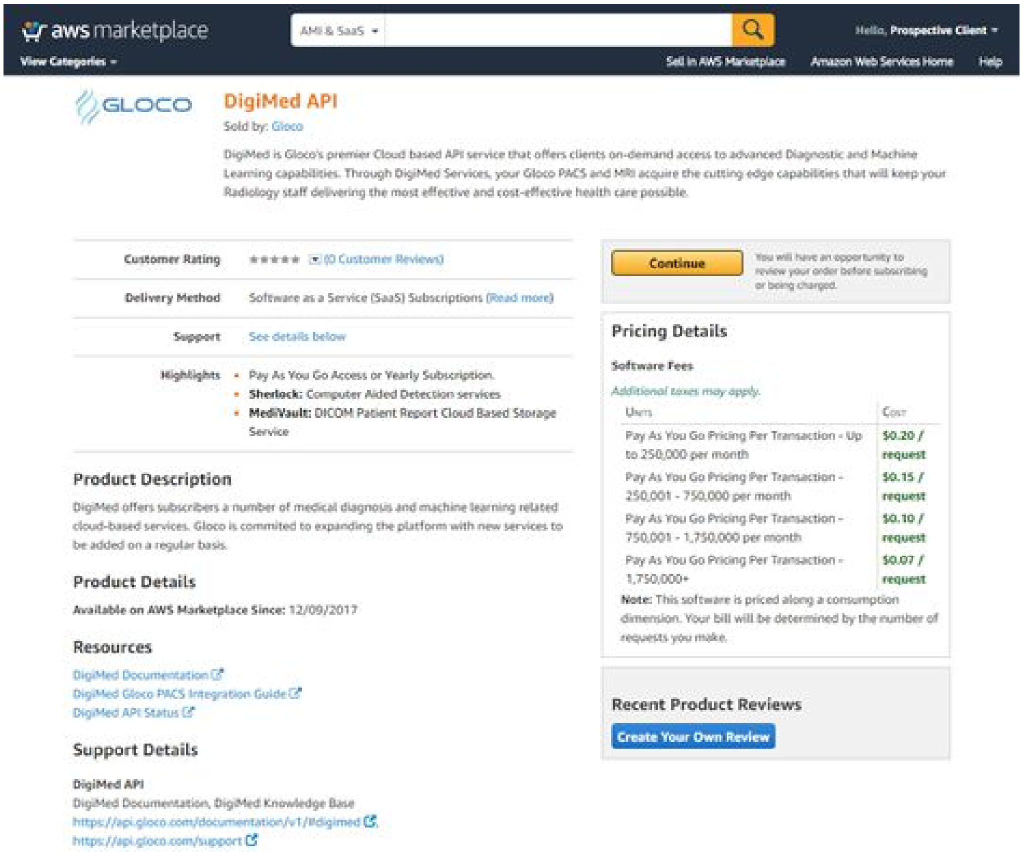


Figure 5: Sample Gloco DigiMed offering webpage mockup on the AWS Marketplace

2.2.2 The AWS API Gateway

Instead of clients calling services directly, their communications are sent through the AWS API Gateway that interacts with the actual service on behalf of the client. The gateway acts as both an API mediator and API Full Lifecycle Management platform. A mediated API is a design pattern in which an API is virtualized, managed, protected and enriched by mediation layers.

AWS API Gateway applies such layers through the management of policies. A policy monitors and enables or constrains particular API related behavior. This policy control is useful when compliance with protocols is required, or when adherence to API templates, patterns or models is mandated. Policies may refer to a wide variety of areas – such as security requirements, format translations and the collection of metrics. There are many types of policies that address operational concerns, including: caching, throttling, load balancing, capacity planning, integrity, confidentiality, authentication and authorization, threat prevention and protection, data transformation (depending on the consumer), data and functionality visibility, and quality of service (Malinverno, 2016).

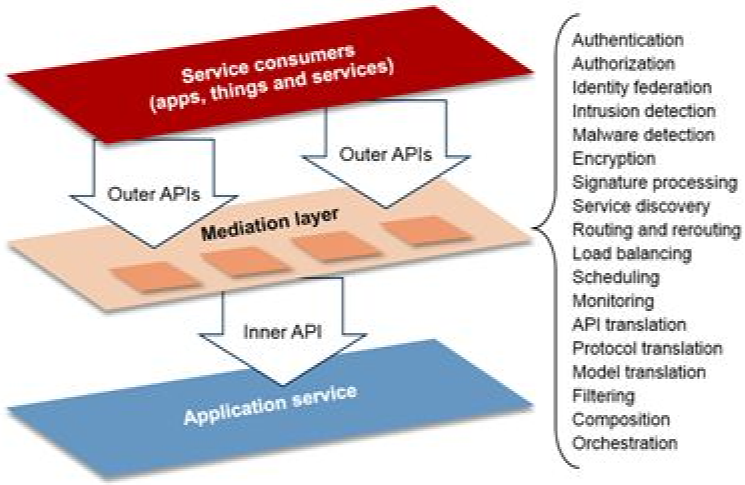


Figure 6. Generic Mediated API Architectural Model (source: Gartner, 2016)

Setup and maintenance of the AWS API Gateway is done through the AWS Console application. Resources are defined in a hierarchical tree structure that translates into RESTful web service URLs. Beneath each resource, one or more methods may be defined that map to a Lambda function deployed in AWS Lambda Serverless Computing framework. If the "Lambda Proxy integration" option is selected, the handler in the Lambda code that receives control is passed an "event" from which it can retrieve details of the incoming call (see Figure 6). Correct Lambda Regions (availability zones) and deployed Lambda function names complete the configuration. Correctly configuring an API method, makes it appear for console browsing as seen in Figure 6.
From the browse screen of any API method, the gateway administrator can run a TEST that simulates an API call arriving at the gateway. Figure 7 shows the results of a simulated call to the "/medivault/patient-report-list – GET" method.

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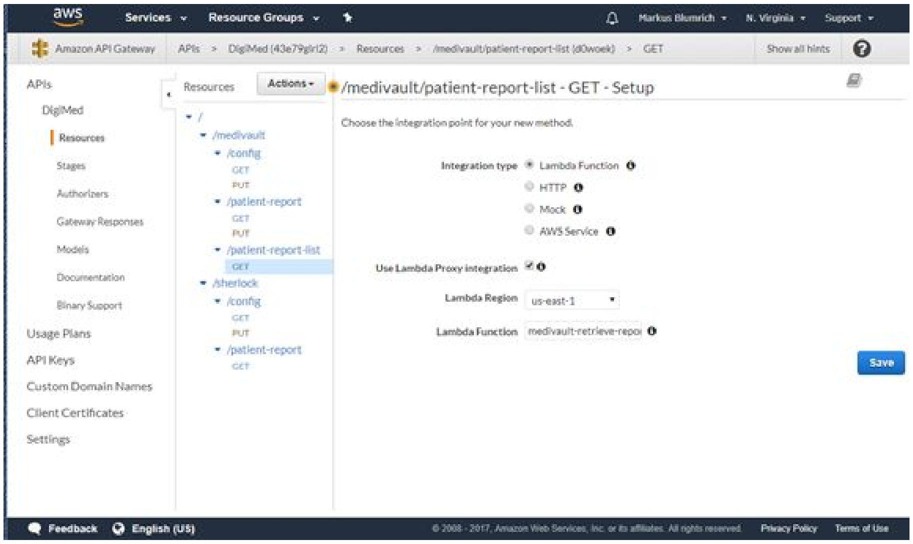


Figure 7. Setting up the resource and method hierarchy in the AWS API Gateway.

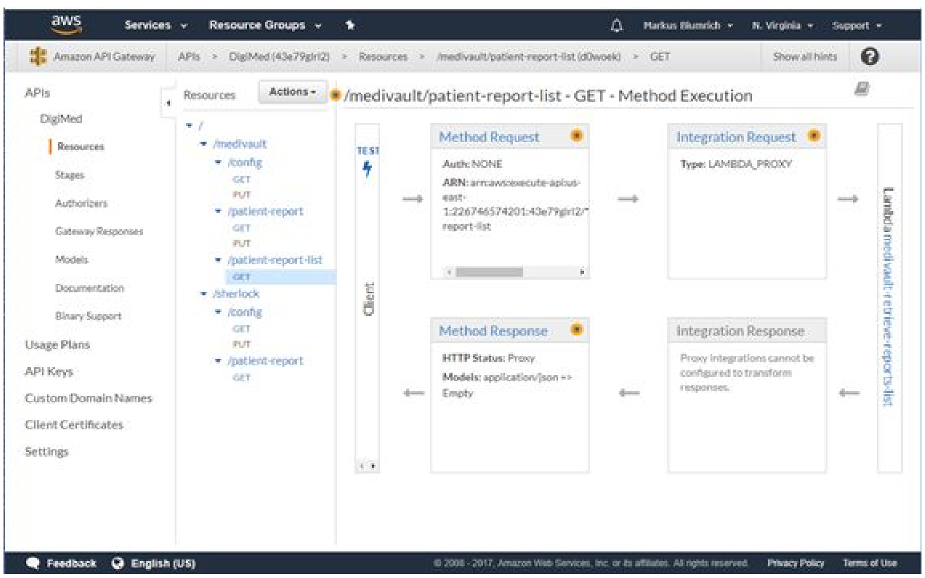


Figure 8. Browsing a 'GET' method that has been configured as a RESTful Webservice in AWS API Gateway.

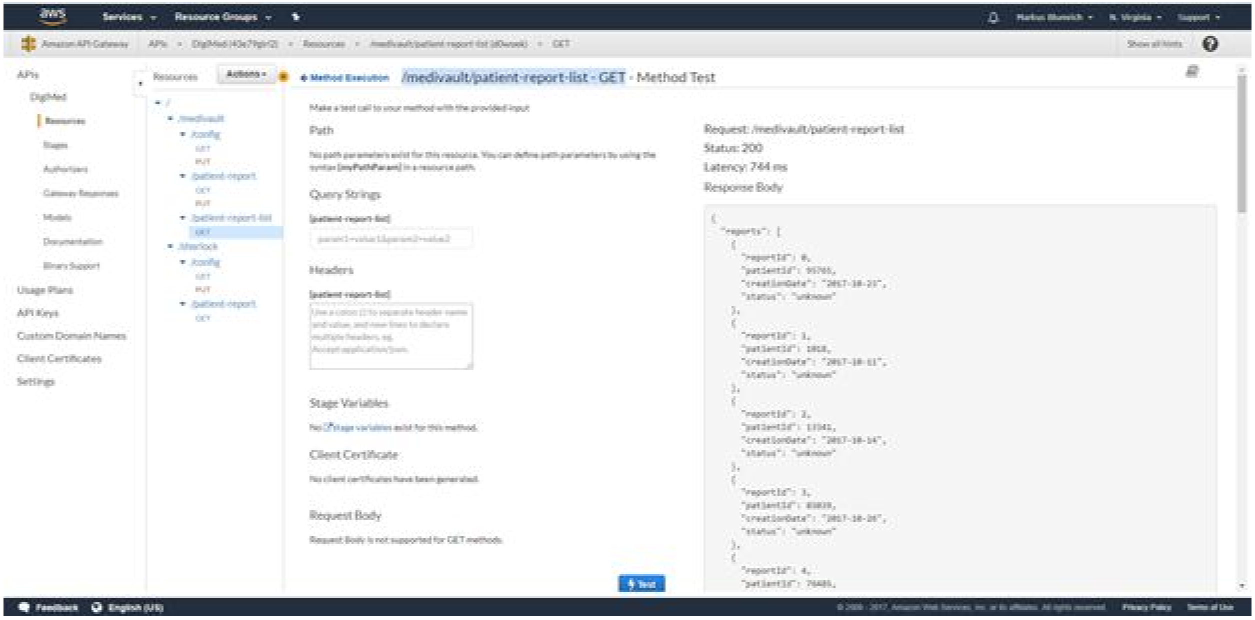


Figure 9. JSON results of a simulated API call to "/medivault/patient-report-list – GET".

AWS Console allows Gateway administrators to configure Usage plans, which are then offered for purchase in the AWS Marketplace. Clients who purchase a plan are issues an API key for authentication purposes. AWS Console allows the management of API keys. Figure 10 shows management options for an active consumer of the 'Regular Client' usage plan.

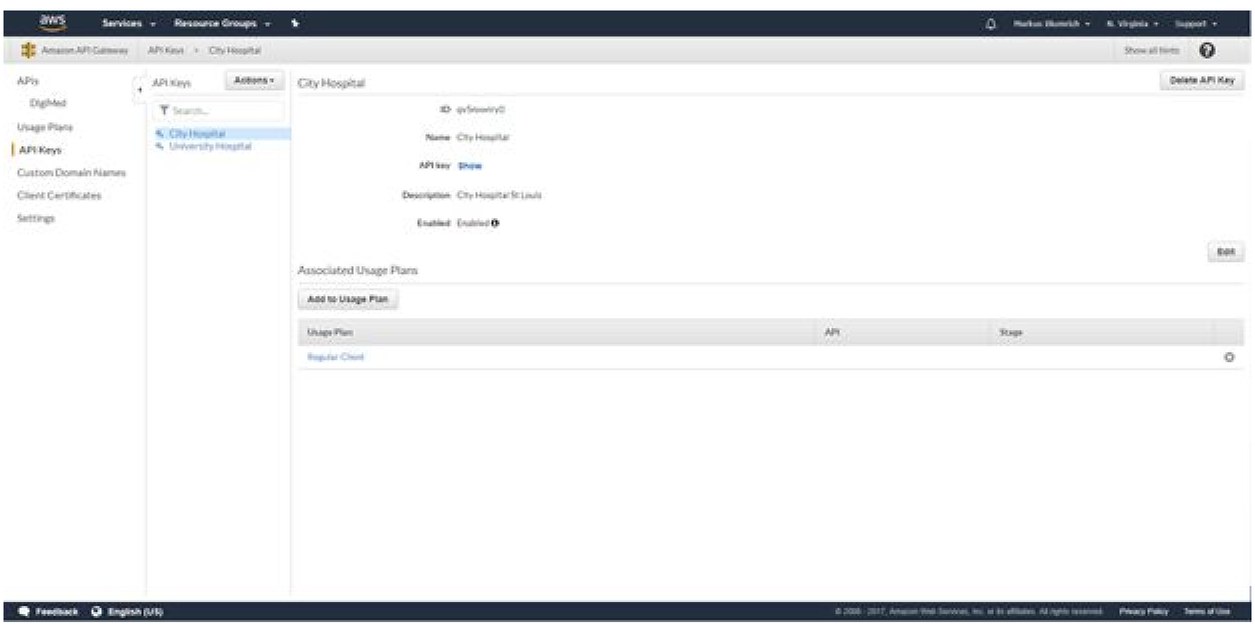


Figure 10. API Key and Usage Plan administration are available in the AWS Console.

Once the API is ready to be deployed (all methods must be mapped to Lambda integration points) a deployment "stage" can be chosen to target the current API version. Stages in Gateway, represent the traditional stages of testing and deploying in the software development delivery lifecycle. Stages can be arbitrarily defined by administrators to suit Gloco's future needs.

A successful deployment of the API will result in a published URL similar to the following:

https://43e79glrl2.execute-api.us-east-1.amazonaws.com/dev/

This URL serves as a base URL for all API REST calls in the API. A tool such as Postman can be used to manually call DigiMed API methods, as shown in Figure 11.

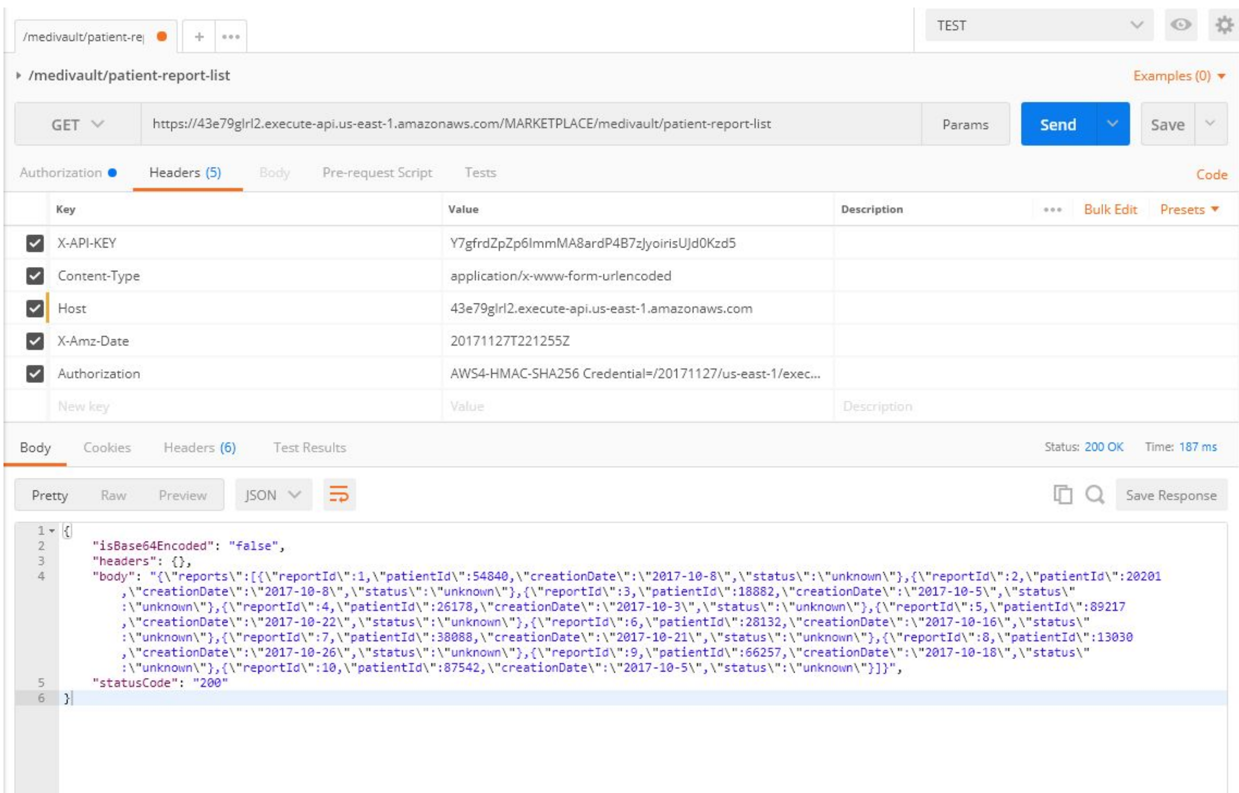


Figure 11. Manually calling API methods with standard REST tools such as Postman is possible once APIs are deployed to a 'stage' by the Gateway.

2.2.3 AWS Lambda Serverless Development

AWS Lambda is Amazon's serverless computing platform. The central tenet of serverless computing, is that the service is not bound to a specific server instance or cluster of server instances as is traditionally the case. Instead the service is instantiated within the cloud, and the service owner does not need to concern themselves with maintaining or scaling server infrastructure.

Lambda supports several development languages for service implementation, including Java 8 which Gloco has standardized its development efforts on. Lambda also supports development on the Eclipse IDE platform – which Gloco has adopted as its standard Java development IDE (Figure 12).

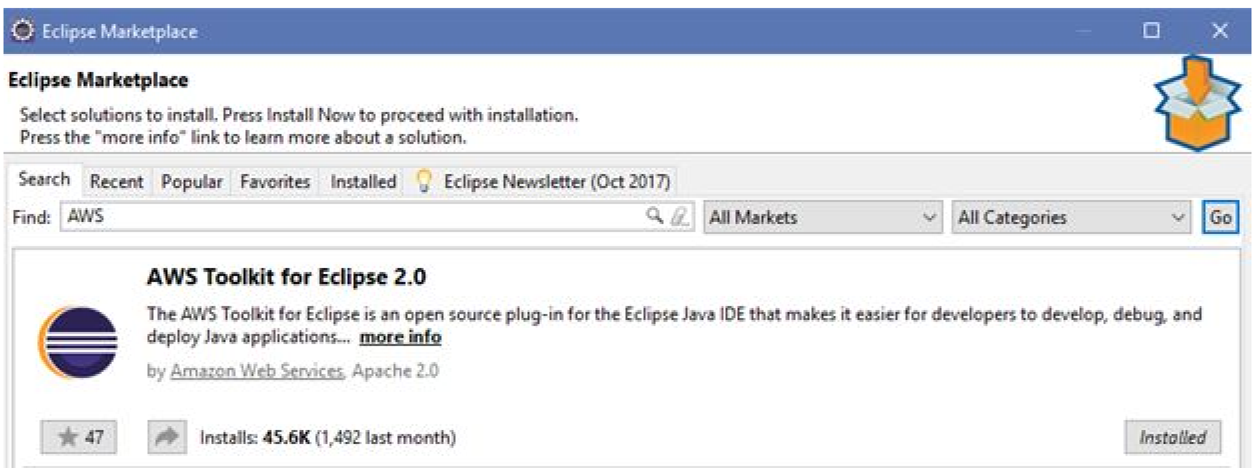


Figure 12. The AWS Toolkit is available through Eclipse Marketplace.

Within Eclipse, Java classes can be developed with the intention of exposing them as Lambda service implementations. See Appendix for a sample implementation for a Lambda service. Once a service project is ready for deployment, it can be done directly from Eclipse (see Figure 13).

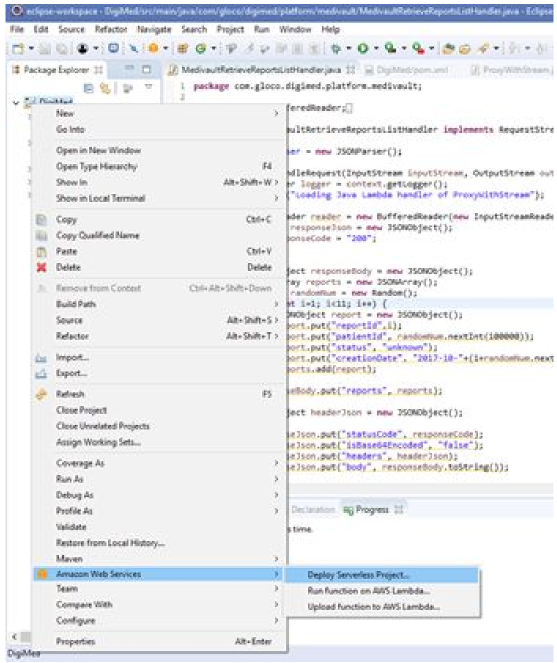


Figure 13. Deployment to serverless environment can happen directly from the IDE.

Once it has been deployed into Lambda, the service is administrable with standard AWS Console methodologies (see Figure 14). A deployed service is available for integration with AWS API Gateway or it can be executed through testing functionality available in Lambda administration.

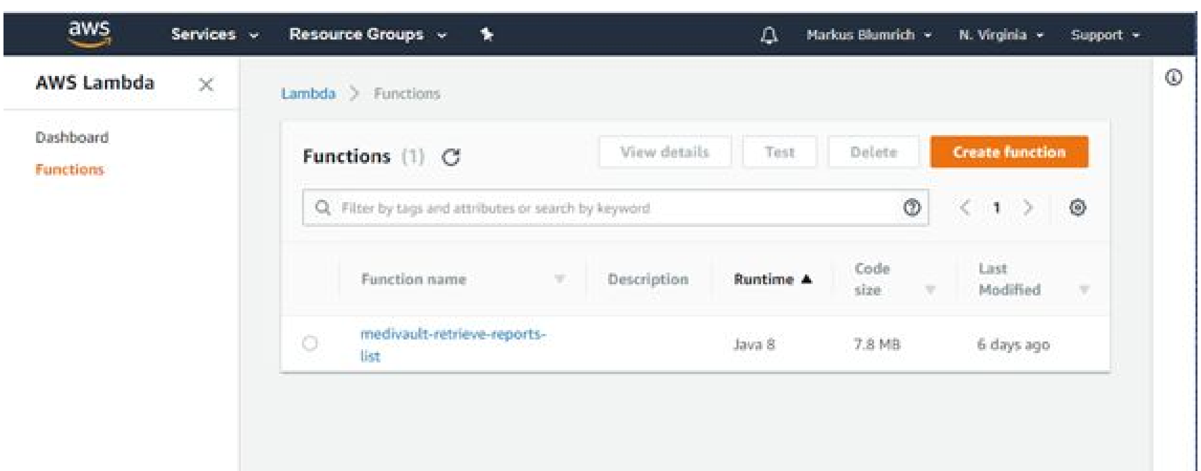


Figure 14. Management of AWS Lambda services occurs in AWS Console – similar to other AWS functionality.

2.2.4 DigiMed Client Portal

DigiMed's Client Portal sits central to user enablement functionality. The Portal allows clients to sign up for DigiMed API access - either directly through the Portal itself or through the AWS Marketplace. In the case of AWS Marketplace, Amazon will redirect marketplace subscription requests to the DigiMed Client Portal by transferring control of the request to a serverless Lambda function related to the portal.

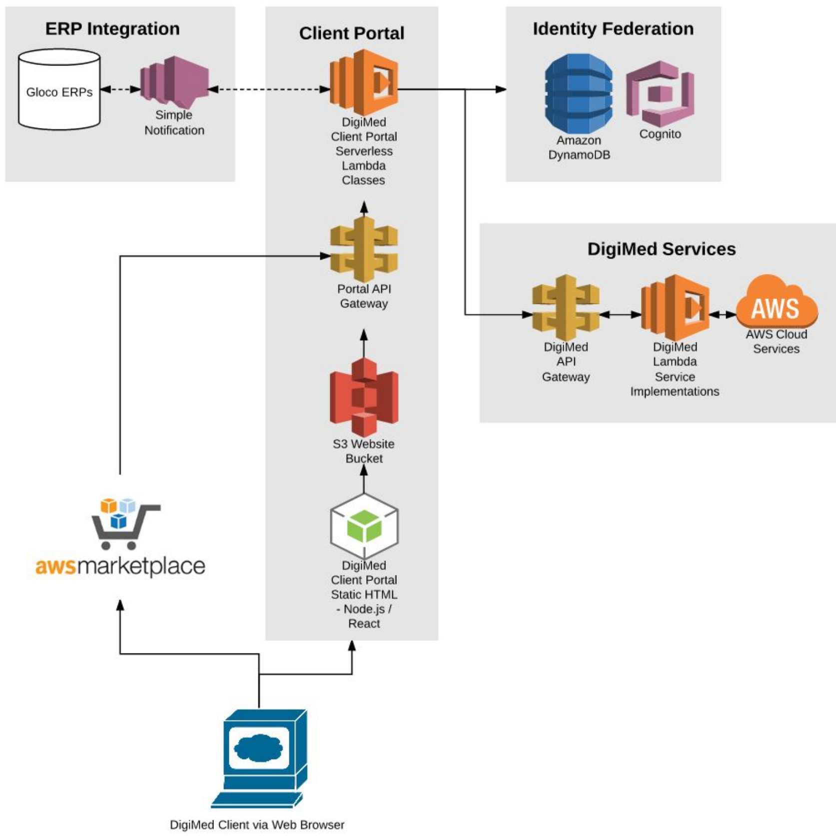


Figure 15. DigiMed Client Portal Architecture

The DigiMed Client Portal's middle and integration tier implementations are based upon the aws-serverless-express library (Github, 2017).

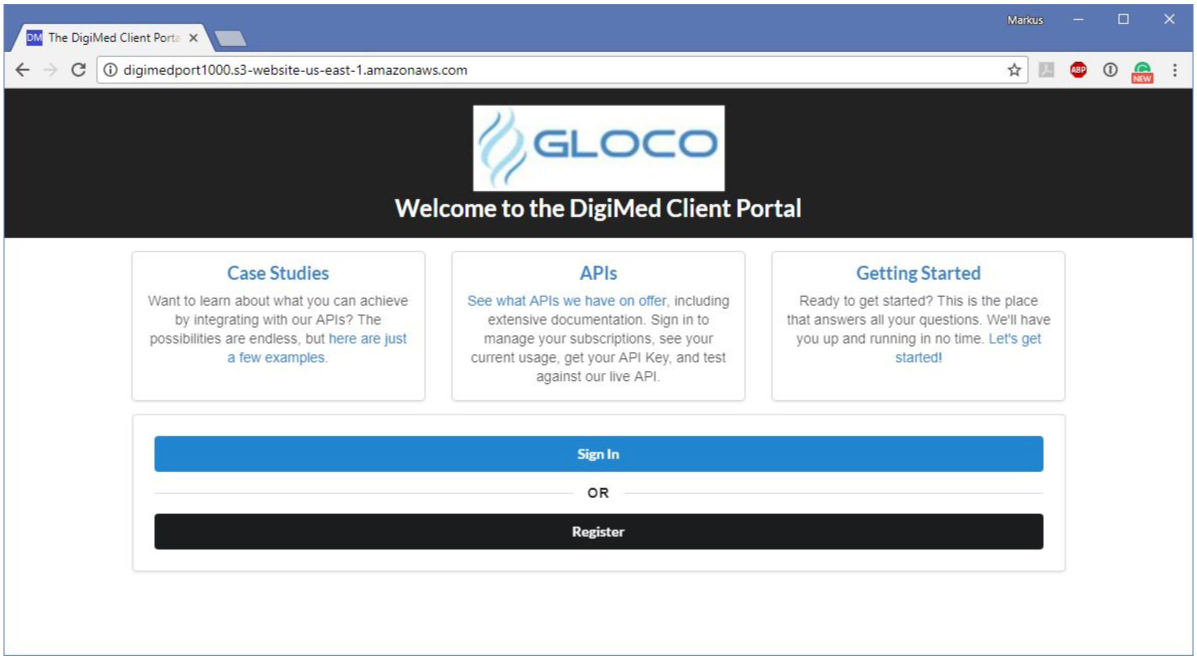


Figure 16. DigiMed Client Portal homepage.

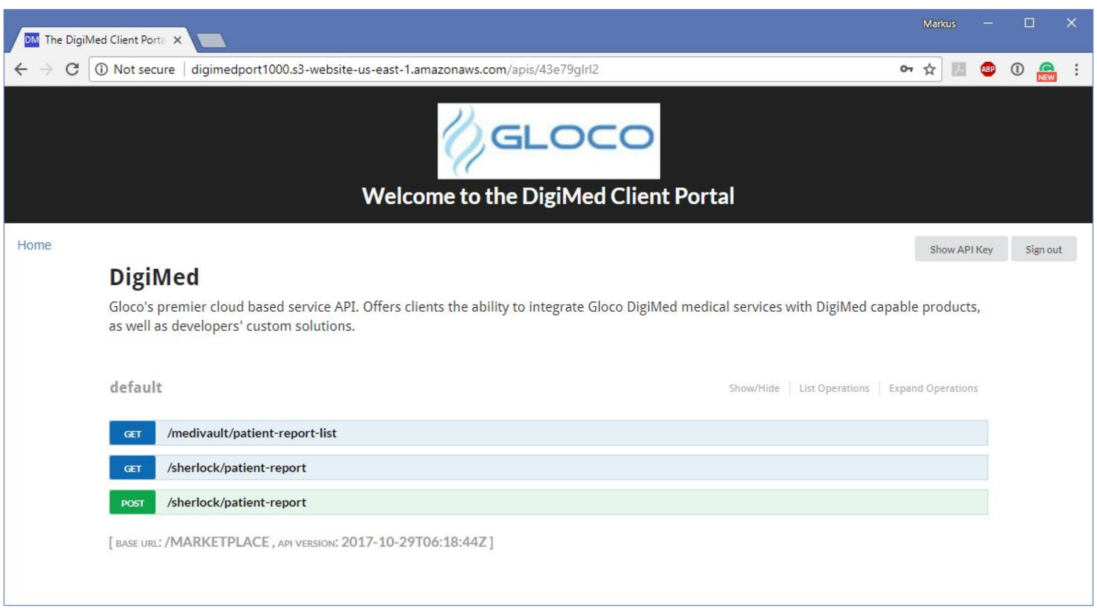


Figure 17. Portal functionality allows for interaction with and exploration of DigiMed API.

End-user training is specific to individual scenarios where DigiMed services are incorporated. Since the initial launch of DigiMed will augment existing PACS functionality, the training of radiologist and hospital staff will initially continue through established Gloco PACS support channels.

Developers who are interested in incorporating DigiMed API functions into their custom products or workflows - can find documentation, examples and developer community support through the DigiMed Client Portal.

2.3 Integration With Other Applications and Data Sources

2.3.1 AWS Marketplace to Gloco ERPs

AWS Marketplace will be responsible for either the metering of access to DigiMed services or for the management of contracts for service access. Gloco clients using AWS Marketplace pay Amazon directly - after which Amazon reimburses Gloco. Gloco CRM ERPs are responsible for binding Gloco's client identities together with their analog identifies in AWS.

Both Gloco ERP and Amazon Marketplace APIs will be mediated through the API Gateway. RESTful based services with JSON payloads are the primary standard for integration communication between applications and should be accessed through the Gateway whenever possible.

2.3.2 Gloco ERP Service Integration through Microservices

Appendix 4.4.1.4, "Reusable Enterprise Integration Microservices" gives detailed information on the microservices that are required for integration between Gloco's ERP. Implementation of these services would ideally follow the same development path as those for DigiMed Client Portal.

2.4 Data Design and Management

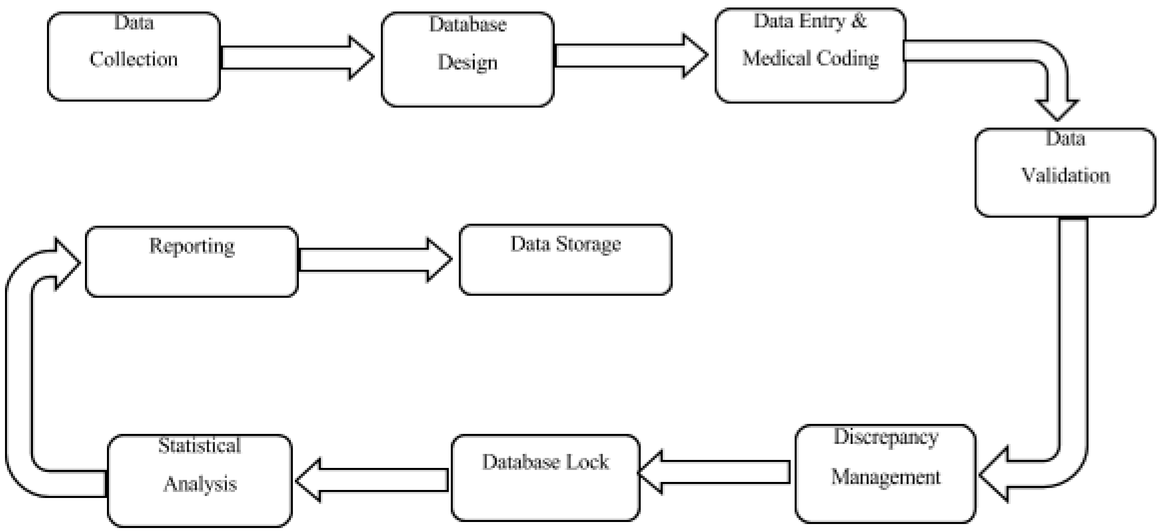


Figure 18. Data Management Plan Flowchart of GLOCO Medivault and Sherlock Service

2.4.1 Data Collection

We expect data collection to be at the respective hospitals for now, with the option of allowing patients the ability to send in their MRI scans to the hospitals in the future. The information collected is formatted using the Digital Imaging and Communication industry file format with a header containing constants series of tags, and the MRI images. The tags hold the patient's protected health information (PHI), such as – name, sex, age in addition to other image scan related data such as equipment used to capture the image and some context to the medical treatment. The contents of the file format are shown in Appendix 5.

2.4.2 Database Design

This phase of data management process strives to show the following:

- Determine the data to be stored in the database from the data collection phase.
- Determine the relationships between the different data elements.
- Superimpose a logical structure upon the data by these relationships

Since we envisage the PHI stripped off the data for privacy and security purposes before being migrated and stored in the cloud solution, this phase also help us map what we have locally to images stored in the cloud. MediValut service database will follow DICOM data format of MRI scan files and file storage will depend on unique identifier (ID) assigned to each image generated from the scan. The ID is referenced at Sherlock service result vector returning from Deep Learning segmentation models.

2.4.3 Data Entry and Medical Encoding

Data entry takes place according to Gloco's Data Management Plan (DMP) guidelines, which stipulates using industry medical terminologies to help identify and correctly classify cases under study. This process involves the use of medical dictionaries and requires the understanding of disease entities, drugs used, and a basic knowledge of the pathological processes involved. Imputed data are entered first, and then peer-reviewed or multiple copies entered and then a comparison made electronically. This provides consistency of the data.

2.4.4 Data Validation, Discrepancy Management and Database Lock

These phases help satisfy the Atomicity, Consistency, Isolation, and Durability (ACID) properties of the database transaction. Medical staff at the hospital play a role in ensuring transaction preserves consistency by double-checking imputed data, but the database helps by rejecting changes that violate constraints expressed in the data schema. These prevent discrepancy in the data. The database implements atomicity, isolation, and durability. We propose to guarantee atomicity and durability using some form of logging and recovery to redo transactions that committed at the time of system crash and undo any such transactions that did not. Isolation would be guaranteed using some form of record-level locks when uploading images to the cloud, and full table locks of overall datasets to prevent changes to dataset at the time of data analysis in the cloud. We will be implementing this using the Amazon DynamoDB Lock Client.

2.4.5 Statistical Analysis

The core analysis is on image file recognition via computer-aided detection services (Sherlock services). Sherlock services are composed of machine learning algorithms on a convolutional neural network (CNN). Each organ's MRI scan will require a specific CNN algorithm, so-called a model. A model is trained via Tensorflow framework since Tensorflow has 6000 open-source model repositories (TensorFlow, 2017). There are lung node and breast MRI scan models available in the repositories. Sherlock service models will utilize better accuracy and efficiency by tuning existing open-source models than constructing a new model from scratch. Existing open-source models were established with the training of more than one million images available to the public (Shen, D., Wu, G. & Suk, H., 2017).

2.4.6 Reporting

The result of MRI scan diagnosis from Sherlock services returns the affected disease area in the image. Moreover, the service will request radiologists to confirm or reject the assisting diagnosis. Each MRI scan record can be searched and reported after the Sherlock service was performed on the scan. The radiologist can sign off Sherlock service confirmation after the report was searched as well. The doctors who ordered the MRI scans for the patients can also pull up the scan image along with the Sherlock service result in a report. We anticipate integrating reporting features with existing PAC web system which utilizes Crystal Reporting Web Viewers (SAP, 2017).

2.4.7 Data Storage

The original MRI scan files are stored on local workstations. Through Medivault data storage service, the image is sent in DICOM format and stored at Amazon S3 with a file storage location reference (AWS, 2017). Gloco is responsible for Amazon S3 data collected from individual MRI workstations and conducts appropriate archives and purges when needed. The local workstation data storage is separated from Amazon S3 after the initial synchronization and technicians can remove the local storage after the Medivault storage service has transferred the image record to the cloud.

2.5 Solution Demonstration

We have created a solution demo site at http://www.team3.pw (username: team3; password: gloco) demonstrating the wireframe of Sherlock service workflow. Figure 19 below. It is the final step of Sherlock service returning segmentation of MRI scan from Deep Learning models. Overall there are 7 steps in the workflow with wireframe diagrams in Appendix 6. Since we take the optional value-added approach to increase radiologist's user journey on adopting Sherlock services, there is no change in the current PAC workflow for radiologists. They can turn on the Sherlock service with a checkbox on the MRI scan review form. The option approach will later be changed to standard item in the PAC workflow once majority of radiologists sign up and use the Sherlock services regularly.

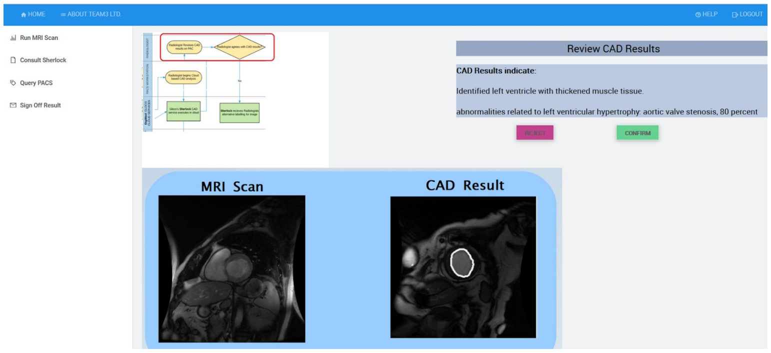


Figure 19. Sherlock service returning segmenting result of MRI scan.

3 Project Implementation

3.1 Solution Delivery Roadmap

This large-scale project for "DigiMed" platform will be implemented by the application of a Multi-Team Scrum approach for distributed agile development (see Appendix 7 for details on why we rule out waterfall methodology). The "DigiMed Solution Delivery Roadmap" (Figure 20) of the following section follows ITIL-terminology. Therin the "Service Design Deliverables" correspond to the Scrum Backlog constructed in section 3.1.3. However, it should be noted that while on a very high-level the Scrum Backlog can be mapped to these "Service Design Deliverables", the Team Backlogs and (initial) Team Sprint Backlogs do not allow for a "milestone-style" detailed planning. This is due to the inherently dynamic nature of "agile", which forms the basis of it being an antithesis to a fine granulated (often unrealistic) project planning.

Section 3.1.3 elaborates on the analytical approach to develop a Product Backlog for DigiMed, consisting of 13 (Big) User Stories, 45 features and 80 functions, most of them interrelated to a certain degree.

3.1.1 DigiMed Solution Delivery Roadmap

The overall solution delivery roadmap (Figure 20) lasts 18 month duration following five ITIL project lifecycle stages from service strategy, service design, service transition to service operation.

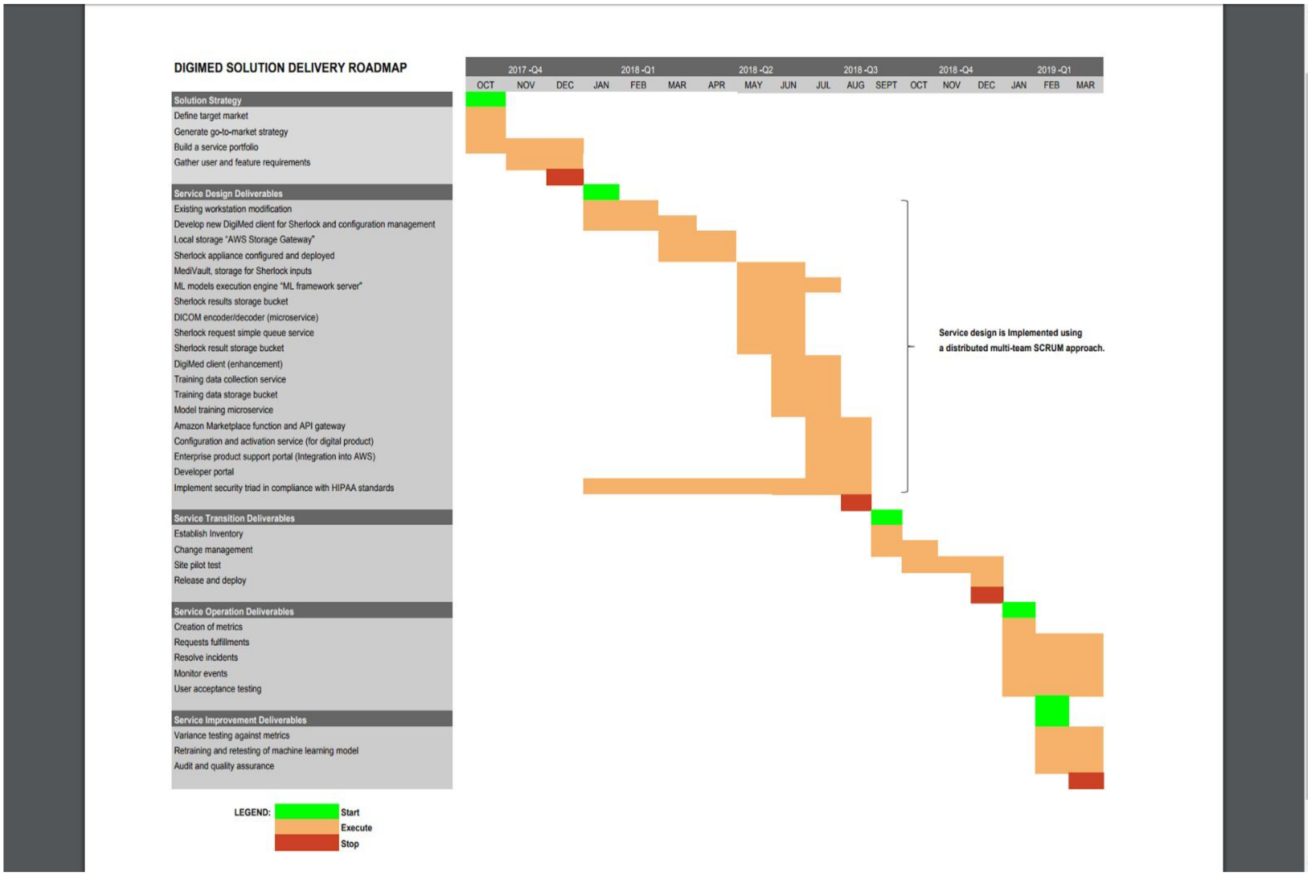


Figure 20. Solution deliverable roadmap in line with ITIL project lifecycle

3.1.2 Product Roadmap and Risk Mitigation

Sherlock service, DigiMed platform, and MediVault service do not only constitute a massive project on their own but are characterized by the design goal to develop reusable components for a digital services delivery platform and their need for integration into the Gloco Enterprise Systems. While we can derive a list of deliverables from the underlying architecture and the specified business processes/features/functions, the question remains how to implement such a complex system within a set timeframe of 18 months with proper risk and change management.

3.1.2.1 Management of Dependencies and Risks

The implementation faces two general risks:

- Incomplete identification of requirements and dependencies in the analytical phase.
- Unforeseen Interdependencies between Functions (or other higher level constructs).

While these are truisms, the implications for a project at this scale are substantial. Any unidentified dependency or unforeseen interdependency showing up in a late waterfall-style phase leads to unwanted iterations with unacceptable delays. It is for these reasons that the state-of-the-art for the realization of such a project is a distributed agile approach such as Multi-Team Scrum (Scrum Institute, 2017).

For this project, an agile approach employing asynchronous sprints for sprint scheduling will be applied. The reason for this is that there are many identified dependencies. Asynchronous sprints allow for the earliest possible delivery of results between development teams. Figure 21 shows a high-level roadmap along the timeline of 18 months.

Furthermore, In this approach "Regression Testing" is a final activity before product acceptance and not a means for the late detection of bugs or unforeseen interdependencies as in the traditional development process.

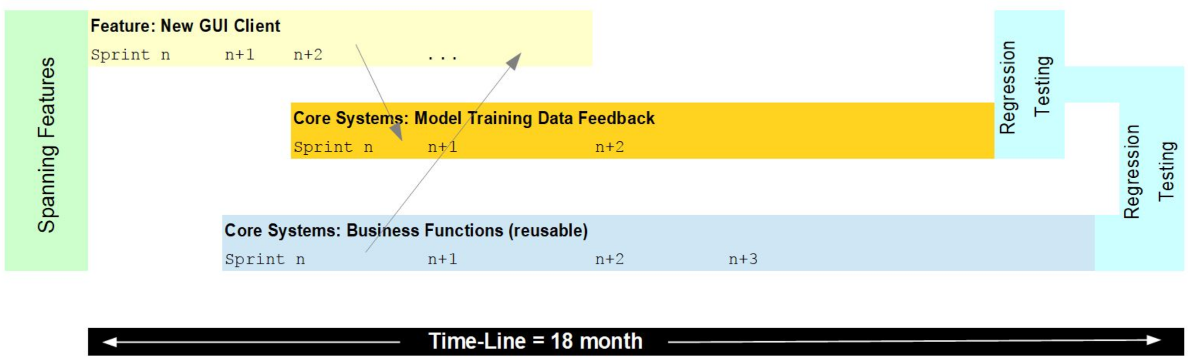


Figure 21. Exemplary Asynchronous Sprints Approach along an 18 Month Timeline.

3.1.2.2 Management of the Multi-Team Scrum Specific Risk of Pipelining

The rationale for the "spanning features" category comes from a detailed dependency analysis of Epics/Themes/User Stories cross-tabulated with (common) features. Figure 22 depicts the structure of the actual analysis which is shown *with full details* in Appendixes 4.7.2 - 4.7.4.

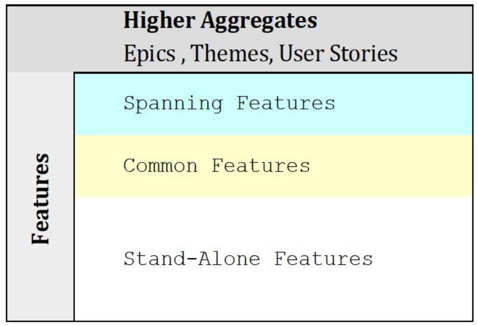


Figure 22. Multidimensional Feature Categorization

The distinction between “Spanning Features” and “Common Features” is not made arbitrarily but specific to this project. Common Features are features shared between User Stories and materialize as sprint results shared between teams in order to progress with software development, while “Spanning Features” are primarily cloud infrastructure and middleware oriented (in Scrum terminology this translates to “infrastructure” as “Component”).

It is this distinction which i.) enables DevOps and allows to plan for it, and ii.) allows for the use of both simultaneously, *“interdisciplinary feature teams”* and *“specific component teams”*. This team formation approach is used to minimize the problem of *pipelining* in large Multi-Team Scrum Projects, see: (Scrum Institute, 2017b).

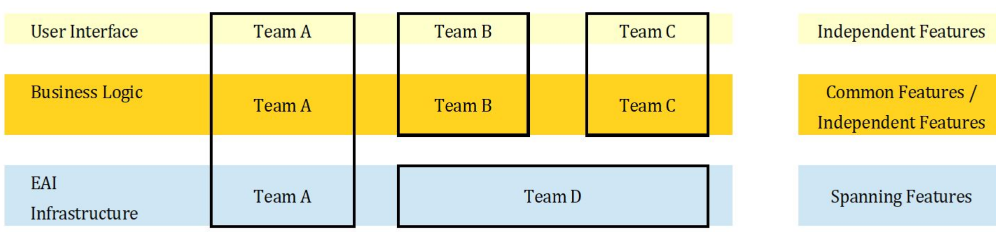


Figure 23. Component and Feature Teams related to GLOCO project specific Features

The project is too large as to show all relevant features-team mappings. In the following table typical examples are given for this type of “team configuration” with respect to Gloco’s undertaking:

Team D	In our case the most prominent example for DevOps. Implementation based on “Infrastructure as Code”, the Amazon Cloud Formation Templates. EAI Task: Implementation of the “Configuration and Activation Service”
Team A	Development of the “DigiMed Client” This feature spans across all component layers (Figure 23)
Team B	Concerned with the Amazon Marketplace Function and API Gateway, which is

primarily about business logic but also implements relevant parts of the customer-facing GUIs.
It builds upon the “Product Support Integration Microservice” delivered by Component Team B for enterprise systems integration.

3.1.3 Multi-Team Planning - Scrum Product Backlog

A list of deliverables along the four categories is presented in Figure 24 (for a detailed description referred to Appendix 4.7.4). These deliverables together form the “Multi-Team Planning - Scrum Product Backlog” (Scrum Institute, 2017).

			“Spanning” Services, Features, Requirements, and Functions					
			PHI Encryption	PHI Read Access Audit Trail	99.9 % Availability	Ability to Cache 12 hours of data	Role Based Security	Secure Non Repudiable Communication
Core Systems “CAD Model Execution by Customer”								
	On Customer Premise							
		Modification existing Workstation						
		Develop new DigiMed Client for Sherlock and Configuration Management						
		Local Storage “AWS Storage Gateway”						
		Sherlock Appliance configured and deployed						
	AWS Cloud – Customer dedicated Services							
		MediVault, Storage for Sherlock inputs						
	AWS Cloud – Common Services							
		ML models execution engine “ML Framework Server”						
		Sherlock Results Storage Bucket						
		DICOM encoder/decoder (Micro Service)						
		Sherlock Request Simple Queue Service						
		Sjerlock Result Storage Bucket						
Core Systems: Model Training Data Feedback								
	On Customer Premise							
		DigiMed Client (Enhancement)						
	AWS Cloud – Common Services							
		Training Data Collection Service						
		Traing Data Storage Bucket						
		Model training Micro Service						
Core Systems: Business Functions (reusable)								
	Amazon Marketplace Function and API Gateway							
	Configuration and Activation Service (for Digital Product)							
	Enterprise Product Support Portal (Integration into AWS)							

Figure 24. Multi-Team Planning - Scrum Product Backlog

It is important to note that the taxonomy of “Product Categories” is a high-level construct used to illustrate the justification for the before mentioned distributed agile approach. For the actual implementation more detailed team product backlogs are to be created.

3.1.3.1 Exemplary Component and Feature Team Division of Labour

The integration with enterprise systems is mediated via microservices (“Product Support Integration Microservice”) developed by a component team dedicated to EAI (exemplary “Team D“ from section 3.1.2.2). Even though billing and subscription sign-up is managed by Amazon Marketplace and custom enhancements (“DigiMed API Client Portal”, see Section 2.2.4) two essential data flows need considerations for these integration microservices:

- Existing Customer information to pre-populate during subscription sign-up

- Metered service usage and billing information for managerial accounting & budgeting (in-house)

A simple (exemplary) style of integration for this could be as shown in Figure 25:

Gloco employs a Master Data Management (MDM) System where among others customer data from dispersed systems are consolidated. As part of the High Availability requirements, relevant data are replicated from the MDM and delivered via a distributed file system or DBMS to the integration services (resync triggered by MDM events). The same mechanism is used to transport information on metered service consumption and Amazon billings of customers back to the in-house systems. A listening service writes this information into a data warehouse which is used as a data store (or any other data store capable of data aggregation such as a post-relational DB) for managerial accounting and budgeting. The example of a Data Warehouse was chosen because it is often used to aggregate record level data for further use in enterprise budgeting systems and as a central data store for the consolidation of accounting data from data silos. A different integration style using the already existing CRM(with its existing synced and replicated DB and SOA-APIs) and messaging to the ERP (from where to data warehouse then gets populated) may be considered as a vision or strategic theme.

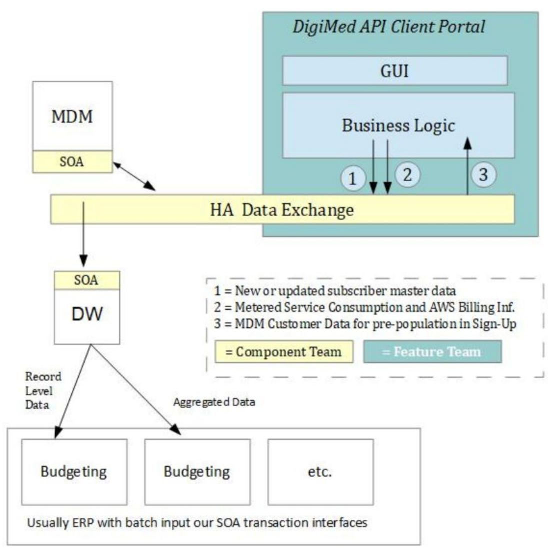


Figure 25: Feature Team and Component Team Division of Labor

Multi-Scrum team backlogs and agile ways of result coordination do not guarantee "perfect coordination", as is seen in the example of this section depicted as asynchronous sprints. The reasons may be manifold, with the simplest a wrong estimation of sprint-points (a concept similar to *function points*).

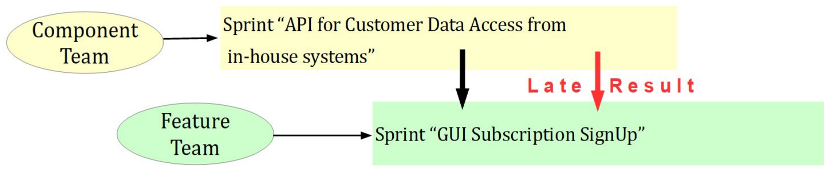


Figure 26: Late Result Delivery in Asynchronous Sprints

The example in Figure 26 expands on Figure 25 and is selected purposely because there is an easy workaround common in GUI Design to use test/mock data which are available in Appendix 6. It is the task of the multi-team and team-specific sprint-scheduling to minimize these risks by assigning proper sprint value-estimates. Sprint values are aggregated values derived from (among others) a *risk estimate*. Figure 27 illustrates how these sprint points are used as an input for the different backlog creation.

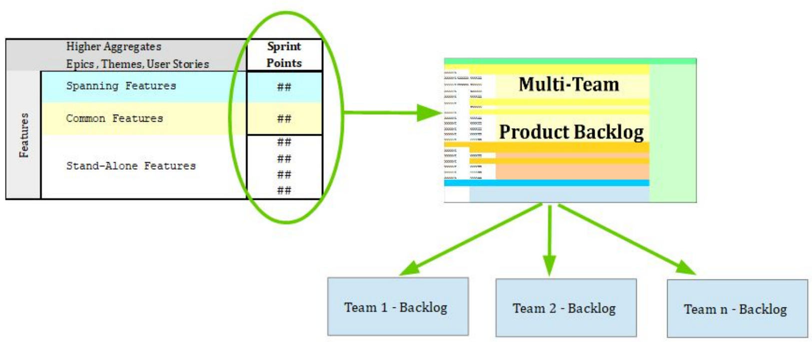


Figure 27: Risk Estimation used as (one) Input for Backlog Creation

In a project, this size pipelining may cause the problems described no matter how diligent risk points estimates and scheduling are done. This is an methodology inherent problem, and the folding of sprints is one solution to this.

3.2 Operations

3.2.1 General Operations Strategy for Launch

Gloco plans to launch DigiMed with a pilot deployment to a small number of carefully chosen customers. These charter clients will be chosen from those who already own and operate Gloco PACS systems. Ideally, they are also clients with redundant PACS capabilities on their premises – specifically ones whose radiologists can continue to work should one of the PACS systems become unusable. This will allow a rolling deployment to PACS systems on-premise, without jeopardizing a complete loss of PACS capabilities for clients. Gloco will implement a number of tactical initiatives to ensure that risk of PACS downtime is minimized.

The initial launch will have the following primary objectives:

1. ensure a smooth migration experience for all customers;
2. learn as much as possible about technical and usability challenges as quickly as possible;
3. look for missed opportunity and oversight that can be added to the product backlog;
4. at a minimum – customers should have access to all the functions that were available prior to DigiMed, regardless of potential issues specific to DigiMed platform.

In order to achieve these goals, Gloco plans to:

1. begin the DigiMed rollout by migrating only a small number of charter clients in a serial fashion;
2. assign support and technical personnel specifically to individual accounts until there is certainty that the volume of support required no longer justifies dedicated resources.

3.2.2 Administration and Support for DigiMed within Gloco

All Gloco DigiMed administrators will be given unique AWS Identity and Access Management (IAM) user accounts. Administrators of DigiMed will be added to a custom IAM group. Subgroups of administrators responsible for Sherlock and MediVault services will be assigned to appropriate IAM groups as well.

The following roles in Table 2 are involved with supporting the operation of DigiMed platform:

Role Name	Description
Development Team	The team responsible for the design and development of the DigiMed platform and services.

On-site Gloco Support Technicians	These are traditional Gloco employed technicians that service and maintain Gloco manufactured equipment on customer premises.
Offsite Gloco DigiMed Customer Service and Technical Support Teams	This is a team of customer service representatives and their management that responds to customer requests for support.
Client Developers	These are software developers with accounts established for access to DigiMed services.

Table 2. DigiMed Operation Roles

The following summary table (Table 3) enumerates the components involved in providing DigiMed support:

Component	Description	Used By Roles
DigiMed Client Portal	Primary knowledge base and community gathering spot for DigiMed developers.	Client Developers DigiMed Technical Support
AWS CloudWatch	Primary dashboard for DigiMed customer service and technical support staff. Performance monitoring. Includes monitoring and elastic scaling of services.	DigiMed Technical Support Development Team
Gloco Internal Customer Support and Ticketing System	Traditional ERP with support capabilities by client account.	DigiMed Technical Support
AWS Cognito / AWS Dynamodb tables	Management of API user accounts linked to API Keys granted by Client Portal. Tables unify accounts with AWS Marketplace accounts.	DigiMed Technical Support
AWS Console	General console and admin capabilities for DigiMed. For example, provides access to API Keys via console's API Gateway management functions. Release management.	DigiMed Technical Support Development Team
AWS Marketplace	Collects entitlement and future metering data. Bills AWS accounts when access to DigiMed is through AWS Marketplace.	DigiMed Technical Support

Table 3. DigiMed Operational Support Components

Since the task of supporting cloud-based operations is a fairly new endeavor for companies such as Gloco - a pool of knowledge around best practices has not been established. As DigiMed deployment and capabilities progress, the intent is for the teams and resources identified above to define best support practices as incidents occur and are resolved.

For example, it is not known how much effort should be dedicated to proactively monitoring resources on AWS - since, in theory, cloud scalability will effectively render these types of concerns mute. However, Team3 believes that only by addressing actual incidents will allow a clear picture materialize around DigiMed support. Therefore, the identified teams and resource owners will be actively involved in defining support processes as DigiMed evolves.

3.3 User Enablement

3.3.1 User Acceptance

To ensure customer acceptance, the rollout plan is based on piloting with charter clients (section 3.2.1) and includes continuous improvement through customer experience monitoring (section 3.4.2). Besides these and defined acceptance criteria for User Stories there are three crucial customer end-user issues, (affecting doctors, radiology technician, and health care providers' management) Gloco addresses with its solution from the beginning:

i.) Radiology Technicians and customer in-house ICT-Department:

Through the use of the various DICOM client-server protocols, Sherlock can be integrated into any current modality viewer with little customization. This is usually done by the customer or third parties. Through cooperation with charter clients, using Gloco Workstations and Gloco Pacs Viewer, the integration of the Sherlock GUI for Radiologist can be done *in advanc*e and *rolled-out* to clients. This way customer side technical limitations are not an issue (ACR, 2017).

ii.) Health Care Provider Management:

The architecture consists of a local storage, not only for technical reasons but also to address an important issue: "Many healthcare organizations do not want to store the processed images results contained in DICOM objects, and especially when they are of the CAD type, on their PACS citing various reasons (e.g. legal reasons, storage capacity, and technical limitations)" (IHE, 2009). The case of a beta-testing non-Gloco customer (Univ. of Virginia Health System) using a competitor's comparable offering is based on the same technical solution (ACR, 2017).

iii.) Radiologists:

If Sherlock is to be accepted as a "second reader" by medical personnel, the preferences of individual radiologists for different hanging profiles must be solved efficiently. This again is leveraged through the selection of charter clients already familiarised with GLOCO's help-desk services, customization support, and interactive e-learning material.
Furthermore, the *versatile Architecture* and implementation of IHE and Dicom standards allow to quickly react to foreseeable customer requirements such as batch processing for retrospective screening, promising a new income stream to our customers. Gloco will be enabled to quickly implement a user story like this one: "Before machines start conducting primary or peer review reads, Dreyer said it is much more likely AI will be used to read old exams retrospectively to help hospitals find new patients for conditions the patient may not realize they have" (ITN, 2017).

3.3.2 Training and Knowledge Management

For a project at this size, the task regarding training of end-users is astonishingly simple. This is primarily due to the fact that the roll-out strategy of Sherlock services focuses on user buy-in. Future, more complex engines such as those for 4D-MRI will require more intensive and advanced training and knowledge .

i.) Radiologists:

Sherlock seamlessly integrates into existing radiology workflows as an "Evidence Creator" (a term form the IHE Radiology Integration Profiles). While Sherlock as a remote CAD system is a novel approach, the integration of on-premise CAD dates back almost twenty years. Customizing a hanging profile (i.e., the "layout" of medical imaging results) to fit personal preferences is also a familiar task. To further facilitate the ease of use, a standard profile for the display of Sherlock results was developed in cooperation with radiologists.
The only training needs arise for the proper use of the feedback service to the Sherlock ML-service. Pilot customers will be instructed on-site, and the knowledge gained from this will feed the development of e-learning products. This is a standard procedure from the Gloco Medical Imaging Division for new product development and roll-out.

ii.) Radiology Technician and IT-Specialists:

Compared to the integration of other Gloco products for radiology, the use of the DigiMed Client Portal for configuration and the installation of the on-site appliance is also relatively simple. Here again, charter clients are personally instructed, and the experiences gained from this will be used in the development of the multimedia e-learning resources accessible through the DigiMed Client Portal.

iii.) Help-Desk Operation:

Gloco's medical imaging division already operates diverse help-desks for the support of customers using software products for radiologists and radiology-technicians. The integration into DigiMed merely means a new GUI for the end-users.

iv.) Developer Training:

Developers who are interested in incorporating DigiMed API functions into their custom products or workflows - can find documentation, examples and developer community support through the DigiMed Client Portal.

3.4 Success Metrics

According to the metric categories and goals identified in Table 1 of the key performance indicator and project success criteria section, we would like to ensure metrics are implemented in the following quantitative and qualitative ways for project success:

3.4.1 Increase in Revenue

a. The majority of $97M USD increase in revenue will come from healthcare providers who already purchased Gloco's medical image hardware devices. MediVault cloud storage service will replace their existing local server storage IT costs. Minimal 400 million medical images are required in medical procedures in the U.S each year and medical image archives are increasing 20-40% each year (AT&T, 2012). Moreover, with an ageing population, CT and MRI scan volumes are doubled and tripled over last ten years (Smith-Binman R., Miglioretti D.L. & Larson B.L., 2008). The pricing model for MediVault will be based on the volume of archive storage and retrieval of individual image records. The increase in revenues will be measured by the monthly billing usage to the image record retrieval as well as the archive storage volume. All the information is available at DigiMed Client Portal to account administrators, users, and DigiMed technical support.

b. As Sherlock service will be charged by subscription fees to radiologist and technician account sign-up, we anticipate the contribution to the increase in revenues will require new healthcare provider sign-up with additional user accounts to the system. The growth of revenue will be measured by the number of subscription accounts added to Sherlock service. For existing healthcare provider customers, we expect **30%** of their radiologists will adopt Sherlock service at the end of project implementation as a good foundation of service usage.

3.4.2 Customer Experience Improvement

a. As Sherlock services are available through self-help resources at AWS Marketplace, we will conduct quarterly CSAT survey through Marketplace and measure the overall experience. Our goal is to achieve **20%** increase in the year to year customer satisfaction survey.

b. MediVault customer experiences are measured by the speed and availability of individual image record retrieval and proper data redundancy and storage space expansion to image record archive growth. There will be initial service level agreement (SLA) setup, and a quarterly survey will be provided to healthcare providers to collect their feedback corresponding to SLA rating results. We expect **20%** increase in the survey as SLA rating requirement is met.

3.4.3 Improvement in MRI Diagnosis Accuracy

a. With Sherlock services available, each MRI scan will receive assisting diagnosis result as radiologists request. We will measure the rejection rate of Sherlock service results and ensure the rejection rate is reduced **30%** quarterly as Sherlock services retrain the diagnosis algorithms with rejection feedback from radiologists.

b. MediVault provides consistent medical image archive services and therefore resources for multiple healthcare providers to cross reference the manual MRI diagnosis accuracy of radiologists. We do not incorporate a performance indicator to this service in this project but anticipate health care providers will consider the service down the road.

3.4.4 Increase in Radiologist Efficiency

a. MediVault will provide a centralized medical image record repository to radiologists. Therefore, radiologists can access the image records from remote locations. We will measure the locations and devices of requesting MediVault records and shows the increase of image record accessibility contributes to **30%** increase in radiologist productivity.

b. Sherlock services will do the proper segmentation of program areas on the medical image records. We will measure the time duration that radiologists navigate and notate an individual image record and measure if the time is being reduced by 30% yearly. Moreover, we will measure by the volume of medical image record diagnosis conducted by radiologists as an indicator to radiologist efficiency increase by **30%**.

3.4.5 Time to Market for New Services and Devices

a. We select MRI scans to be our first medical imaging device to roll out this service in the project. We expect that future roll-out to other medical imaging devices including CT, Ultrasound, X-ray, PET and SPECT will be shortened as the same DigiMed infrastructure with MediVault and Sherlock services will be adopted. We already incorporated HIPAA security compliance in the DigiMed infrastructure and availability is benchmarked at 99.99% service level agreement. As a result, we expect **40%** reduction in implementing next medical imaging services on DigiMed in future projects.

b. This project is estimated six months for upgrading existing PACs to be DigiMed compatible. Once the work is completed, future project will already have PACs compatible with DigiMed for more services to be deployed onto the PAC system.

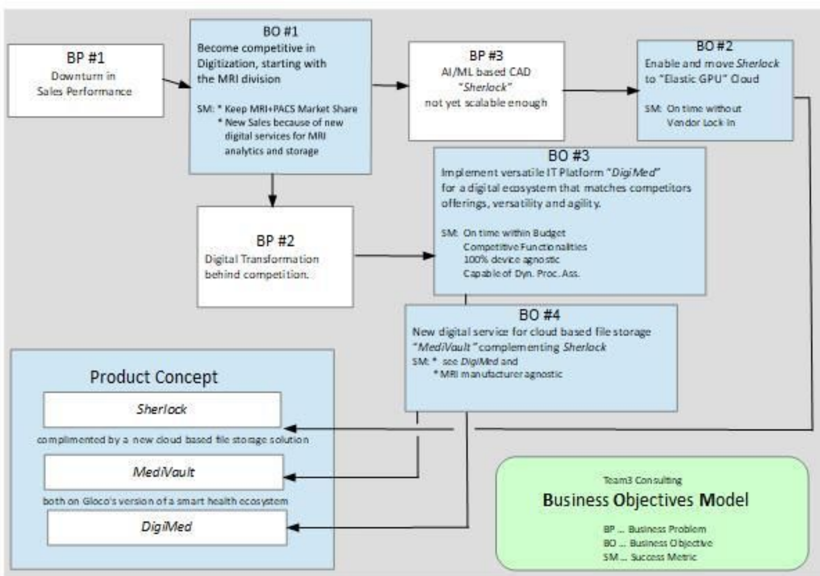
c. This project's implementation is expected to finish with 18 months from solution delivery roadmap. Since data for MRI records (average 200 records per patient) is much bigger than X-ray records (average 3 - 5 records per patient), we anticipate the data quality assurance of this project will be a good benchmark for other medical image records.

4 Appendix

4.1 Appendix 1: SWOT for Objective: Time to Market for AI/ML MRI imaging

	Helpful To achieving the objective	**Harmful** To achieving the objective
Internal Origin	**Strength** AI/ML engine ready to market	**Weakness** Digital Transformation hindered by missing ICT-Ecosystem and services such as cloud based file storage
External Origin	**Opportunities** Well established and strong Market position	**Thread** Competition ahead with digitization and alignment of ICT-Ecoystem

4.2 Appendix 2: Business Objectives Model



4.3 Appendix 3: Business Benefit Calculation Details

	2017	2018	2019	2020	2021	2022
REVENUES						
Avg. Price per CAD Sherlock service		$20	$19	$18	$17	$16
Nr of CAD cognitziv imaging service		300,000	390,000	507,000	659,100	856,830
Revenue CAD		$6,000,000	$7,410,000	$9,151,350	$11,301,917	$13,957,868
Avg. Price per Cloud File Storage Image		$5.00	$5.25	$5.51	$5.79	$6.08
Nr of Files stored in the Cloud		1,500,000	1,950,000	2,535,000	3,295,500	4,284,150
Revenue File Storage		$7,500,000	$10,237,500	$13,974,188	$19,074,766	$26,037,056
Revenue		$13,500,000	$17,647,500	$23,125,538	$30,376,683	$39,994,923
COST						
Year	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**
Up-Front Costs for Sherlock CAD Development	$5,000,000					
Integration with Gloco systems (includes bandwidth and other parameters)	$1,000,000					
Staff training & continuing education**	$500,000	$525,000	$551,250	$578,813	$607,753	$638,141
Software and licensing*	$1,000,000	$1,050,000	$1,102,500	$1,157,625	$1,215,506	$1,276,282
Storage in the cloud		$75,000	$1,023,750	$1,397,419	$1,907,477	$2,603,706
Implementation and maintenance of platform in the cloud		$10,000,000	$11,000,000	$12,100,000	$13,310,000	$14,641,000
Total Costs	$7,500,000	$11,650,000	$13,677,500	$15,233,856	$17,040,736	$19,159,128
Profit /Loss	-$7,500,000	$1,850,000	$3,970,000	$7,891,681	$13,335,947	$20,835,795
Discount Rate	1.00	1.05	1.10	1.16	1.22	1.28
Discounted Profit/Loss	**-$7,500,000**	$1,761,905	$3,600,907	$6,817,131	$10,971,517	$16,325,391
ROI 2017-2022	**$31,976,850**					
* Software and licensing are estimated to increase at a rate between 5-10% every year						
** Staff training and continuing education is estimated to increase 5% every year						
*** This is assuming the IoT sensors are replaced every year to mitigate unforeseen issues. This case pertains to when the platform is able to support IoT devices in the future						

4.4 Appendix 4: Architecture Details

4.4.1 Architecture Component Descriptions

4.4.1.1 Architecture Components Common To All DigiMed Services

The following DigiMed components are common to all services and are unique to the DigiMed digital service offerings.

4.4.1.1.1 Clinical Workstation Software

The Clinical Workstation Software provides the Graphical User Interface for all clinical users of the DigiMed cloud services. This existing software currently provides user interaction for the existing GLOCO PACS product. This software is being modified to support the user interaction use cases of the the new cloud services. This software integrates with the cloud services by interacting with a new component, the DigiMed Client, which mediates access to the AWS Storage Gateway and the cloud based services.

The workstation software is already HIPAA compliant, providing role based access. To support HIPAA compliance for the new cloud services the software will be modified to map the identities of the users with roles that trigger cloud service API service calls to provisioned AWS Identity and Access Management (IAM) identities. This will enable the cloud based system to enforce HIPAA security and enable the Amazon Cloudtrail function to log service access events to support required HIPAA PHI access audit logs.

4.4.1.1.2 DigiMed Client

The DigiMed Client mediates integration between the Clinical Workstation Software and all DigiMed services. This client interacts with the AWS Storage Gateway to retrieve images and Sherlock reports, and to store MRI images. The DigiMed Client performs service calls through the AWS API Gateway to interact with DigiMed Cloud services. The DigiMed Client publishes events monitored by other GLOCO cloud services, and subscribes to events published by other GLOCO cloud services. The DigiMed Client interacts with the Clinical Workstation Software to provide information needed to populate the GUI for cloud services, and publishes events in response to actions taken by users at the Workstation GUI that are needed by the cloud services. Finally, the DigiMed Client provides a way continue operations whenever there is a cloud outage. In the event of an outage, the Client queues events locally. The Client maintains a local cache consisting of configuration information. The client and is able to access images and Sherlock reports cached locally by the AWS Storage Gateway.

4.4.1.1.3 AWS Storage Gateway

The AWS Storage Gateway service provides on premises storage that acts as a local cache to cloud based AWS S3 Storage. In this architecture, the AWS Storage Gateway provides sufficient local storage to cache 12 hours of imaging data. The Storage Gateway mounts a local NFS file system that is visible to the DigiMed Client.

When the Clinical Workstation Software requests access to an image or Sherlock result through the DigiMed Client API, the client reads the file from that local file system. Conversely, whenever an MRI Scan is performed, the Workstation Software provides the associated files to the DigiMed Client. The DigiMed Client writes the files to the Gateway NFS file system. The contents of the NFS file system get transparently and automatically transferred to the cloud S3 Image Storage Bucket by the Gateway. The Gateway automatically caches most recently used files on local storage to provide faster local image access, and to provide a local cache that is available in the event of cloud outages.

All data is encrypted, whether on the Storage Gateway file system or in motion to or from the cloud based S3 buckets attached to the Storage Gateway.

4.4.1.1.4 DigiMed Edge Appliance

The DigiMed Edge Appliance provides a hardware and software hosting environment for the AWS Storage gateway, and the DigiMed Client software. In this architecture, the AWS Storage Gateway is configured to run on a virtual machine (either Microsoft HyperV or VMWare are supported by AWS) local to the customer site. The appliance contains sufficient local storage to cache 12 hours of images. The appliance is configured as a small 1U server with redundant power supplies, Raid 10 storage, ECC Server memory, and multiple CPUs. The GLOCO MRI machine is a multi million dollar device that comes with a small rack of supporting computing equipment. The appliance will be added to this rack when deployed to the customer site.

The DigiMed Edge Appliance is not involved in any direct user interactions.

4.4.1.1.5 Amazon CloudTrail Function

Amazon CloudTrail is used to enable HIPAA compliance use cases including providing an access log of what users saw what personal health information when. Cloudtrail is also used to provide an indication of Sherlock machine learning model accuracy by aggregating the number of times the training data collection service is instantiated. When this service is instantiated, that means the Radiologist has overridden the machine learning algorithm diagnosis. When this happens the training data collection service adds the Radiologist's manually entered diagnosis to the training data used to improve the machine learning models.

4.4.1.1.6 Amazon Cloudwatch Function

AWS Cloudwatch is used in the architecture to monitor service availability and provide alerts in the event of outage. Cloudwatch is also used to provide elastic autoscale. Whenever the Sherlock Request Simple Queue service queue size and/or service time changes, Cloudwatch automatically increases or decreases the compute resources in the EC2 clusters that are running the Machine Learning Framework and Machine Learning Framework Server.

4.4.1.2 Components Supporting The MediVault Service

The following components are needed to support the MediVault digital product.

4.4.1.2.1 MediVault Storage Bucket

This is an instance of the AWS S3 Storage Bucket Service dedicated to storage of MRI DICOM images that are to be stored and/or processed as input to the Sherlock Service. This bucket instance is linked to the AWS Storage Gateway located at the customer site and is allocated as the cloud based storage used by that Gateway. Images stored in this bucket are configured to automatically archive to the Amazon Glacier MediVault Archive provisioned for the customer. When images are retrieved from archive storage, they are restored to this bucket by the Archived Image Retrieval Lambda Function, and resynchronized with the customer AWS Storage Gateway local file system through the S3 and AWS Storage Gateway APIs.

4.4.1.2.2 Amazon Glacier Image Archive

The Amazon Glacier Image Archive provides storage for MRI Images and Sherlock reports that are older than 90 days. The S3 Storage Buckets containing MRI Images, and Sherlock results are configured so that the files contained within them are automatically archived to Amazon Glacier after 90 days.

4.4.1.2.3 Archived Image Retrieval Lambda Function

This function provides an ability to retrieve archived MRI Images when requested by a Radiologist and approved by a manager. MRI Images are archived after 90 days to Amazon Glacier. This function is triggered when a Healthcare provider manager approves a request by a Radiologist to retrieve an archived image or diagnosis. This function is metered at the API Gateway by Amazon Marketplace. Each time the function is used, the customer is automatically billed by Amazon Marketplace.

4.4.1.3 Components Supporting The Sherlock Product

The following components are needed to support the cloud based Sherlock digital product offering.

4.4.1.3.1 Model Training Service

This service provides an ability to orchestrate machine learning model training when triggered to do so. This service interacts with the Machine Learning Framework to train models, providing that framework with which training data to use, what algorithms to execute, and what hyperparameters to use during that model training. Models are created based on parameter specifications provided by the GLOCO Product Operations team during their process of selecting training data. These specify the hyperparameters to be used during training. The outputs of this service include trained models, and model performance reports and dashboard inputs stored in the Training Data Storage bucket for analysis by GLOCO Product Operations.

4.4.1.3.2 Training Data Collection Service

This service collects machine learning training data originating from feedback provided by the Radiologist. Whenever the Radiologist overrides a Sherlock diagnosis and annotates an MRI Scan with their own diagnosis, the GLOCO Services Client triggers an event referencing the Sherlock report overridden, and the DICOM file. This service collects that data when the event occurs, de-identifies it, and moves the image along with the Radiologists diagnosis into the Training Data Storage bucket for analysis by GLOCO Product Operations. This service API is monitored by Amazon Cloudwatch and Amazon Cloudtrail in combination. GLOCO Product Operations look at dashboards and metrics that show the number of times this service is triggered to understand how Sherlock models are performing, and to determine which models need to be retrained and when.

4.4.1.3.3 Training Data Storage Bucket

This S3 storage bucket is populated by the Training Data Collection microservice with new training data when a Radiologist overrides a Computer Aided Diagnosis with their own diagnosis. This bucket is also used by GLOCO Product Operations to hand select the training data that want to use for model training and retraining. Finally, this bucket is used to trigger model retraining performed by the Model Training micro service.

4.4.1.3.4 Computer Aided Diagnosis (Sherlock)

This micro Service handles interaction with the Machine Learning Framework Server to execute Sherlock Machine Learning models, per the customers configuration. Invocations of this micro service are metered at the API Gateway and customers are charged for CAD services through this mechanism by the Amazon Marketplace Function. This micro service subscribes to the Sherlock Request Simple Queue service and orchestrates model execution when triggered. Orchestration includes retrieving the MRI DICOM image file from the appropriate S3 Storage Bucket, converting that file into images and text consumable by the Machine Learning model, providing the files to the model, and packaging model execution results into a Sherlock report. The report is stored in the Sherlock Request Storage Bucket. Finally, the service asks the S3 API to resync the file contents of the S3 bucket with the attached AWS Storage gateway. This causes the Sherlock result to materialize on the local file system of the AWS Storage gateway at the customer location. Finally, like all services published by the API gateway, the gateway can be configured to throttle service access to prevent denial of service attacks.

4.4.1.3.5 Machine Learning Framework

The responsibility of the Machine Learning Framework is to train machine learning models that perform the type of Computer Aided Diagnosis configured as part of the customers product subscriptions. Model training is orchestrated by the Model Training microservice in response to events triggered by the Gloco Product Delivery team when they provide new training data in the Training Data Storage Bucket.

4.4.1.3.6 Machine Learning Framework Server

The responsibility of the Machine Learning Framework Server is to execute machine learning models created by the Machine Learning Framework during model training. The server interacts with the Computer Aided Diagnosis microservice to execute the correct configured machine learning models based on the customer's configuration parameters. Configuration parameters include which models to execute along with any model hyperparameter that should be used to perform that model execution.

4.4.1.3.7 DICOM Encoder Decoder

This Micro Service converts DICOM files into a form suitable for machine learning training or classification (Diagnosis). In general DICOM image documents wrap images and text data that are not directly consumable by machine learning algorithms. This service performs the first step in transforming the embedded files into standard image formats and de-identified text, suitable to be "Vectorized" by the machine learning framework prior to model execution or training . Conversely, this service performs the opposite function for Sherlock Diagnostic result images, wrapping them back up into DICOM with tokenized text substituted for Personally Identifiable information. When the images are retrieved for viewing at the customer site, the actual identity of the patient is substituted for the tokens, which contain patient record linkage information.

4.4.1.3.8 Sherlock Request Lambda Function

The AWS Lambda function instance that monitors for Sherlock requests and triggers their execution if configured to do so. This function is provisioned by the system when the customers configures Sherlock to occur automatically each time they perform an MRI scan. When triggered, this function retrieves the metadata about the MRI Image from the S3 Image storage bucket and places a queue entry on the Sherlock Request Simple Queue Service. This function is configured at provisioning time to trigger when a new MRI Image appears in the S3 Image storage bucket.

4.4.1.3.9 Sherlock Request Simple Queue Service

This component is an Amazon SQS instance dedicated to queueing Sherlock request events. The Computer Aided Diagnosis micro service subscribes to this queue and orchestrates execution of a Computer Aided Diagnosis when the enqueued events occur. The Amazon Cloudwatch Function monitors the size and wait time in this queue and autoscales the EC2 compute resources running the Machine Learning Framework Server in response to queue wait times.

4.4.1.3.10 Sherlock Result Storage Bucket

This is an instance of an AWS S3 Storage Bucket Service dedicated to storage of Storage of Computer Aided Diagnosis results. Diagnosis results are stored in this bucket by the Sherlock micro service. Once a diagnosis result has been stored, the Sherlock Microservice signals the S3 service to sync the files contained in the bucket with the AWS Storage Gateway at the client site. This causes the Sherlock result to materialize on the local filesystem of the customer's AWS storage gateway.

4.4.1.4 Reusable Components That Can Be Employed For New Digital Products

The following DigiMed components are reusable when GLOCO rolls out new digital products. When reused, these components will accelerate the rollout of new GLOCO digital products.

4.4.1.4.1 Amazon Marketplace Function

Amazon Marketplace provides the mechanism that allows Healthcare Provider Managers to subscribe to GLOCO digital services. Marketplace also provides service utilization dashboards cross referenced with AWS billing for the services, supporting use cases for the Provider Manager, GLOCO Sales and Marketing, and GLOCO product operations.

4.4.1.4.2 Developer Portal

The Developer Portal provides the API's and examples and a forum for interaction with developers who use GLOCO's APIs.

4.4.1.4.3 API Gateway

The API Gateway publishes and mediates APIs for GLOCO digital services and GLOCO Enterprise systems. All digital services provided by GLOCO are metered through the API gateway. This metering is enabled and monitored by Amazon Marketplace. Whenever a customer accesses a metered service, the customer is charged by Amazon Marketplace based on service access counts. During the service provisioning process, access to metered services is enabled and the linkage to AWS Marketplace billing is set up.

The API Gateway also provides an important security function. It has the ability to throttle service usage on a per user basis, enabling prevention of denial of service attacks. In addition, services on the gateway can only be accessed by AWS IAM provisioned authorized users.

4.4.1.4.4 Configuration And Activation Service

This service handles initial and ongoing configuration of digital products based on the customer's individualized preferences and configuration.

When a customer subscribes to a product, this service knows which cloud resources need to be provisioned in order to activate and configure the product. The data describing the cloud resources needed is maintained in the form of Amazon Cloud Formation templates, stored in an S3 Bucket dedicated to the customer. These templates, once populated with configuration parameters, are used to instantiate cloud resources needed to deliver the services to the customer. Whenever the customer makes configuration changes, and adds or removes services, the Cloud Formation Templates used and the parameters used to populate them are updated by this service. Once populated, the Cloud Formation Templates are used by the Provisioning micro service to instantiate, change, or decommission the cloud resources used to deliver the product for a customer.

4.4.1.4.5 Provisioning Service

This service consumes the Cloud Formation Templates associated with a customer's product subscriptions, and provisions all AWS Cloud resources needed to deliver the services, including things like IAM roles, identities, S3 storage, compute clusters, Lambda functions, message queues, and load balancers necessary to deliver the service. This service subscribes to changes in the customer's Cloud Formation Template S3 bucket and executes any necessary provisioning and deprovisioning needed to support providing and decommissioning the service. Using Cloud Formation Templates, this service interacts with the respective AWS APIs of each AWS resource involved in delivery of the service to the customer.

4.4.1.4.6 Cloud Formation Template Storage Bucket

This is an instance of the AWS S3 Storage Bucket Service dedicated to storage of the Cloud Formation Templates of a customer's configuration. This bucket provides encrypted highly available storage for the templates. The Configuration and Activation microservice stores templates into this bucket that have been initialized with parameters that reflect the customer's product configurations and subscriptions. The Provisioning Micro Service monitors this bucket for changes and performs automated provisioning to reflect those configuration changes.

4.4.1.4.7 Status Reporter Service

This service reports the current status of DigiMed services including availability, performance, and subscription status on an ongoing real time basis. This service is agnostic to the product it is collecting information about, and is reusable when GLOCO introduces new digital services. This service collects selected information from AWS Cloudwatch by monitoring the Cloudwatch events associated with a customer's provisioned resources, and is able to provide service processing times and information used to construct friendly messages to the users of the GLOCO digital services end consumers. This service aggregates status across both product subscription issues and cloud infrastructure resource utilization and issues, providing a single point of reporting.

4.4.1.4.8 Enterprise Product Support Portal

The existing Enterprise Product Support portal is used by GLOCO Customers and Support Personnel to enter, track, and resolve issues with GLOCO products. This portal currently supports resolution of customer issues with GLOCO MRI Machines and MRI Machine Client Workstation Software. To support the new digital products, this system will be configured to add relevant support information to its knowledge bases, making this information available to support representatives for the new digital products.

Whenever a customer subscribes to a new Digital Product, the relevant product and customer information will be populated in this system through existing SOAP Web Services by the cloud based Product Support micro service. Whenever a Customer's configuration changes in a way that affects product support, that information will be updated by the Customer Support microservice. This enables seamless support for DigiMed using the standard mechanism used today by the GLOCO enterprise.

The product support integration being done in this project is reusable when new digital products are created by GLOCO.

4.4.1.4.9 Product Support Integration Micro Service

This service provides integration with the Gloco Enterprise Product Support portal, providing information needed to satisfy product support issues related to the new digital services. This service does not implement an API Gateway Interface, it consumes events published by the other cloud based services and the AWS Cloudwatch function, and provides that information to the Gloco Enterprise Product Support Team through the SOAP API's, of the existing Product Support portal software. These APIs are republished on the AWS API Gateway. The GLOCO Enterprise Product Support portal currently supports resolution of customer issues with it's MRI Machines and MRI Machine Client Workstation Software. The integration provided by this service allows extension of that support to include the new Digital Products.

4.4.1.4.10 Enterprise Customer Service

The existing Enterprise Customer system is used by GLOCO Customer Service representatives to answer questions and resolve issues not related to direct support. This portal currently supports customers of GLOCO MRI Machines and all other GLOCO OEM products. This system will be configured to add relevant information needed by Customer Support representatives to support the new digital products. Whenever a customer subscribes to a new Digital Product, or changes their product subscription, the relevant information will be populated in this system through its existing SOAP Web Services by the Customer Service micro service. This enables seamless customer service for DigiMed using the standard mechanism used today by the GLOCO enterprise.

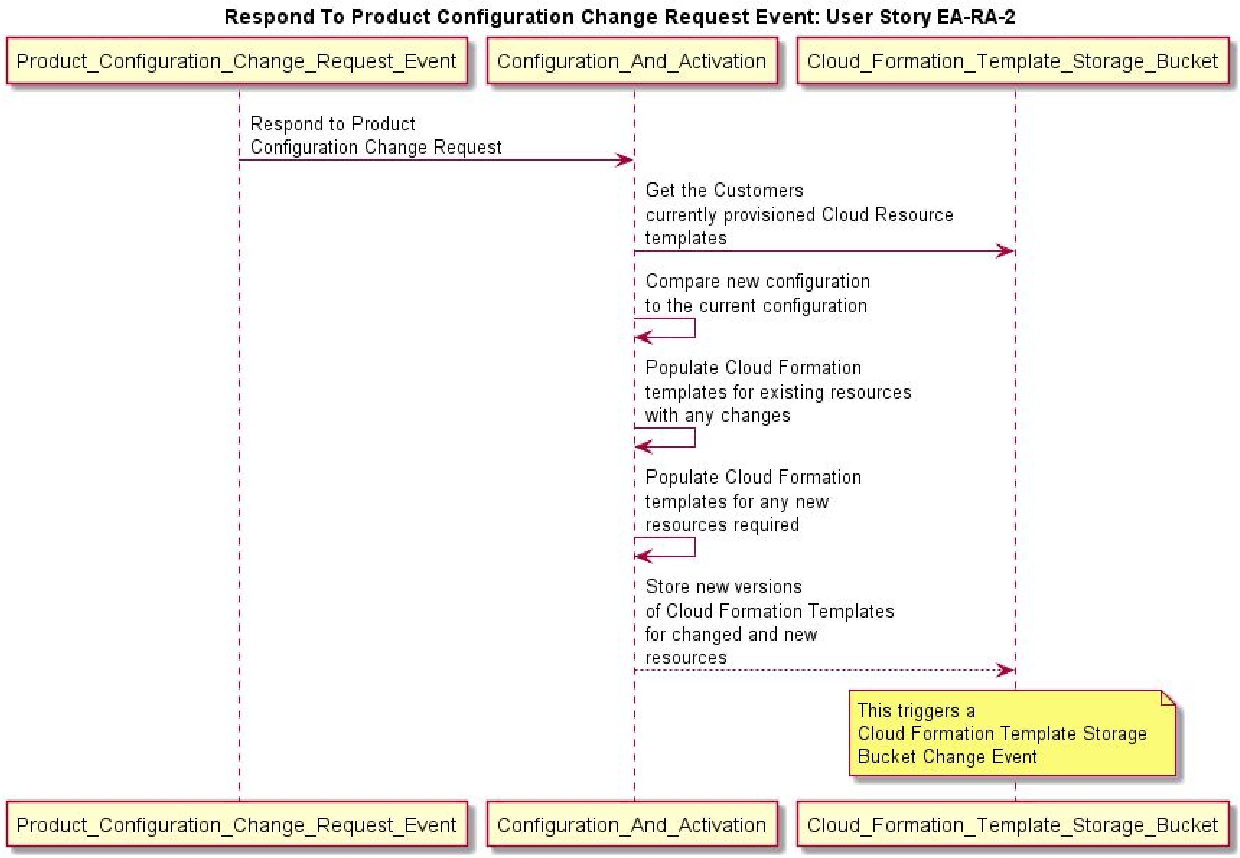
4.4.1.4.11 Customer Service Integration Micro Service

This service provides the Gloco Enterprise Customer Service system with information needed to satisfy service requests related to Digital Products that are not related to billing or direct product support issues. This service does not implement an API Gateway Interface, it consumes the interfaces of other services and provides information back to the enterprise customer service system over it's SOAP API's, which have been published on the AWS API Gateway.

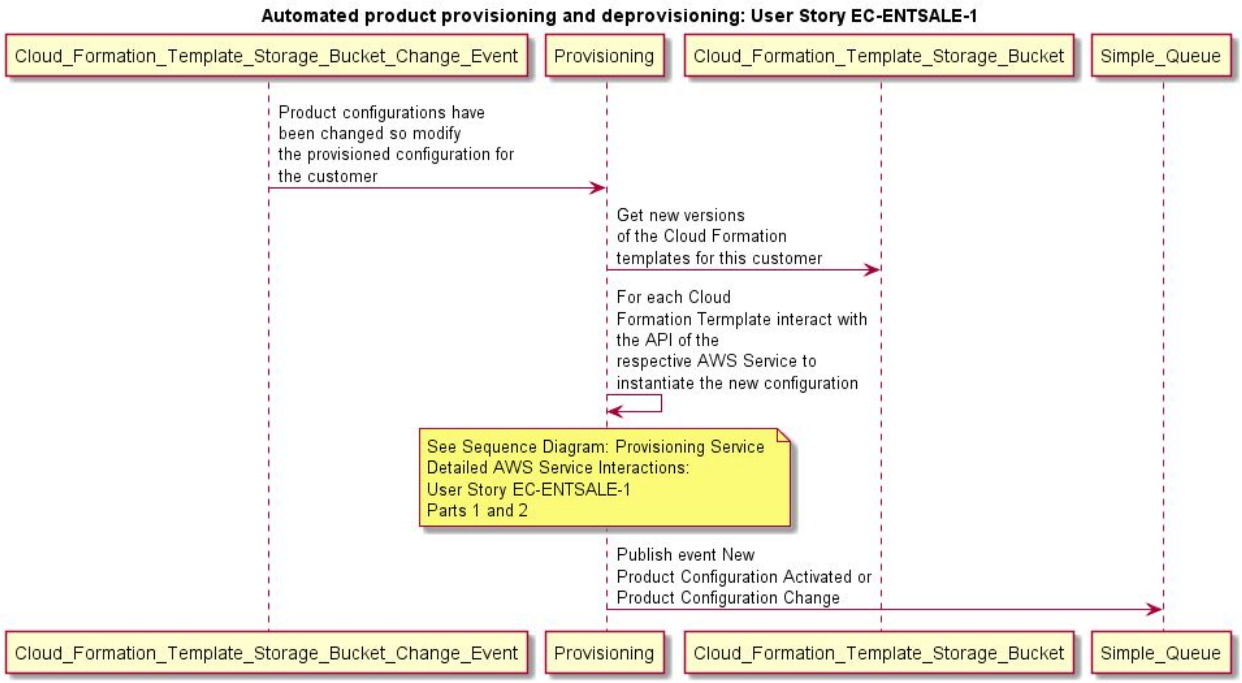
4.4.2 Architecture Sequence Diagrams

The sequence diagrams below show each architecture component in action while executing a DigiMed user story.

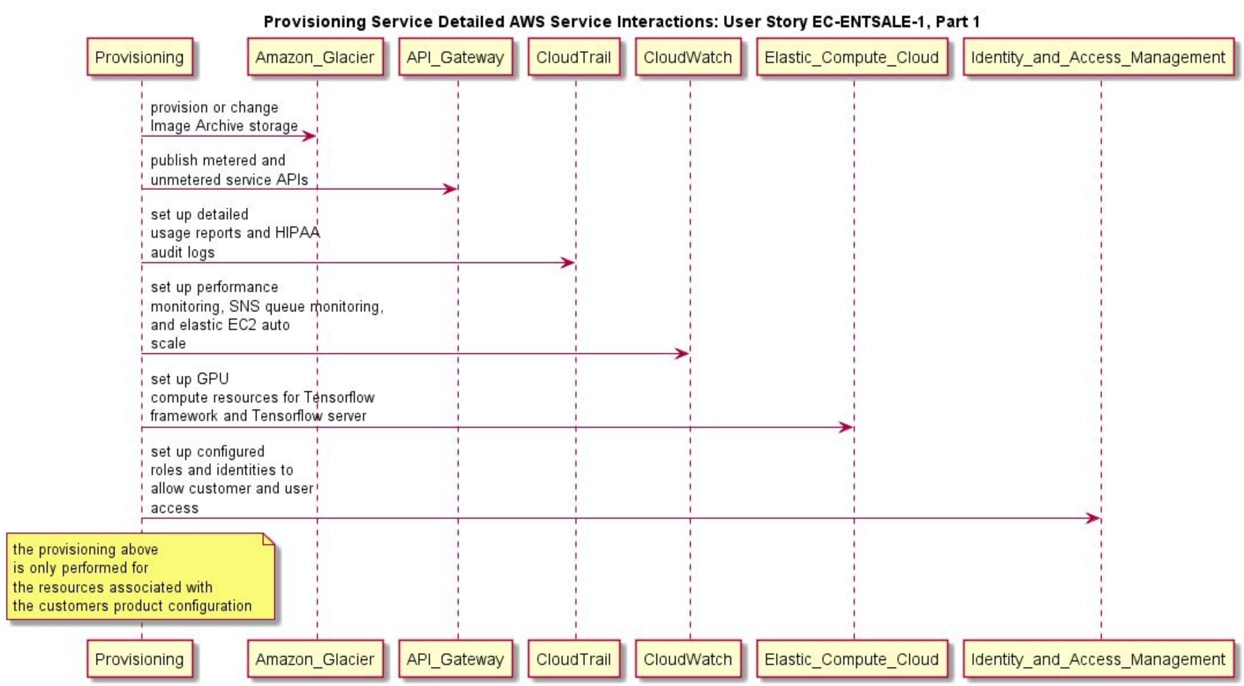
4.4.2.1 Respond To Product Configuration Change Request Event: User Story EA-RA-2



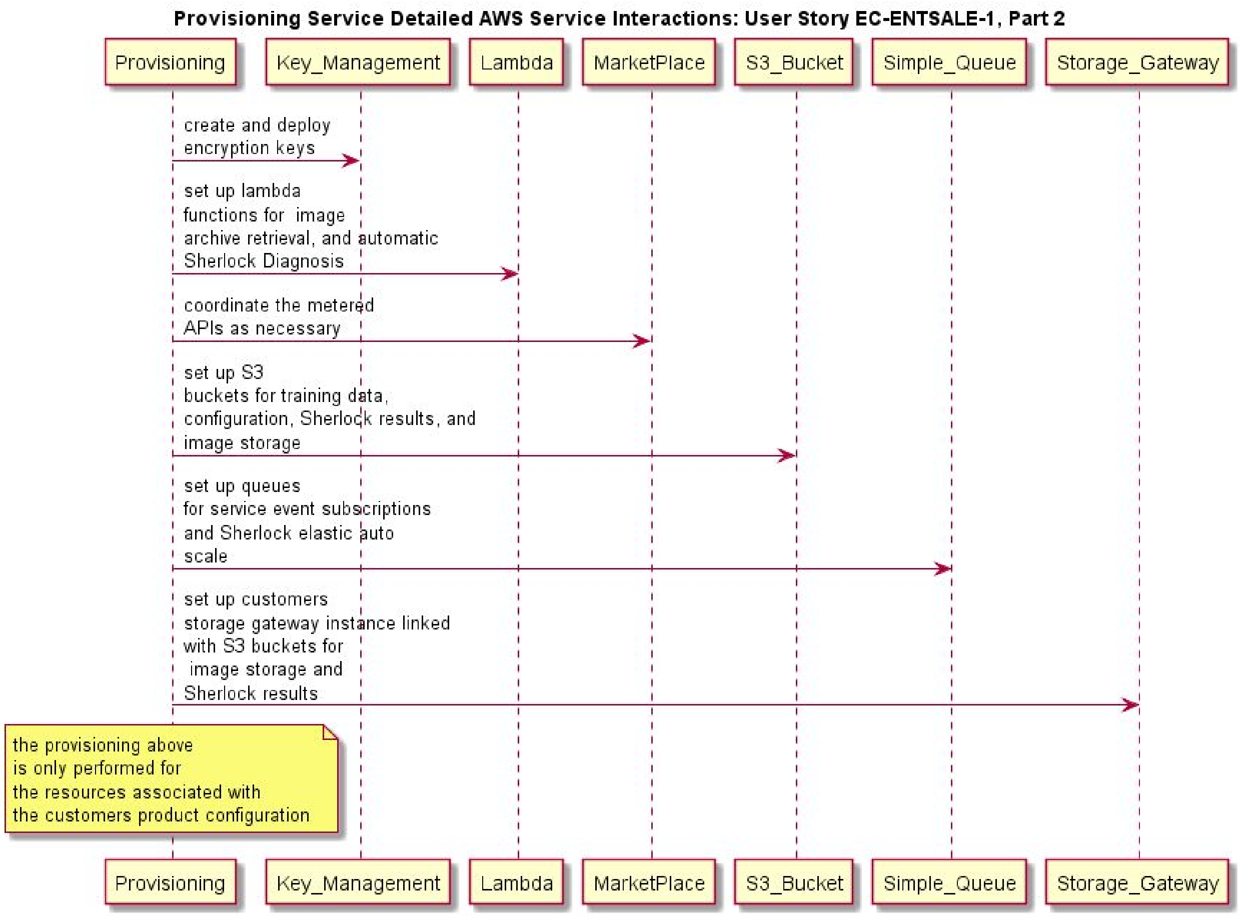
4.4.2.2 Automated product provisioning and deprovisioning: User Story EC-ENTSALE-1



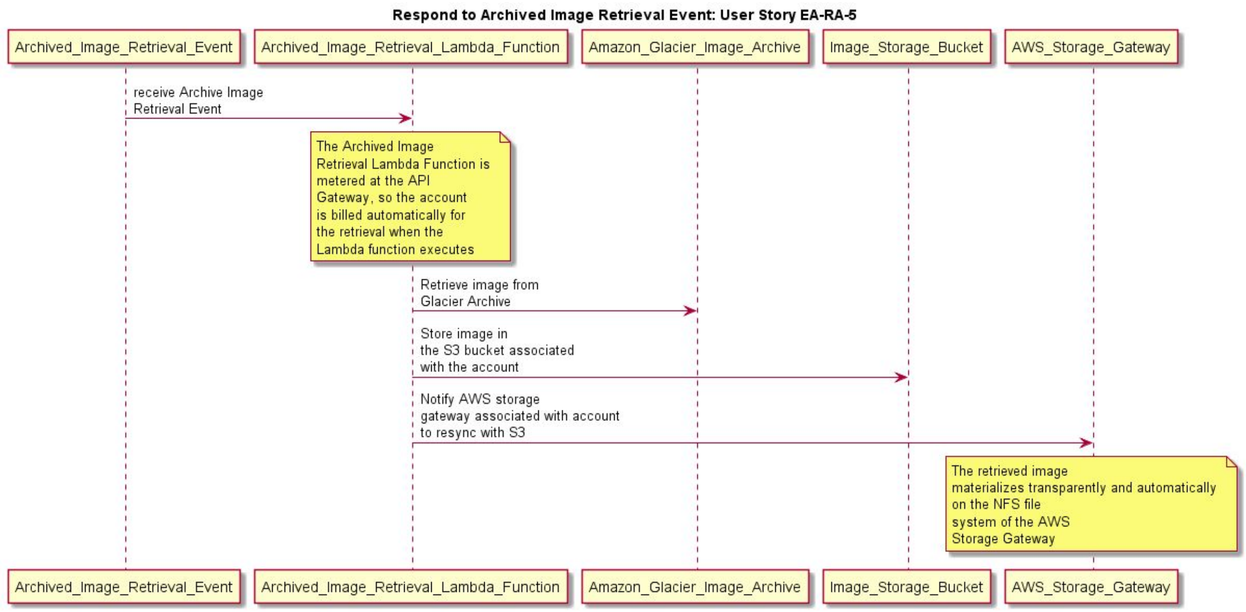
4.4.2.3 Provisioning Service Detailed AWS Service Interactions: User Story EC-ENTSALE-1, Part 1



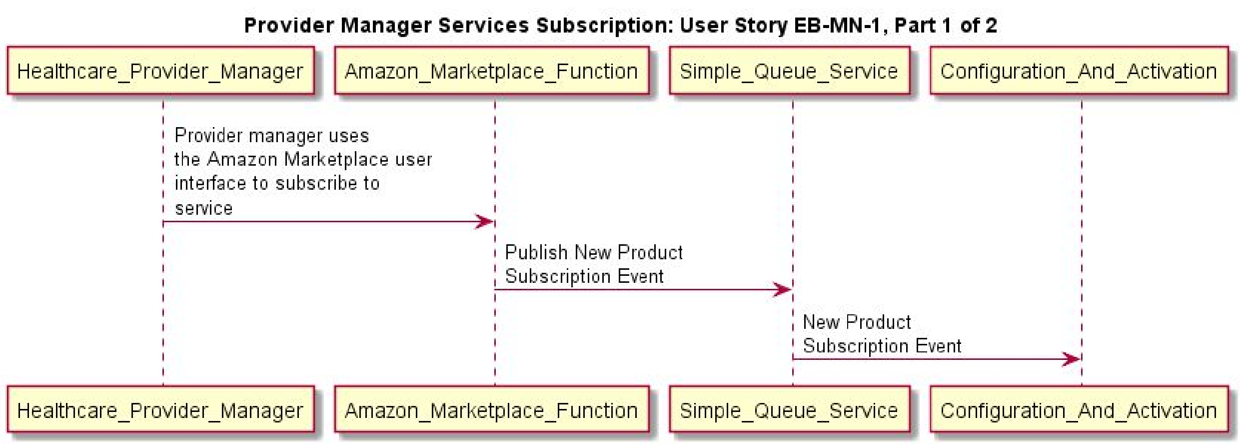
4.4.2.4 Provisioning Service Detailed AWS Service Interactions: User Story EC-ENTSALE-1, Part 2



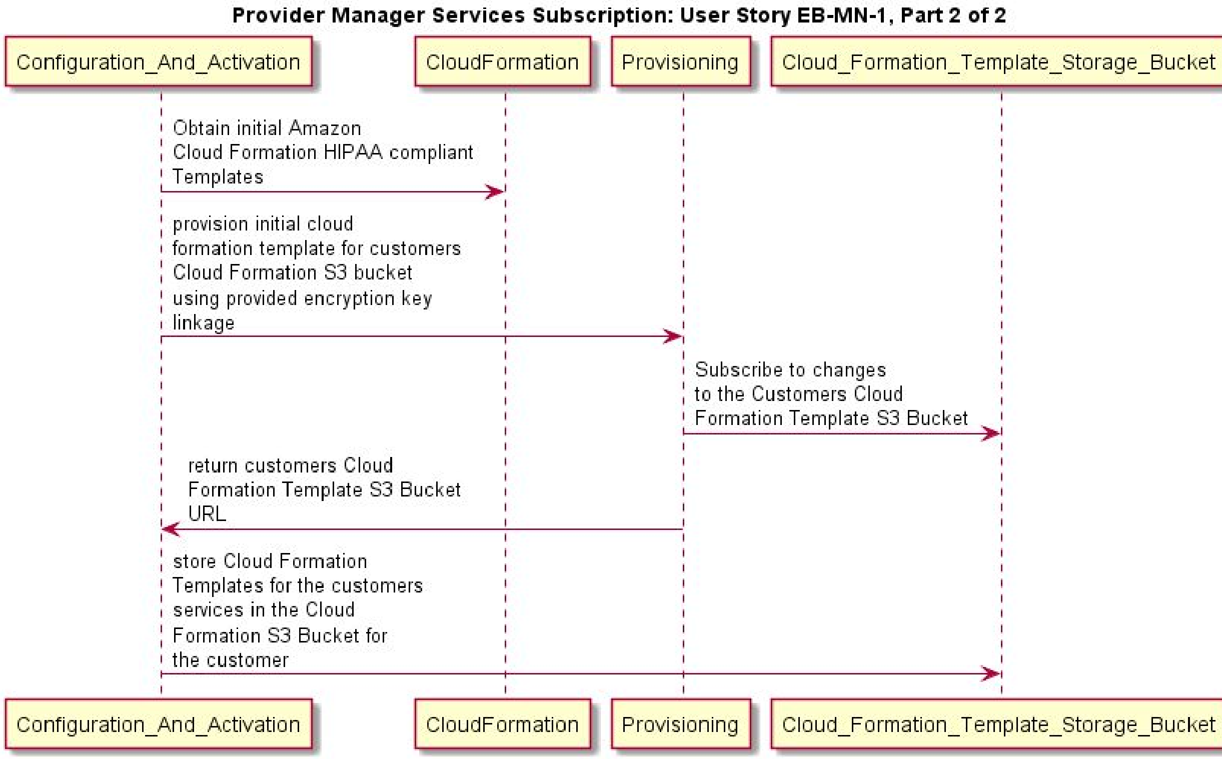
4.4.2.5 Respond to Archived Image Retrieval Event: User Story EA-RA-5



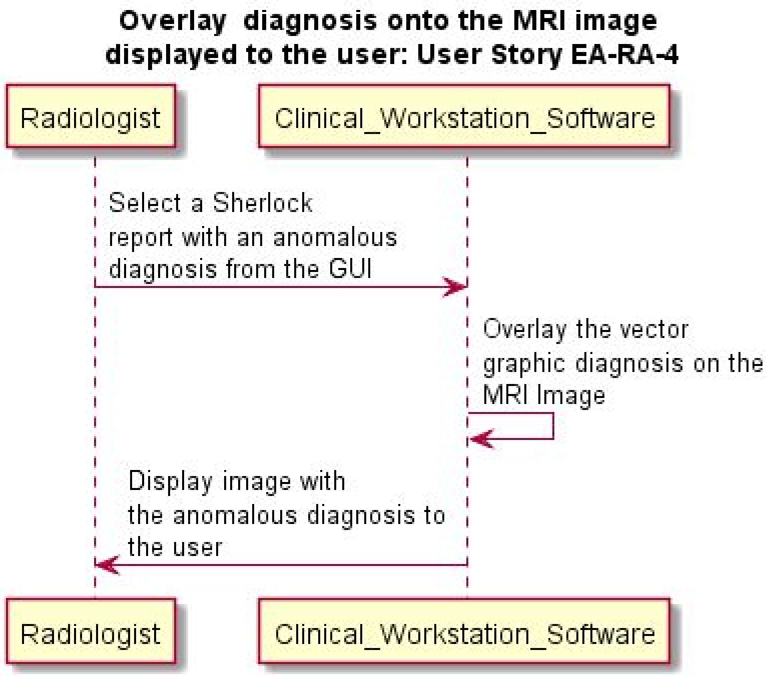
4.4.2.6 Provider Manager Services Subscription: User Story EB-MN-1, Part 1 of 2



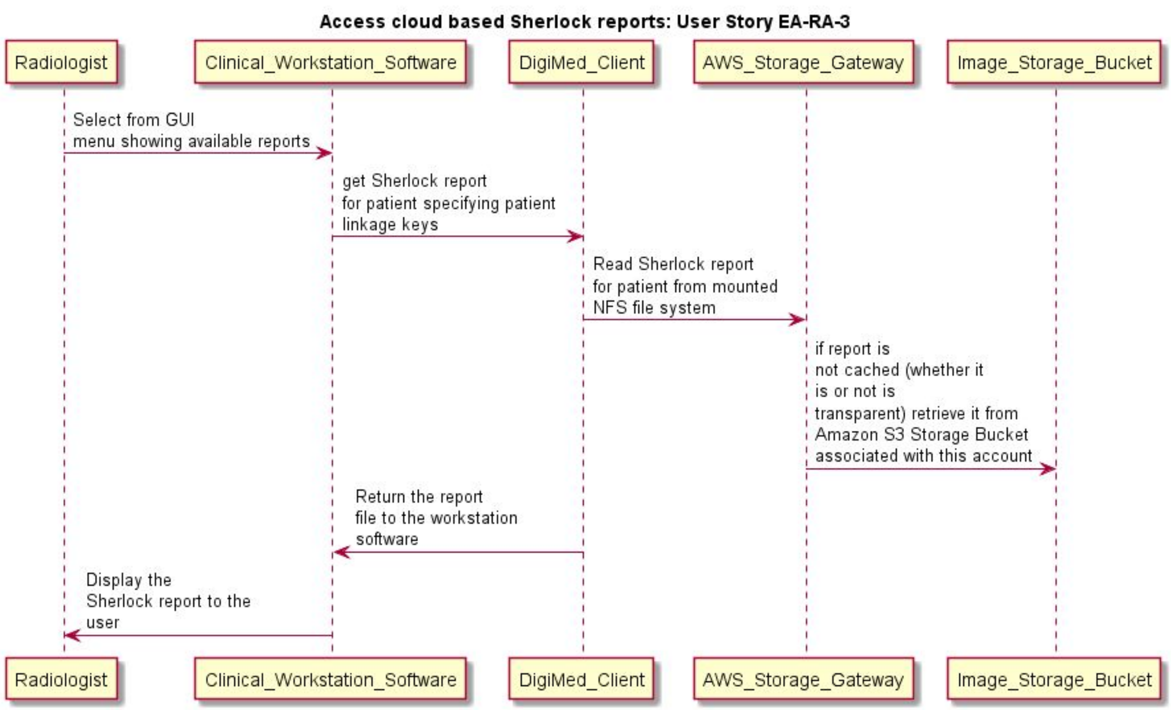
4.4.2.7 Provider Manager Services Subscription: User Story EB-MN-1, Part 2 of 2



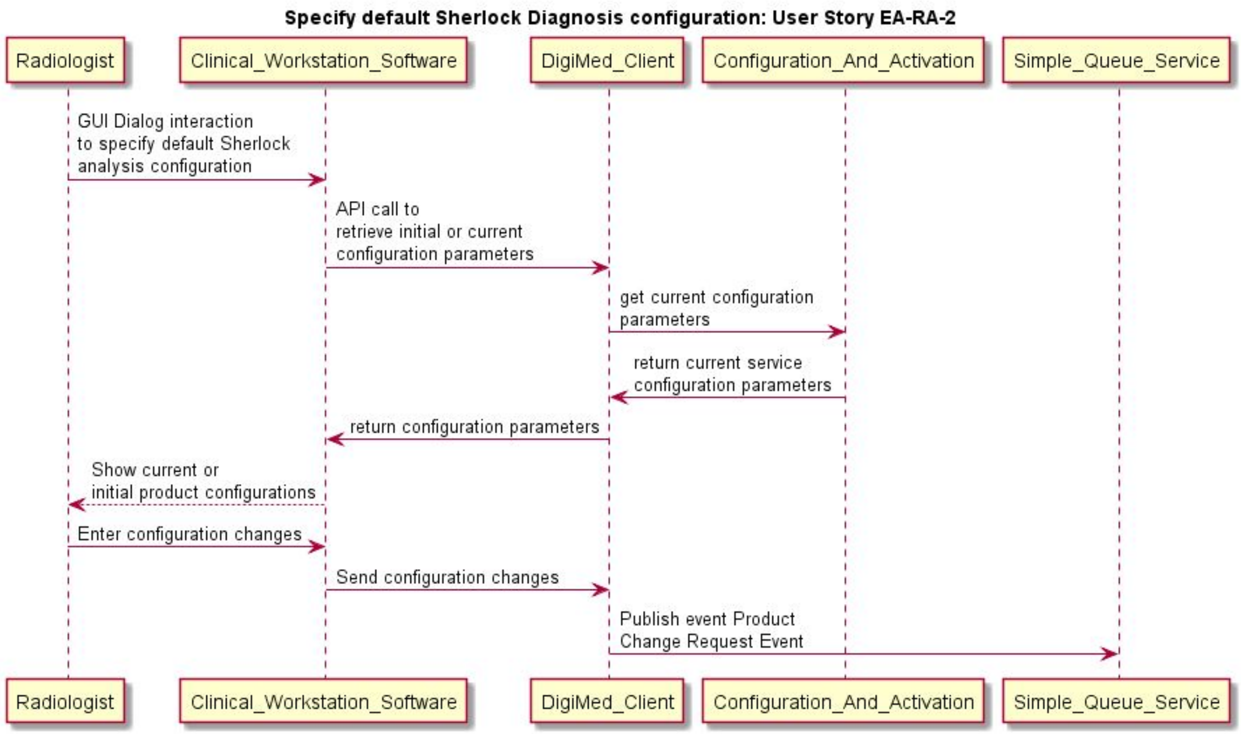
4.4.2.8 Overlay diagnosis onto the MRI image displayed to the user: User Story EA-RA-4



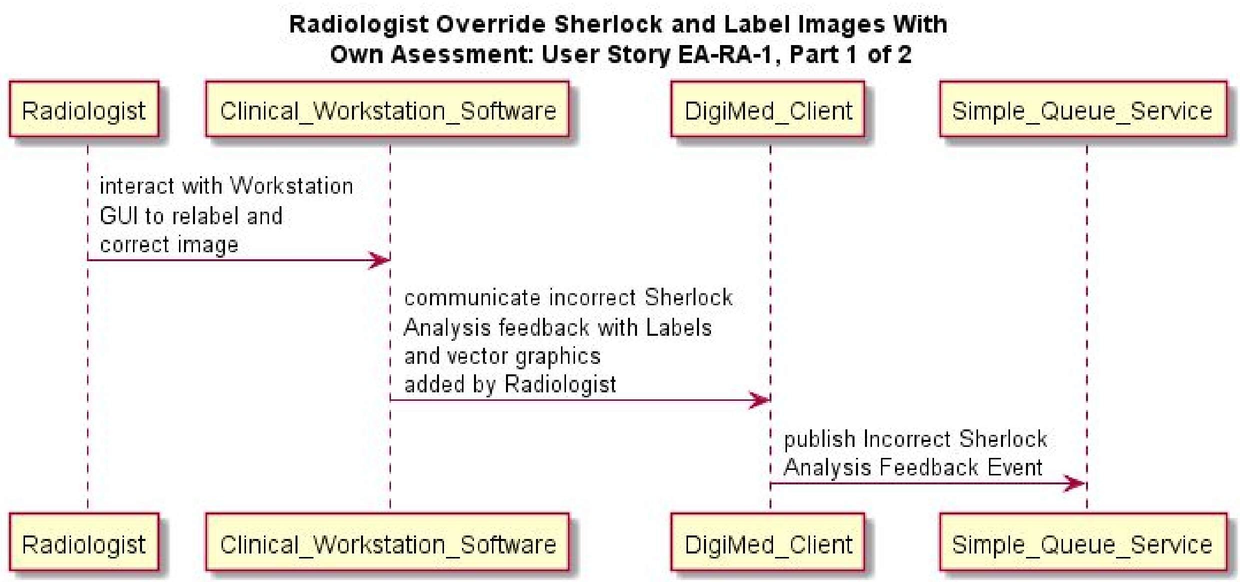
4.4.2.9 Access cloud based Sherlock reports: User Story EA-RA-3



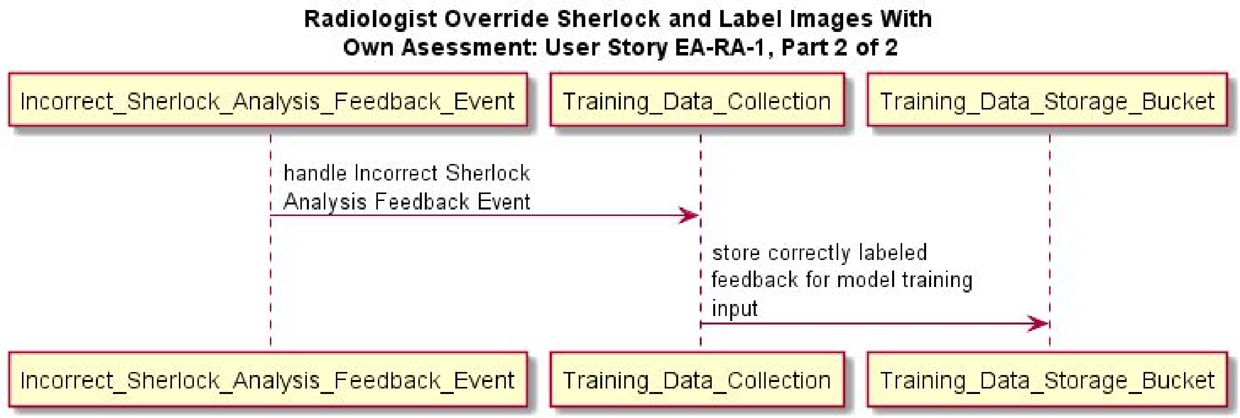
4.4.2.10 Specify default Sherlock Diagnosis configuration: User Story EA-RA-2



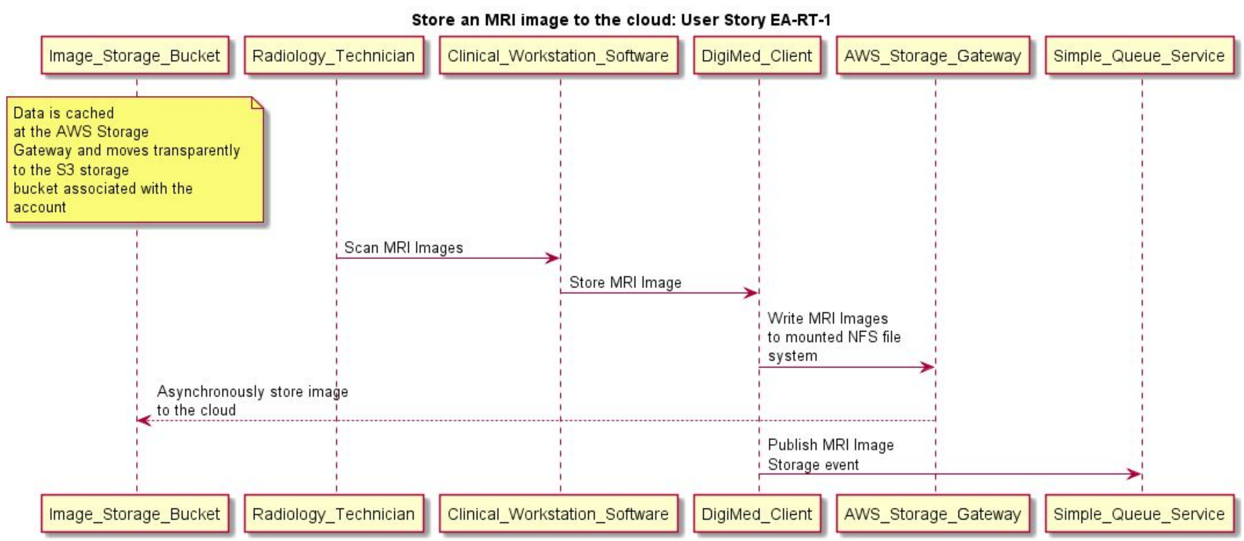
4.4.2.11 Radiologist Override Sherlock and Label Images With Own Assessment: User Story EA-RA-1, Part 1 of 2



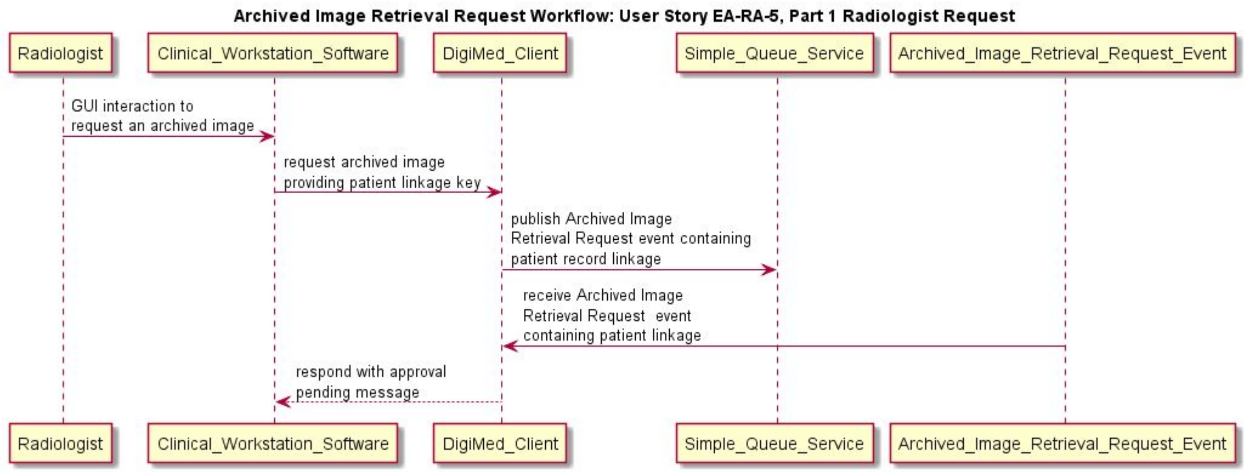
4.4.2.12 Radiologist Override Sherlock and Label Images With Own Assessment: User Story EA-RA-1, Part 2 of 2



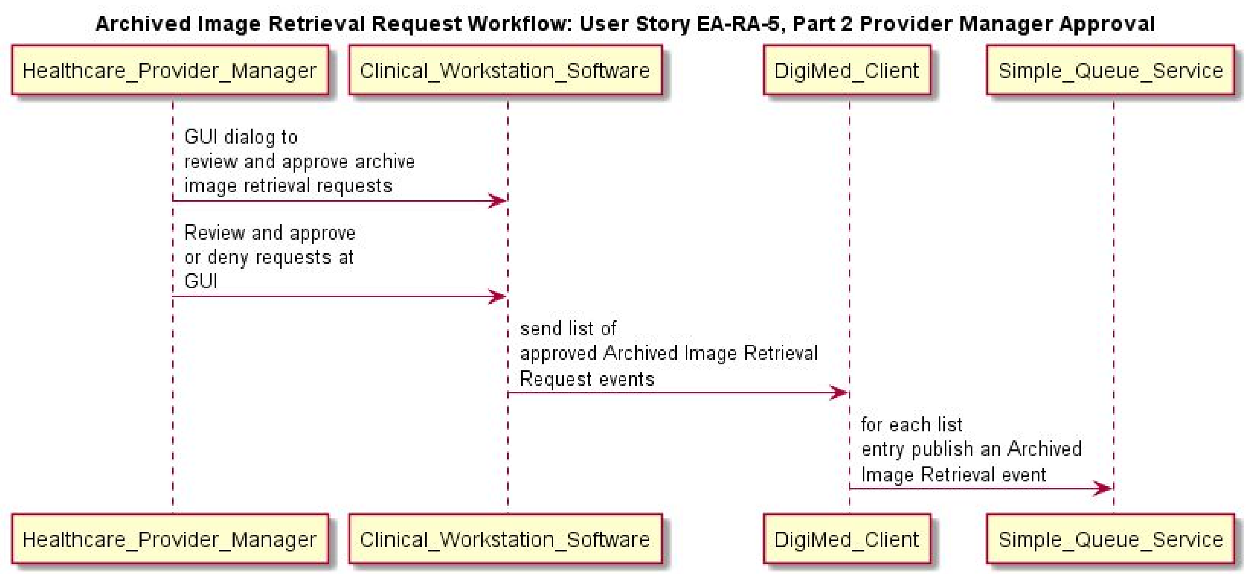
4.4.2.13 Store an MRI image to the cloud: User Story EA-RT-1



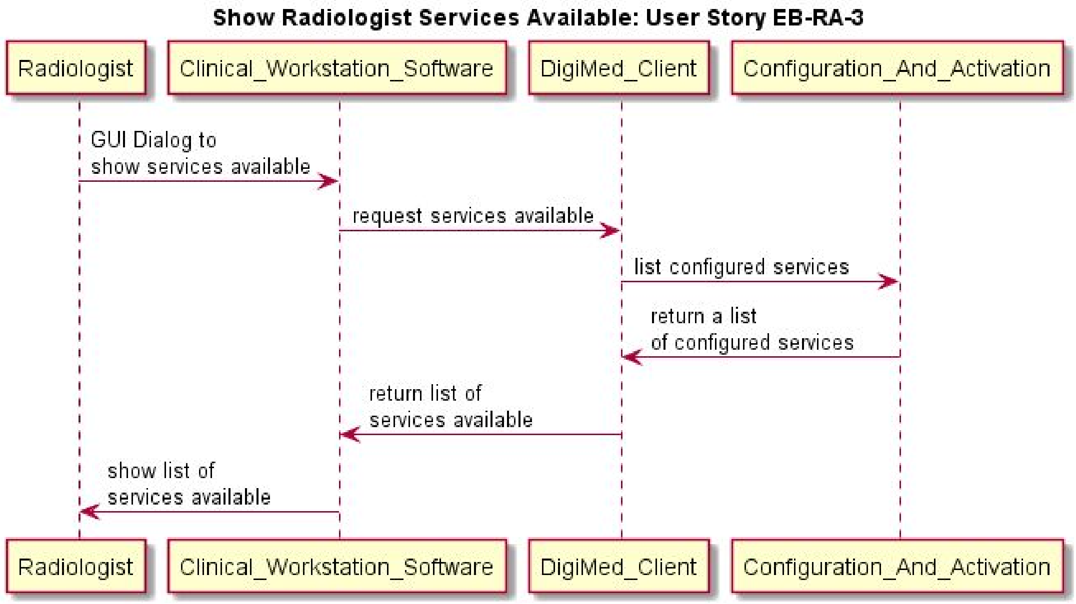
4.4.2.14 Archived Image Retrieval Request Workflow: User Story EA-RA-5, Part 1



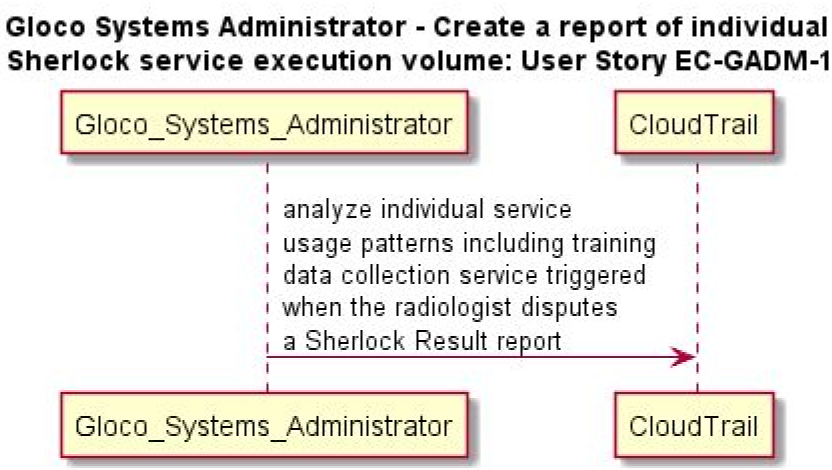
4.4.2.15 Archived Image Retrieval Request Workflow: User Story EA-RA-5, Part 2 Provider Manager Approval



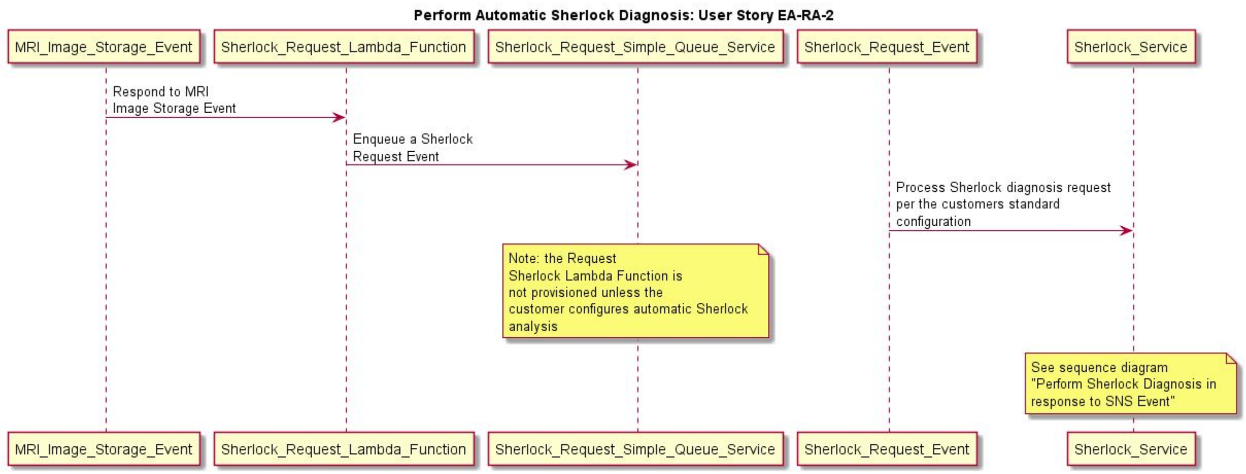
4.4.2.16 Show Radiologist Services Available: User Story EB-RA-3



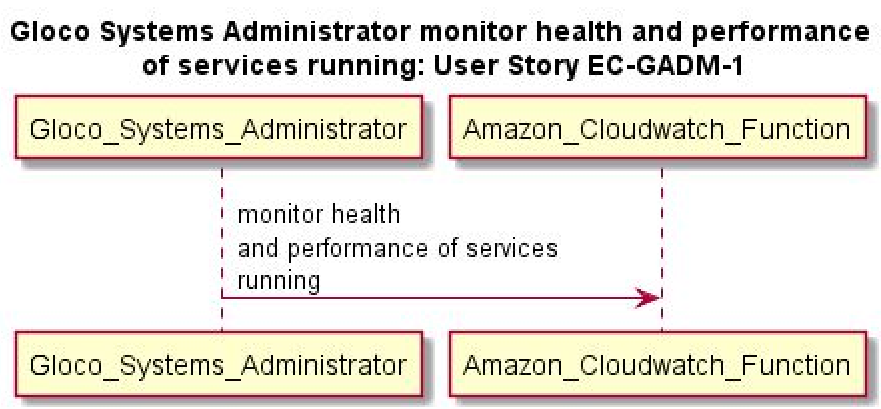
4.4.2.17 Gloco Systems Administrator - Create a report of individual Sherlock service execution volume: User Story EC-GADM-1



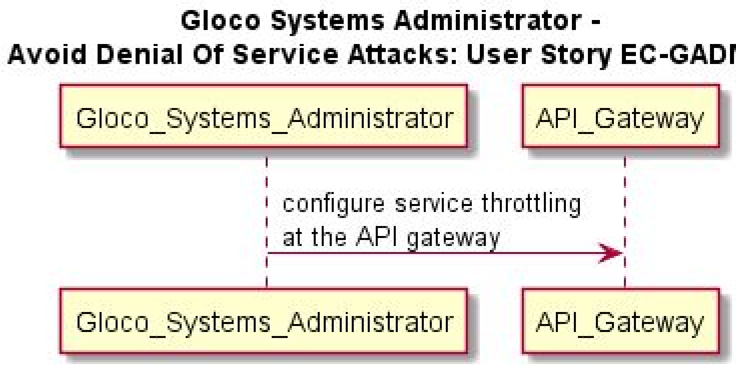
4.4.2.18 Perform Automatic Sherlock Diagnosis: User Story EA-RA-2



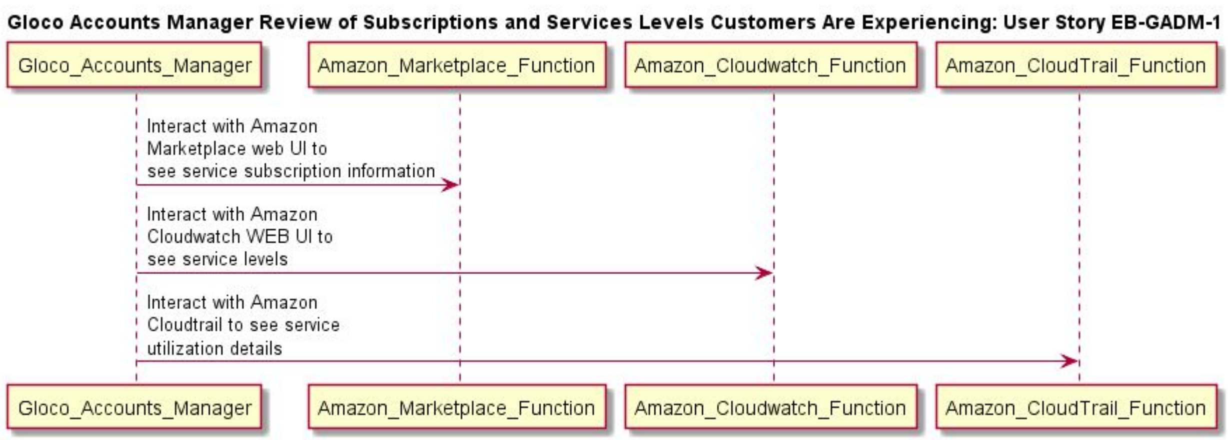
4.4.2.19 Gloco Systems Administrator monitor health and performance of services running: User Story EC-GADM-1



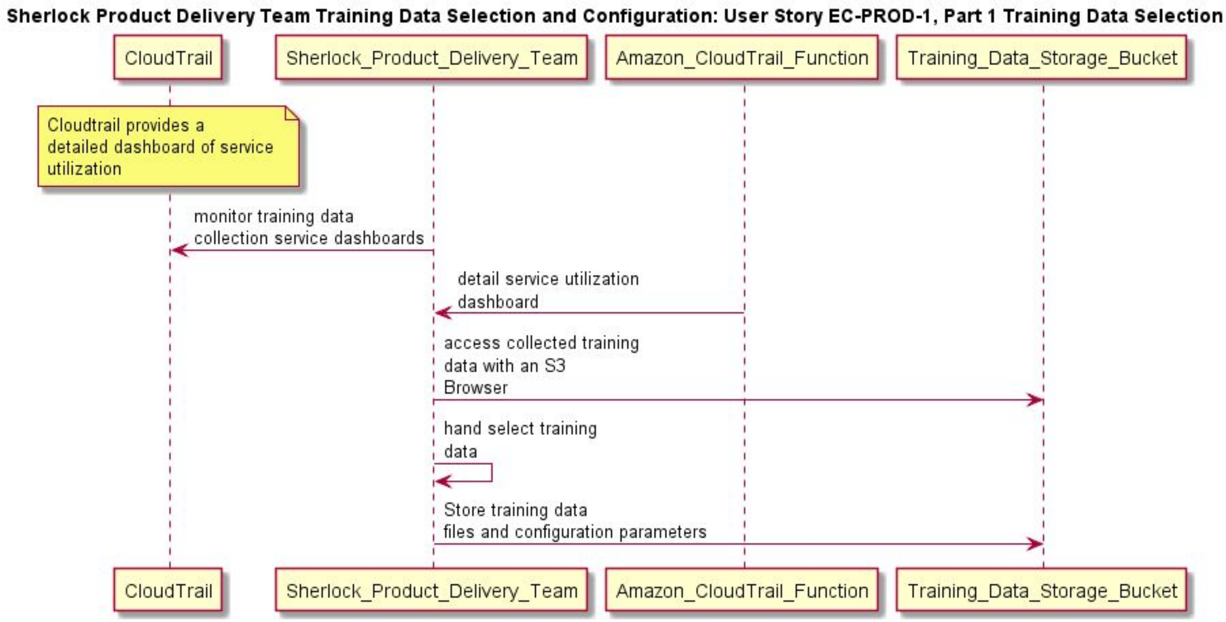
4.4.2.20 Gloco Systems Administrator - Avoid Denial Of Service Attacks: User Story EC-GADM-1



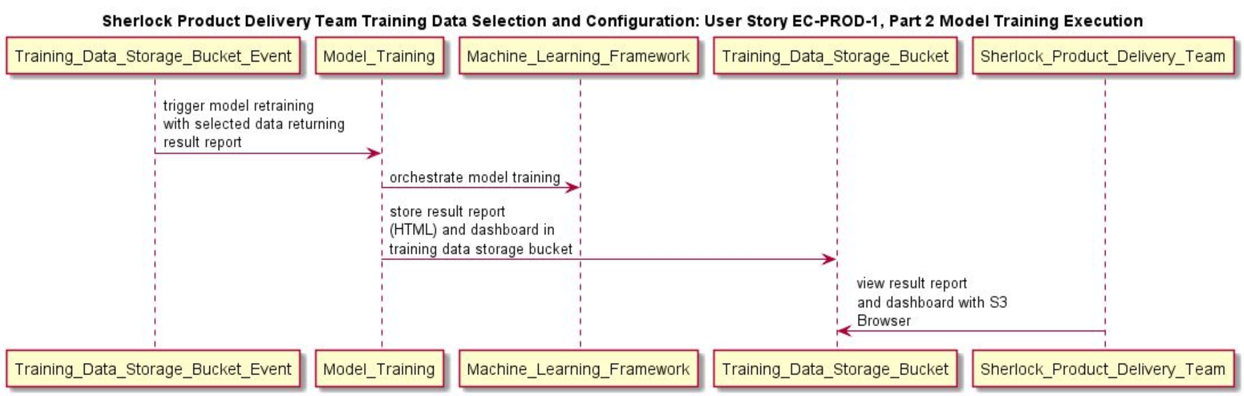
4.4.2.21 Gloco Accounts Manager Review of Subscriptions and Services Levels Customers Are Experiencing: User Story EB-GADM-1



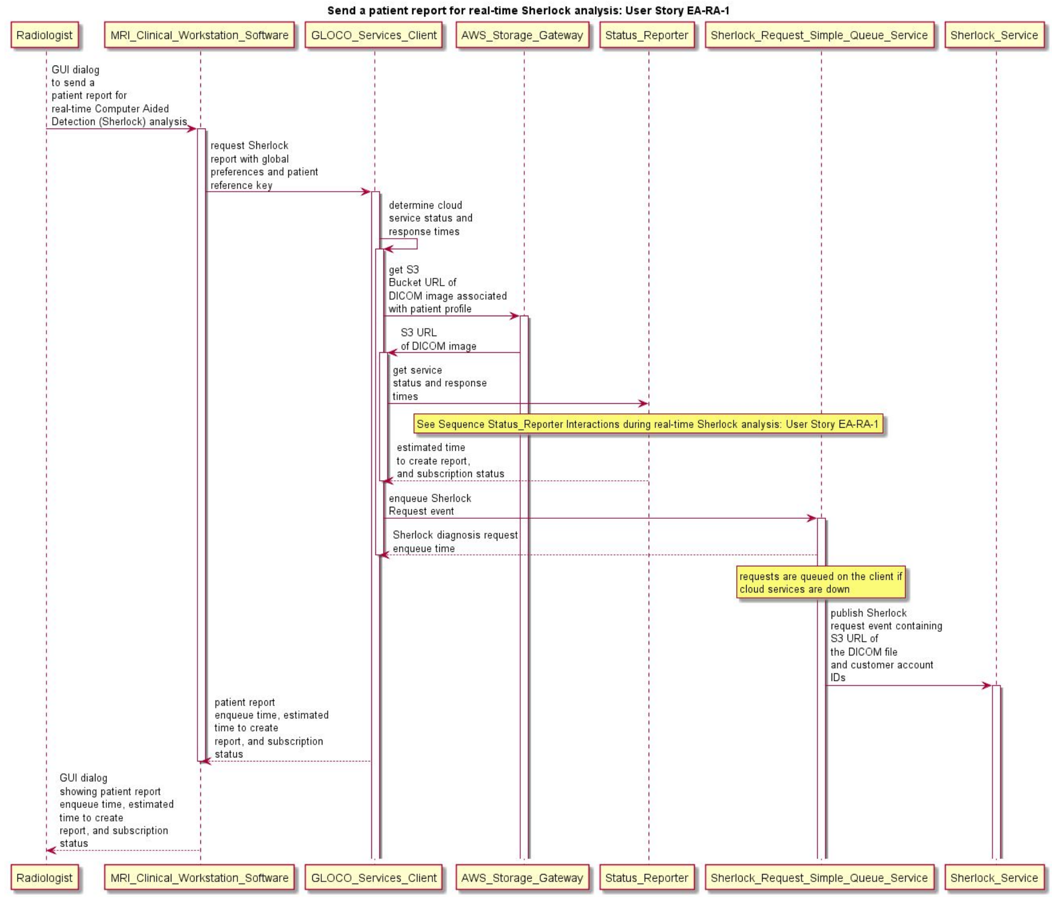
4.4.2.22 Sherlock Product Delivery Team Training Data Selection and Configuration: User Story EC-PROD-1, Part 1 Training Data Selection



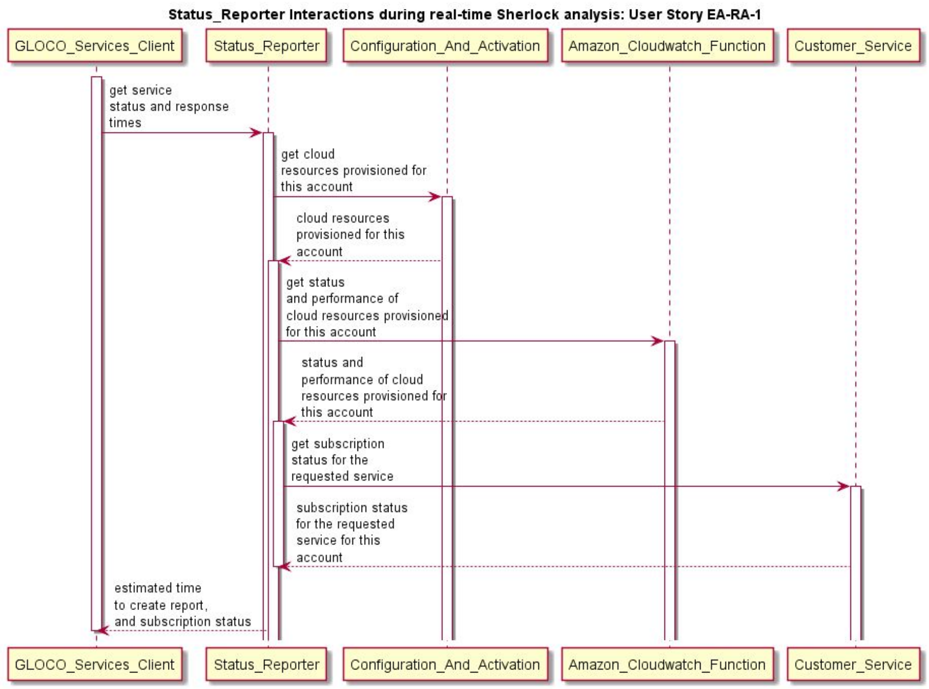
4.4.2.23 Sherlock Product Delivery Team Training Data Selection and Configuration: User Story EC-PROD-1, Part 2 Model Training Execution



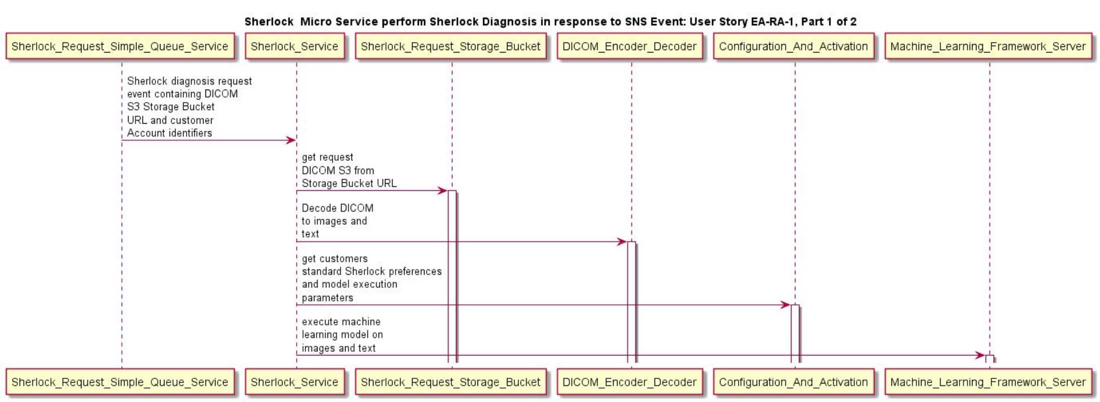
4.4.2.24 Send a patient report for real-time Sherlock analysis: User Story EA-RA-1



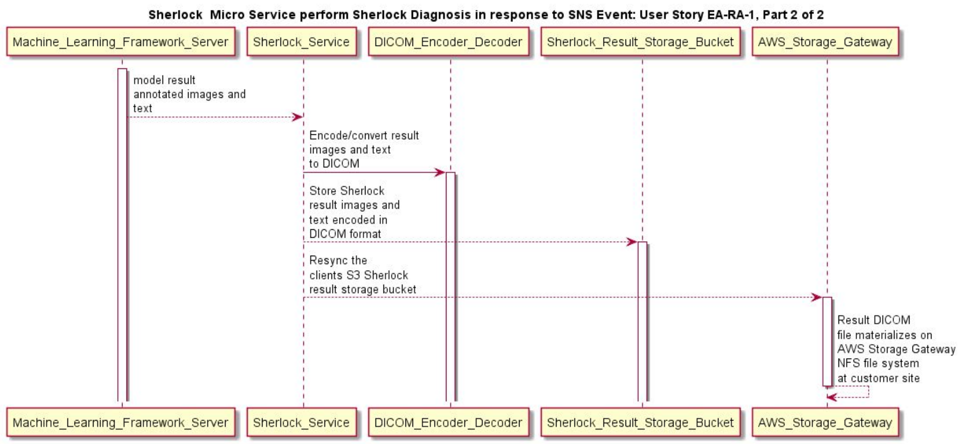
4.4.2.25 Status_Reporter Interactions during real-time Sherlock analysis: User Story EA-RA-1 and subscription status



4.4.2.26 Sherlock Micro Service perform Sherlock Diagnosis in response to SNS Event: User Story EA-RA-1, Part 1 of 2



4.4.2.27 Sherlock Micro Service perform Sherlock Diagnosis in response to SNS Event: User Story EA-RA-1, Part 2 of 2



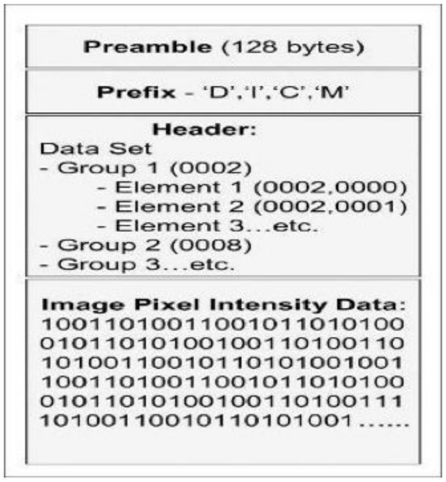
4.4.3 Table of Significant Events

The events outlined in the table below were discovered during project analysis and planning.

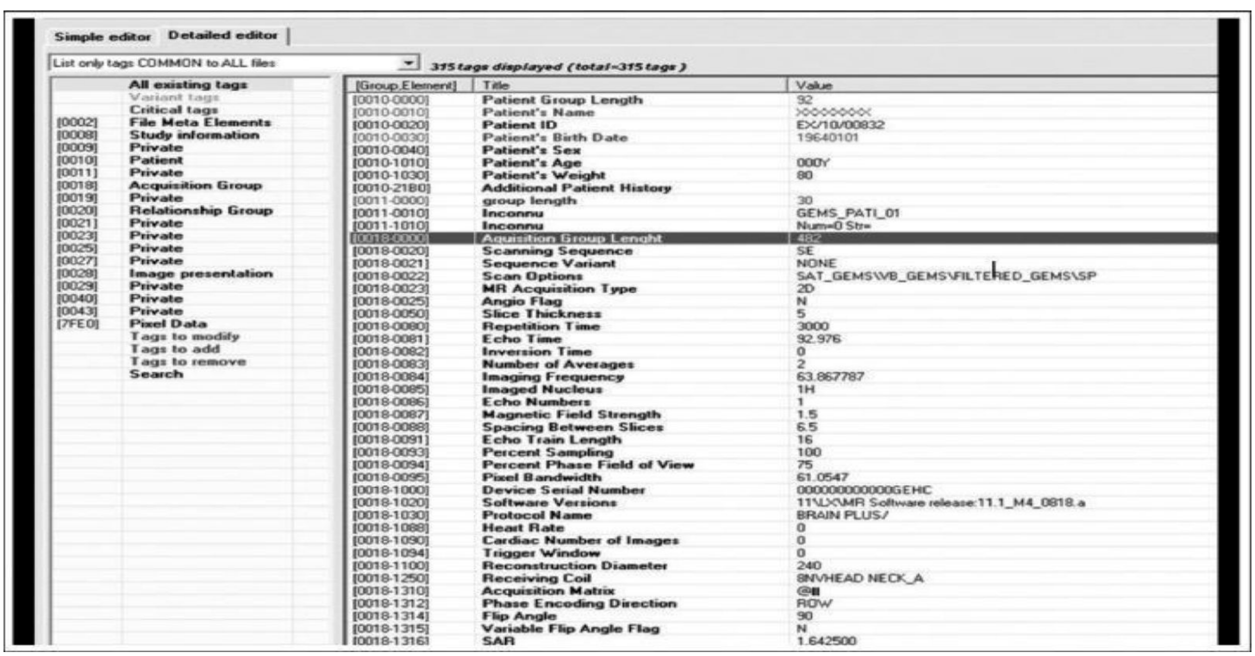
Publisher	Name	Subscribers
DigiMed Client	Archived Image Retrieval Event	Archived Image Retrieval Lambda Function
DigiMed Client	Archived Image Retrieval Request Event	DigiMed Client
Sherlock Request Lambda Function	CAD Request Event	Computer Aided Diagnosis (Sherlock)
Cloud Formation Template Storage Bucket	Cloud Formation Template Storage Bucket Change Event	Provisioning Microservice
DigiMed Client	Incorrect CAD Analysis Feedback Event	Training Data Collection Service
DigiMed Client	MRI Image Storage Event	Sherlock Request Lambda Function
Configuration And Activation Microservice	Product Configuration Change Event	Product Support Portal Integration Microservice
DigiMed Client	Product Configuration Change Request Event	Configuration And Activation Microservice
Training Data Storage Bucket	Training Data Storage Bucket Event	Model Training Service

4.5 Appendix 5: DICOM File Format Showing Data Attributes

The structure of the file consists of an aggregate of a header and image(s), and information in the header contains standardized constant series of tags. The header contains information regarding the patient's protected health information (PHI), such as - name, sex, age in addition to other all information required by the computer to correctly display the image, such as equipment used to capture the image. The header also contains context information to the medical treatment, such as medical practitioners seen and appointment information.



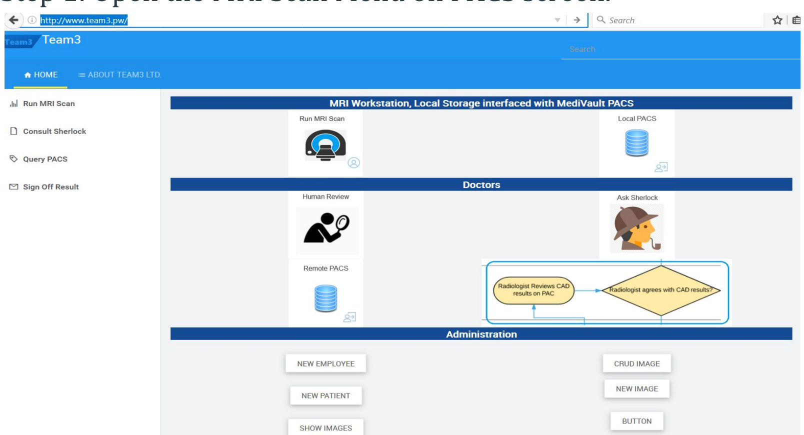
Following the header is a single attribute (7FE0) that contains all the pixel intensity data for the image. Storage of the data is in binary series of 0s and 1s, which can be reconstructed into the corresponding image using the information from the header. This attribute may contain information regarding a single image, multiple frames of a study, or a cine loop, depending on the modality that has generated the image. The header data information is encoded within the file to prevent separation from image data; else computers will not know how to reconstruct the scans or not able to map images with corresponding PHI, leading to a potential medico-legal situation (Managing DICOM images, 2017).



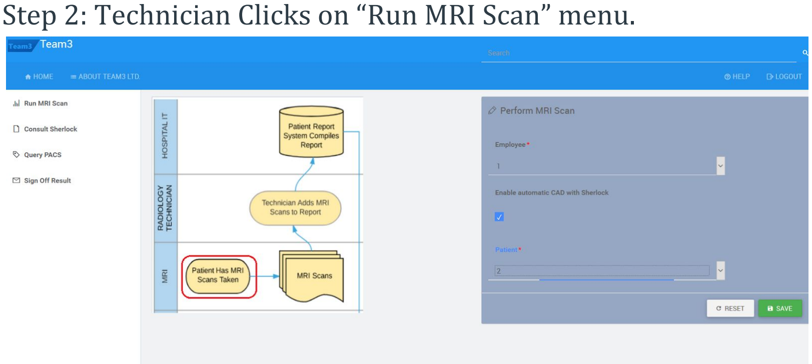
Grouping of the already mentioned tags forms data elements. The figure below is an example of how this is formatted. The group “0010” contains patient information and is 92 bits in length. It contains the patient's name in the tag “0010–0010,” the patient's identification number in the tag “0010–0020,” birth date in the tag “0010–0030,” and so on. Similarly, the group “0018” contains information regarding the acquisition. It is 482 bits long and contains several elements that convey the MRI acquisition parameters. The group “0028” encodes image presentation and is responsible for display of the image on a monitor.

4.6 Appendix 6: Wireframe of Sherlock Service Workflow

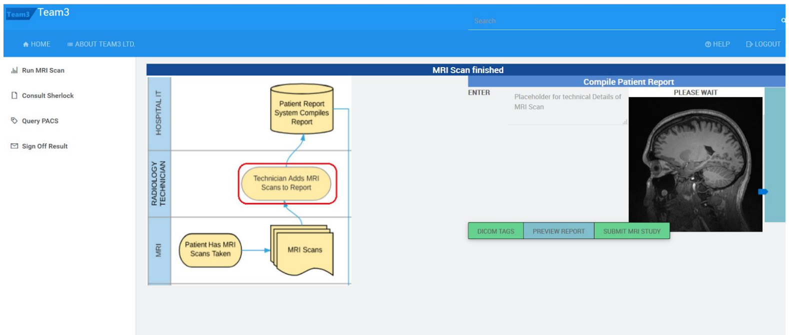
Step 1: Open the MRI Scan Menu on PACS screen.



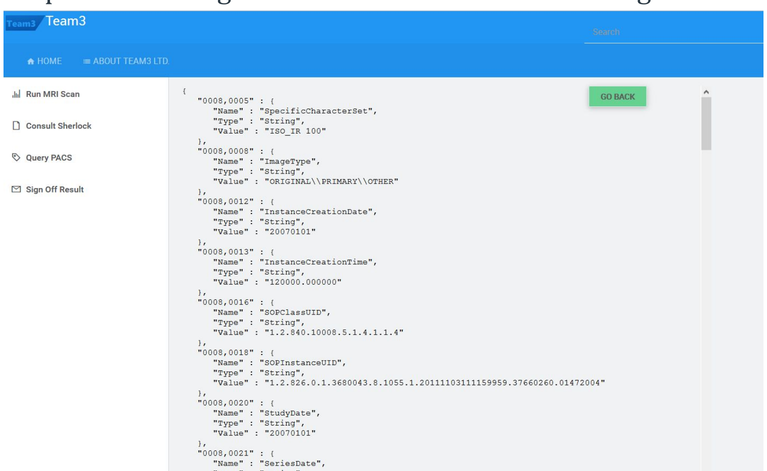
Step 2: Technician Clicks on “Run MRI Scan” menu.



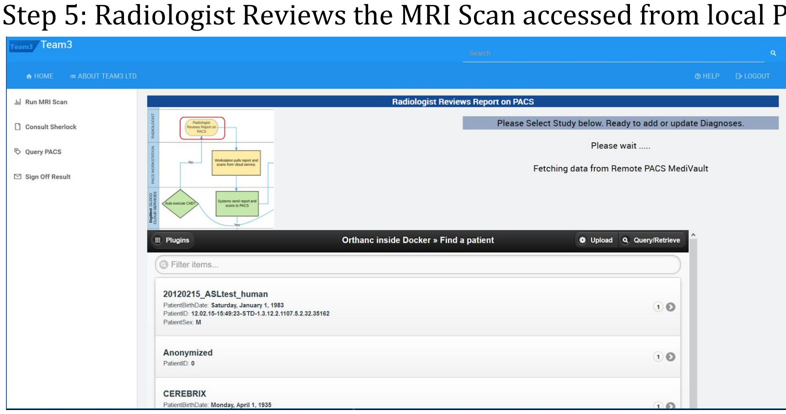
Step 3: Technician Adds MRI Scan to Report.
Button Pressed: “DICOM Tags” first, then “Submit MRI Study”

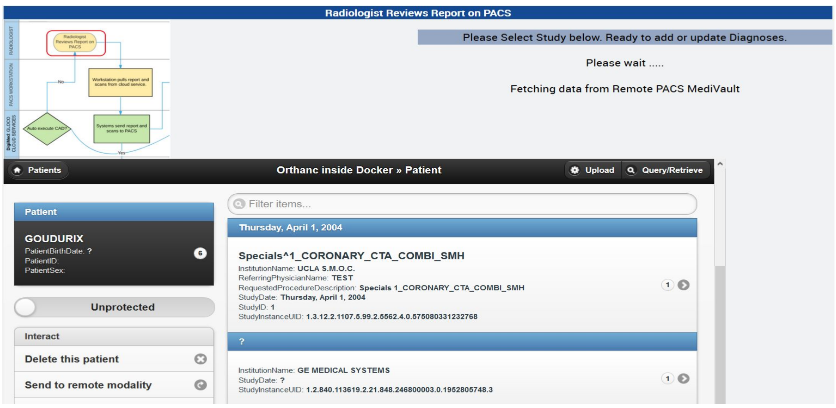


Step 4: DICOM tags will be fetched from local storage to MediVault cloud storage.

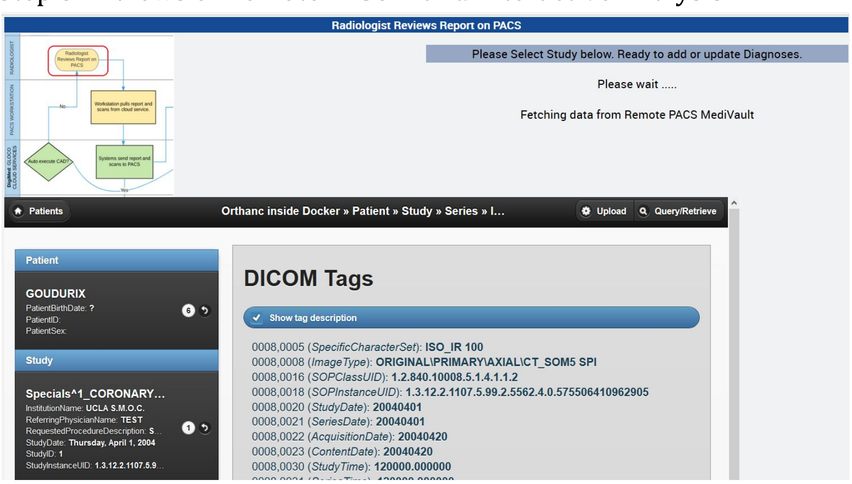


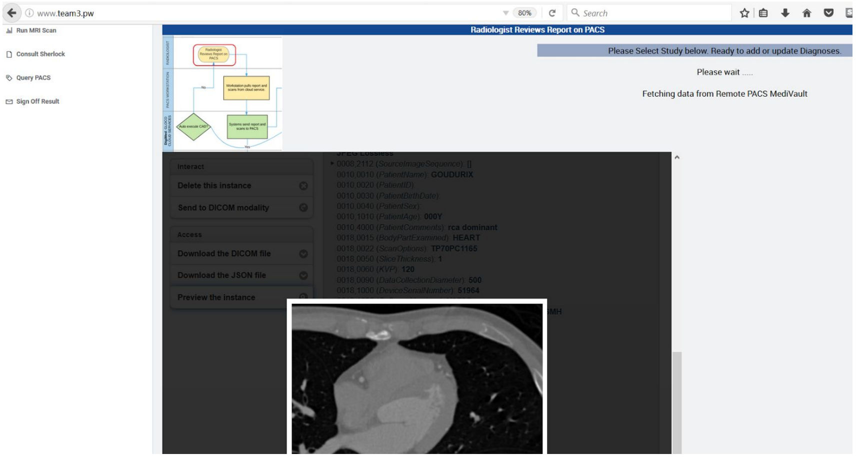
Step 5: Radiologist Reviews the MRI Scan accessed from local PACS machine.



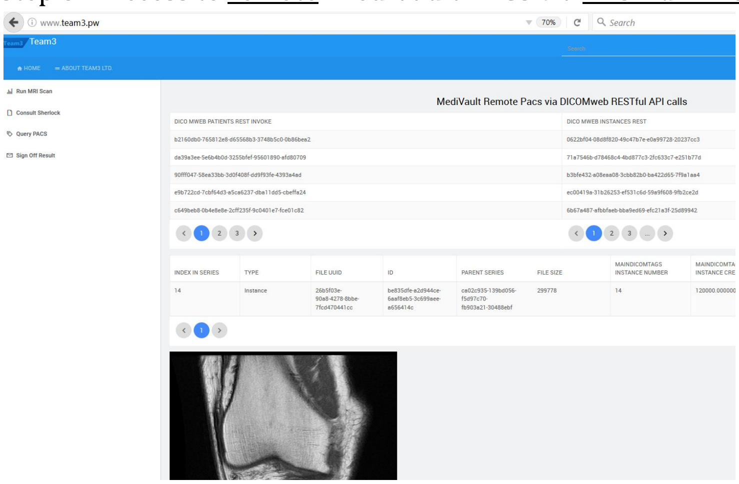


Step 5.1: Views of Remote DICOM and Interactive Analysis

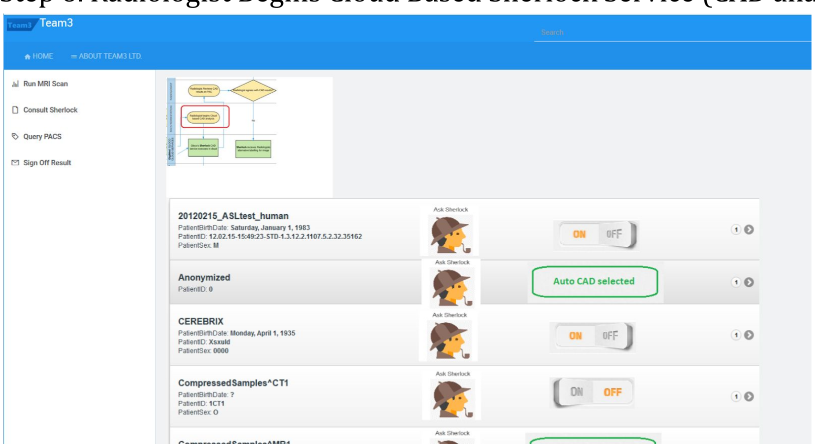




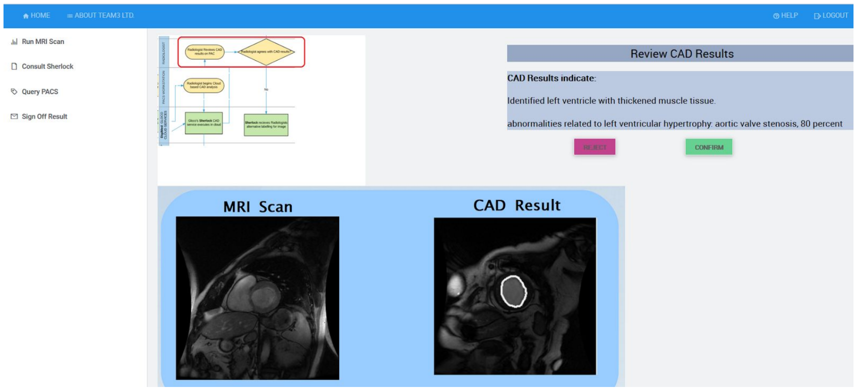
Step 5.2 Access to remote MediVault PACS via RESTful "DICOMweb" API



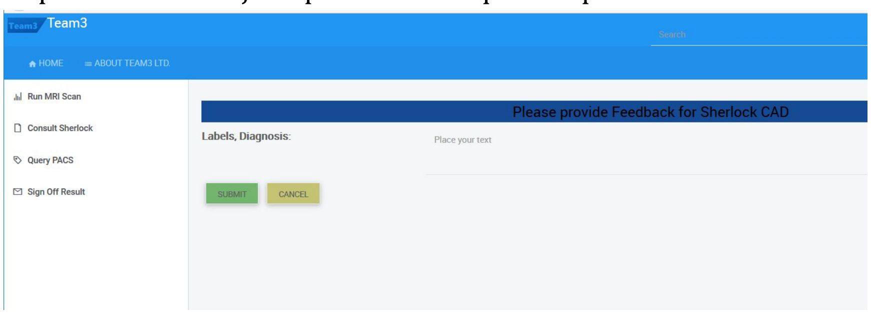
Step 6. Radiologist Begins Cloud Based Sherlock Service (CAD analysis).



Step 7. Radiologist Reviews Sherlock service results and confirmation.



Step 7.1 Button “Reject” pressed -> Request to provide Feedback



4.7 Appendix 7: Implementation Methodology

4.7.1 Top-Down Decomposition of the overall Product

Independent from a specific software development approach the overall final product can be broken up into three different “Product Categories” which can be developed independently from each other to a high degree. Another category consists of features and functions spanning these three product categories which must be incorporated into the development process.

If the overall product were to be developed by a single team in a waterfall style nevertheless a particular sequence, derived from a top-down decomposition from general to specific, would be required to allow for unforeseen interdependencies occurring during each of the design phases or even later in regression tests. Figure 28 shown below depicts this approach.

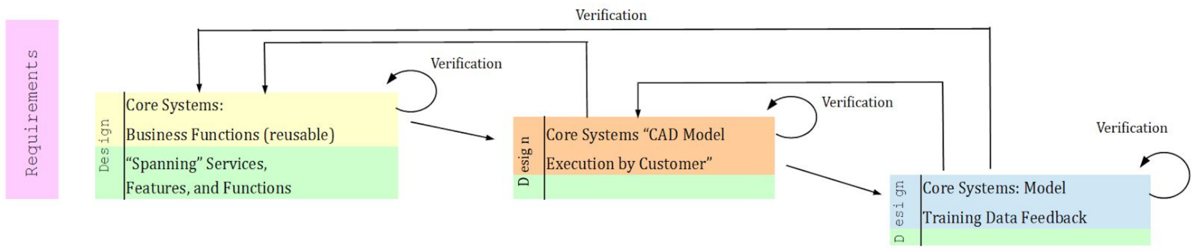


Figure 28. An (impractical) Sequence of Waterfall Models based on Feature Decomposition

Even large and complex distributed systems were planned and implemented this way. However, this usually relates to systems which have evolved over a long period of time. Gloco's endeavour is *different* as it is a new development. The waterfall model only serves as a model for risk identification and a more appropriate way to manage implementation.

4.7.2 Appendix Shared Features Analysis for distributed Agile Teams

	USER STORY													
FEAT	US_1	US_6	US_7	US_2	US_4	US_3	US_5	US_13	US_12	US_9	US_8	US_10	US_11	SUM
FID_2	1	1	1	1	1	1	1	1	1	1	1	1	1	13
FID_15	1	1	1	1	1	1	1			1	1			9
FID_24	1	1	1	1	1	1	1		1	1				9
FID_37	1			1	1	1	1	1						6
FID_52	1	1	1		1	1								5
FID_33								1	1			1	1	4
FID_48		1	1		1	1								4
FID_78	1	1			1		1							4
FID_82		1	1	1	1									4
FID_112	1	1	1											3
FID_119	1					1	1							3
FID_43	1			1			1							3
FID_63	1			1	1									3
FID_70	1			1	1									3
FID_75		1	1		1									3
FID_86	1	1	1											3
FID_89	1			1		1								3
FID_103	1					1								2
FID_105	1									1				2
FID_110	1			1										2
FID_115			1	1										2
FID_117		1	1											2
FID_123		1	1											2
FID_125		1	1											2
FID_127								1	1					2
FID_46								1			1			2
FID_61	1				1									2
FID_66	1			1										2
FID_68	1			1										2
FID_73		1	1											2
FID_92	1			1										2
FID_99		1	1											2
SUM	20	15	15	14	12	9	7	5	4	4	3	2	2	

4.7.3 List of Features and Description used in Appendix 4.7.2

Feature ID	Feature Description
FID_2	Provide elastic compute resources
FID_15	Directly connect the GLOCO Enterprise Systems with AWS
FID_24	Direct Connect the GLOCO Enterprise to AWS
FID_37	Provide encrypted file based storage in S3 buckets for DICOM images
FID_52	Import and Export a materialized view of data that is necessary to provide info to the GLOCO Enterprise Integration Micro Service.
FID_33	Provide an ability to manage encryption keys that is secure, compliant, and auditable
FID_48	Provide service utilization and billing data at a sufficiently granular level to support required customer utilization reports and dashboard use cases.
FID_78	Proactively insure Enterprise Customer Service has the same information as has been provided to the customer
FID_82	Publish and mediate Customer Service Web Services
FID_112	Provide service billing and utilization information
FID_119	Aggregate service access logs
FID_43	Provide an ability to notify the Machine Learning framework and Machine Learning framework server that there is new model training or CAD work to do
FID_63	Act as a workflow orchestrator to the Machine Learning Framework Server based on the customer's configuration for CAD automation
FID_70	Subscribe to the CAD request Queue and orchestrate CAD report execution
FID_75	Provide a seamless Customer Service experience to Digital Product customers
FID_86	Publish existing SOAP service for consumption by Digital Service Cloud Services
FID_89	Convert DICOM images to standard images and de identified text for machine learning
FID_103	The gateway will be configured to mount an NFS File System to the DigiMed Client
FID_105	Provide application monitoring
FID_110	Store training data for machine learning training
FID_115	Provide initial product configuration to the product support portal
FID_117	Publish new DigiMed sales events along with sufficient information needed to provision the service
FID_123	Provide unified product support to customers including digital products
FID_125	Provide sales and subscription events to enable new product provisioning
FID_127	Configured AWS Storage Gateway built in integration with AWS CloudTrail, AWS KMS, and IAM.
FID_46	Provide a storage cache for MRI Images
FID_61	Store an MRI DICOM image into an S3 bucket that is visible to the respective customers AWS Storage gateway when the customer requests retrieval of an archived image
FID_66	Support optional CAD service parameters, which can vary on a per user basis, from the Configuration Micro Service. It then syntactically and semantically translates those configurations into the right sequence of MLF Server API calls so that the CAD Diagnosis is done in the manner the customer specified
FID_68	Perform detailed orchestration of the CAD process per the customer's individual configuration parameters
FID_73	Provide unified product customer service
FID_92	Convert from Standard Image and Text format back to DICOM
FID_99	Provide notification of Digital Service initial or reconfigurations to other services such as the CAD Micro Service, Billing, Customer Support etc.

4.7.4 List of User Stories and Description Used in Appendix 4.7.2

ID used in Appendix	Identifier in Model	Description
US_1	EA-RA-1	Request CAD Analysis
US_2	EA-RA-2	Configure Automatic CAD Reports for all MRI Images
US_3	EA-RA-3	Access Cloud Based PACS Reports
US_4	EA-RA-5	Medical Image Profiles and Archive Image requests
US_5	EA-RT-1	Radiology Technician Storage of MRI Images
US_6	EB-MN-1	Provider Manager Services Subscription
US_7	EB-RA-3	Radiologist Display of Services Available
US_8	NF-CRS-1	Ability to Cache 12 hours of data
US_9	NF-ICP-1	99.9 % Availability
US_10	NF-ICP-3	Secure Non Repudiable Communication
US_11	NF-ICP-6	Role Based Security
US_12	NF-ICP-7	PHI Read Access Audit Trail
US_13	NF-ICP-8	PHI Encryption

5 References

ACR, (2017). *Imaging 3.0 Case Study: An Extra Set of Eyes*, retrieved from: https://www.acr.org/Advocacy/Economics-Health-Policy/Imaging-3/Case-Studies/IT/An-Extra-Set-of-Eyes

Architecting for HIPAA Security and Compliance on Amazon Web Services, https://d0.awsstatic.com/whitepapers/compliance/AWS_HIPAA_Compliance_Whitepaper.pdf

AT&T.(2012). Medical Imaging in the Cloud - AT&T - ATT.com. Retrieved November 25, 2017, from https://www.corp.att.com/healthcare/docs/medical_imaging_cloud.pdf

Daher, N.M. (2016, March 17), *The Internet of Medical Imaging Things is Here,* in: DiagnosticImaging, Retrieved from http://www.diagnosticimaging.com/pacs-and-informatics/internet-medical-imaging-things-here

Flannery, J. L. (2017, June 1). *GE Healthcare 2017 investor summary.* Retrieved from GE: https://www.ge.com/investor-relations/sites/default/files/GE%20Healthcare_Bernstein%20Annual%20Strategic%20Decisions%20Conference_060117.pdf

GE. (2016, June 23). GE Digital. Retrieved from GE: https://www.ge.com/sites/default/files/ge_webcast_presentation_06232016_1.pdf

Github (2017). AWS Serverless Express, retrieved from: https://github.com/awslabs/aws-serverless-express

Gutierrez-Martinez, Josefina (2015, Aug 28). *Business Model for the Security of a Large-Scale PACS, Compliance with ISO/27002:2013 Standard*. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4501951/

IHE, Integrating the Healthcare Enterprise (2017), *IHE Radiology integration profiles from the IHE Radiology Technical Framework*, Retrieved from https://www.ihe.net/Technical_Frameworks/#radiology

IHE, (2009). *Presentation of Processed Images - Brief Proposal*, retrieved from: http://wiki.ihe.net/index.php/Presentation_of_Processed_Images_-_Brief_Proposal

IT, (2017). How Artificial Intelligence Will Change Medical Imaging, retrieved from: https://www.itnonline.com/article/how-artificial-intelligence-will-change-medical-imaging

Li, F.F. (2015). *How we are teaching computers to understand pictures.* Retrieved from TED: https://www.ted.com/talks/fei_fei_li_how_we_re_teaching_computers_to_understand_pictures

Malinverno, Paola. Magic Quadrant for Full Life Cycle API Management. (October 27, 2016). Retrieved from https://www.gartner.com/document/3488151 on October 6, 2017.

Massat, Mary Beth. (April 9, 2008). *Building the PACS ROI Case*. Retrieved from https://www.itnonline.com/article/building-pacs-roi-case

MITA, Medical Imaging and Technology Alliance (2017), *The DICOM Standard*, Retrieved from: http://dicom.nema.org/standard.html

Panda, R., (2012, February 1), *Ins and Outs of Cloud-Based PACS* , in: Imaging Technology News, Retrieved from: https://www.itnonline.com/article/ins-and-outs-cloud-based-pacs

Royce, W.W., 1970, March. Managing the development of large software systems: concepts and techniques. In Proceedings IEEE Wisconsin (pp. 1-9). IEEE Computer Society Press.

SAP Crystal Reports Viewer | Crystal Solutions - SAP.com. https://www.sap.com/canada/products/bi-platform/crystal-reports-viewer.html. Accessed 28 Oct. 2017.

Scrum Institute, (2017a). *Multi-Team Coordination & Planning*, retrieved from: http://www.scrum-institute.org/Multiteam_Coordination_and_Planning.php

Scrum Institute, (2017b). *Distributed & Large Scrum Projects*, retrieved from: http://www.scrum-institute.org/Distributed_and_Large_Projects.php

Shen, D., Wu, G., & Suk, H. (2017, June 21). Deep Learning in Medical Image Analysis. Annu Rev Biomed Eng, 10: 221-248.

Siemens, (2017, August), What's new in TeamPlay?, Retrieved from https://bps-ealthcare.siemens.com/teamplay/sites/default/files/downloads/2017-09/170257_teamplay_customer_info_sheets_V070_en_0.pdf

Smith-Binman R, Miglioretti D.L. & Larson B.L.(2008). Rising Use Of Diagnostic Medical Imaging In A Large ... - NCBI - NIH. Retrieved November 25, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2765780/

Thomas, Anne. Mediated APIs: An Essential Application Architecture for Digital Business. Gartner (August 26, 2016). Retrieved from https://www.gartner.com/document/3418842 on October 7, 2017.

(n.d.). TensorFlow. Retrieved October 28, 2017, from https://www.tensorflow.org/

(n.d.). Managing DICOM images: Tips and tricks for the radiologist - NCBI - NIH. Retrieved October 29, 2017, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3354356/

(n.d.). Amazon Simple Storage Service (S3 .... Retrieved October 28, 2017, from https://aws.amazon.com/s3/