

# **Diagnostic Laboratory Manager**

## **PD2: Project Elicitation Plan and Result**

Submitted by – Group 5

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# **Diagnostic Lab Manager**

## **Project Elicitation Plan and Result**

### **Problem Description**

Through the digitalization of lab management tasks in compliance with the DISHA act, this project primarily aims to reduce the amount of manual work and paper used in a diagnostic centre's workflow. It allows the customer to manage everything electronically, view tasks, and take control of them without having to search for the paperwork again in various protocols and file formats. The end users can follow the test's development as well. The other parties involved can manage everything electronically with the aid of this application. It makes managing inventory and keeping track of all stocks much easier for the warehouse administrator.

#### **1.How does a current system work?**

The current system is operated manually. Every appointment is made through a walk-in, a phone call, or a WhatsApp message. The lab technician collects the sample and brings it to the laboratory after receiving the appointments. The lab technicians test these samples, which are labelled with the customer's name. After the sample has been examined, the findings are compiled, and the reports are either printed or sent via email. Additionally, the report is manually reviewed by the doctor via email. Reports from the imaging department must be carried physically because email copies do not allow for a clear view. All of the inventory is currently tracked manually, and there is no report available on how things are going.

#### **2. Common issues faced with the system?**

The current system involves a lot of paperwork, most of which is thrown away. All of these documents must be physically securely stored after the introduction of the DISHA (Digital Information Security in Healthcare Act) act in 2018. This creates a lot of tedious tasks and takes up a lot of space. Additionally, it is becoming difficult to manually email the report to the doctor and patients as well as generate and store reports and find the test's status. Some reports, such as imaging, need to be printed out and carried by the patient to the doctor. Sometimes we schedule the appointments without being aware that we are out of stock and must ask the patient to reschedule.

### **3. What are some reasons why you would create the new product??**

We use these diagnostic laboratory software to automate and streamline the laboratory testing process, reduce manual errors, reduce paper work, and increase efficiency and reporting of the inventory. The objective is to adhere to all security regulations while promptly delivering reliable and accurate test results to various stakeholders. It will be advantageous and easy to manage and view the status of each process flow to have a single platform for all parties involved.

### **5. Are there any constraints or rules to which the product must conform?**

Should be compliant with the DISHA regulations.

[https://www.nhp.gov.in/NHPfiles/R\\_4179\\_1521627488625\\_0.pdf](https://www.nhp.gov.in/NHPfiles/R_4179_1521627488625_0.pdf)

### **6. Which aspects of the product are most critical to creating business value?**

Giving the customer a thorough understanding of the process and delivering the results while maintaining all necessary security precautions will greatly enhance the value of the final product.

### **7. Is there any existing project/system documentation?**

There is no any existing system documentation provided.

### **8. Who are the different stakeholders in the system?**

Different stakeholders in this system will include laboratory technicians, lab assistants, doctors, patients, administrators, and supervisors.

### **9. What are the requirements of different stake holders.**

Laboratory technicians need a user-friendly interface to perform tests, manage test results, and generate reports.

Lab Assistant need to get the details of the patients who booked the test and need a sample to be collected.

Doctors need access to test results in real-time and the ability to view patient reports.

Patients need access to their test results and the ability to request appointments and view their medical history.

Administrators need a system that can manage appointments, billing, and

Supervisor needs to be able to look after the inventory, and generate reports and statistics

## **Functional Requirements**

### ***Functionality:***

#### **What will the system do?**

These diagnostic laboratory software helps to automate and streamline the laboratory testing process, lower manual error rates, eliminate paper work, improve inventory reporting efficiency, and give all stakeholders access to a single platform.

#### **When will the system do it ?**

The application/system is available 24/7 and can be accessible from anywhere over the internet.

#### **Are there several modes of operation?**

This application uses cloud-based mode and is hosted on remote servers and is accessed through the internet.

#### **What kinds of computations or data transformations must be performed?**

Data is encrypted for security purposes as it includes personal information of the patients. The data is normalized for storing the data into the database. Several analytics will be drawn for the inventory and the summary reports.

#### **What are the appropriate reactions to possible stimuli? Essential**

The application will respond according to the user inputs and also should have the proper backup mechanism even in the event of system failure. Proper communication need to be done in the event of failure or when running out of inventory.

#### **How will the system handle the transfer of billing and payment information? Essential**

This system uses payment gateways for performing bill payments.

### ***Data:***

#### **For both input and output, what should be the format of the data?**

For the input like patient information, the data is entered in text fields from the GUI applications and assigning the labels to the test samples require barcodes reading in UPC format. Other data formats are required for uploading test results in the form of images and videos and can be pdf documents containing the results. For the imaging reports, the report data for both input and output is DICOM format.

#### **Must any data be retained for any period of time? Essential**

As per the government regulations, the patient data should be retained for at least three years.

### **Design Constraints**

#### ***Physical Environment:***

##### **Where is the equipment to be located?**

The devices used for interaction with the application are located at the diagnostic laboratory, at the doctor, inventory managers PD, patients and sample collectors.

##### **Is there one or several locations? Desirable**

The devices are located at several locations and can be accessed from anywhere.

##### **Are there constraints on size of the system (Handheld/Server/PC etc)? Essential**

No, there are no special constraints on size of the device used for accessing the application runs as it is deployed on cloud web server.

##### **Are there any COTS or other constraints on programming language, OS because of existing software components?**

We need to deploy the product on the cloud, so we will be using the COTS solution for cloud where the application requires the cloud-based infrastructure management tools and cloud security solutions.

## ***Interfaces:***

### **Is input coming from one or more other systems (“upstream”)?**

The input can be from payment gateways, bar code scanner, imaging devices and other diagnostic devices in the laboratory.

### **Is output going to one or more other systems (“downstream”)?**

The data is stored in the database, print requests to the printers, payment gateways, web-based image viewing APIs.

### **What is the protocol for the upstream and downstream systems?**

HTTPS, TLS, API, DICOMweb, Code 39 for barcode scanners are the protocols used in this system.

## ***End-Users:***

### **Who will use the system?**

Different stakeholders in this system will include laboratory technicians, lab assistants, doctors, patients, administrators, and supervisors.

### **Will there be several types of users?**

Yes, there will be several types of users and they will be having the role based access to the data and interface.

### **What is the skill level of each user? Desirable**

All the users should have basic knowledge of operating a computer and web. The technicians should be skilful to operate the equipment and enter the correct details as per the prompt from the system.

### **What type of training and support will be provided for users of the system?**

For the naive user, the documentation and videos for interaction and flow will be provided for different roles.

## **Quality Requirements**

### ***Performance:***

**Are there constraints on execution speed, response time or throughput?**

**Essential**

Yes, the response time should be faster without any delays and the test life cycle have a standard time for operating.

**How much data will flow through the system?**

As a rough estimate, a single diagnostic lab may generate hundreds of gigabytes of data each year. For larger labs or those that perform a high volume of tests, this number could be even higher.

**How often will data be received or sent?**

The data will be sent and received frequently and data is handled between different systems as different stake holders are involved.

**How will the system handle quality control and quality assurance processes for laboratory testing?**

Using workflow management, data validation and reporting and compliance to the all the security measures and policies that are involved.

### ***Usability and Human Factors:***

**What kind of training will be required for each type of user? Optional**

Basic knowledge of understanding the application language which is English and using of the application using web and mobile interfaces.

**How easy should it be for a user to understand and use the system?**

It is very easy to use and operate the system even by the naïve user as now a days everyone is handling smart phone and having basic knowledge on computers usage.

## ***Security:***

### **Must access to the system or information be controlled?**

Yes, this application deals with patients sensitive data and all the access to the information is to be restricted. Only authorized users can access the required data and follows DISHA Act.

### **Should each user's data be isolated the data of other users? Essential**

Yes, the details of one patient should not be revealed to others patients.

### **Should user programs be isolated from other programs and from the OS?**

Yes, it should be isolated and this system should not be accessed by other programs running on the same device as it deals with sensitive data.

### **How will the system ensure the security and privacy of patient information?**

The system uses proper encryption standards and all the security protocols while exchanging the data with external entities and compliant to DISHA Act.

## ***Reliability and Availability:***

### **Must the system detect and isolate faults? Essential**

Yes, the system should be resilient to faults, if there is any failure or any resources running out of stock, the system should automatically detect and communicate with relevant stakeholders.

### **What is the prescribed Mean Time between Failures?**

The system should be available 99% of the time.

### **Is there a maximum time allowed for restarting the system after a failure?**

The downtime should not be more than 15 min during peak period and 2 hours during non peak.

### **How often will the system be backed up? Essential**

The system need to be backed up twice a day.

### **Must backup copies be stored at a different location? Essential**

Yes, if there is any problem with the current storage of data then this backup is quite helpful to restore the data.



### ***Maintainability:***

**When and in what ways might the system be changed in the future?**

**Desirable**

The system is hosted on the cloud and based of the policies and security requirements, the system will be altered.

**How easy should it be to add features to the system?** **Desirable**

The system should be adaptable and integrable for new features in the future.

**How easy should it be to port (or migrate) the system from one platform to another?** **Desirable**

It should be done easily and we are hosting on the cloud and there should be no cloud provider lock in to the application.

### ***Precision and Accuracy:***

**What is the acceptable level of error in the software's output?**

This system cannot tolerate error and it make causes health risk for patients.

**How will the software handle errors in input data?**

Proper validation methods need to implemented for handling the errors in input data.

### ***Timeline /Cost:***

**When should the application need to be delivered?**

The first prototype should be delivered within two quarters.

**Does this application requires ongoing maintenance?**

Yes, this application requires maintainence and frequent updates based on the requirements

**Stakeholder List**

SNo	Name	Role
1	Suresh Pamu	Customer
2	Ram Dharavath	Doctor