

Electronic Trial Master File

INTERNSHIP REPORT

Submitted By

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MARWADI EDUCATION FOUNDATION GROUP OF INSTITUTIONS

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CERTIFICATE

This is to certify that the project entitled “**ETMF**” has been carried out by “**Niyati Pithadiya (200570116505)**” under my guidance in partial fulfilment for the degree of Bachelor of Engineering in **Information Technology** – 8th Semester of Gujarat Technological University, Ahmedabad during the academic year 2022- 2023.

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DECLARATION

I hereby declare that the Internship / Project report submitted along with the Internship Project entitled “ETMF” submitted in partial fulfillment for the degree of Bachelor of Engineering in Information Technology to Gujarat Technological University, Ahmedabad, is a Bonafede record of original project work carried out by me, at Creole studios under the supervision of Mr. Virendra barad and that no part of this report has been directly copied from any students reports or taken from any other source, without providing due reference.

Name of the Student

Sign of Student

Niyati Pithadiya

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I would like to extend my heartfelt thanks with a deep sense of gratitude and respect to all those who have provided me immense help and guidance during this project. I would like to express my sincere thanks to sarjen systems, mentor Mr virendra barad, and internal faculty guide Prof. Mitesh patel, for providing a vision of the system and for giving me an opportunity to undertake such great work. I am grateful for the guidance, encouragement, understanding, and insightful support in the development process. I would like to extend my immense gratitude to Prof. (Dr.) Damodharan Palaniappan, Head of Information Technology Department, Marwadi Education Foundation Group of Institutions, Rajkot, for continuous support, encouragement and motivation.

Yours sincerely,
Niyati Pithadiya
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ABSTRACT

Electronic Trial Master File (ETMF) An electronic trial master file is a specialized content management system used to manage clinical documents; collection of essential documents such as IEC Approved Protocol, Information Boucher (IB), CRF, ICD, CV, Insurance Certificate, etc., across the life cycle of a clinical trial – conducting of a clinical trial to be reconstructed .

Methods of Capturing the data clinical trials. Electronic Trial Master File (eTMF) solution is a clinical collaboration platform for managing the Data of Subject, Activity, Tracking, Maintaining, Archiving clinical trial documents. It allows life sciences companies to streamline processes, automate information exchange, and reduce the administrative overhead associated with running clinical trials.

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CHAPTER 1 OVERVIEW OF THE COMPANY

1.1 History

Sarjen System was established 25 years ago by the intellectuals to provide such software solutions that are functional, reliable, maintainable and cost-friendly to our existing and growing client and customer base. To consistently cater to their growing needs for an optimal solution, ensuring excellent support and service platform to give a hassle-free experience in achieving their dreams.

1.2 Different Product

Our company provides a variety of services Software development, Web-Portal development, Website Designing, E-commerce development, SEO, Customized App Development, Data Management Software with cloud hosting facility, etc.

1.3 Organization Chart

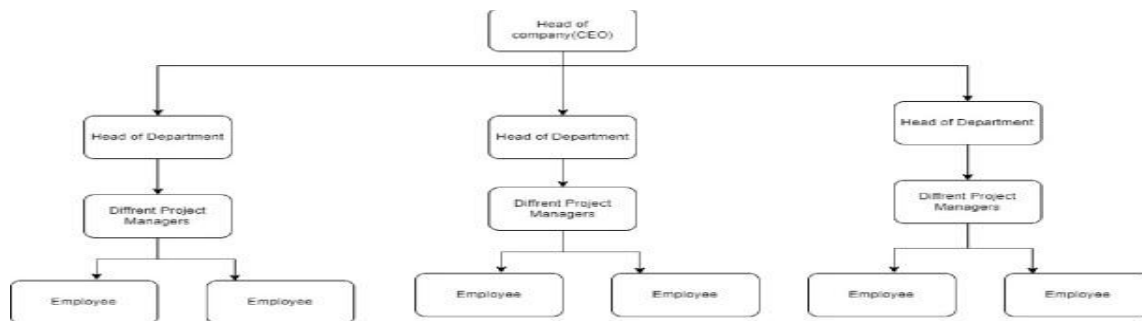


Figure 1. Organization Chart

1.4 Capacity of Department

There are currently 50-100 employees working in this company and there is a different capacity of each department. The Web development department has the capacity of developing around 30 big full-fledged websites a year. App development department has the capacity of developing around 10 big full-fledged mobile applications a year.

CHAPTER 2 OVERVIEW OF DEPARTMENT

2.1 Work being carried out in Department

- Planning
- Analysis
- Designing
- Implementation
- Testing
- Deployment
- Maintenance

2.2 Technical Specifications of each Department

React js:

React.js is an open-source JavaScript library that is used for building user interfaces specifically for single-page applications. It's used for handling the view layer for web and mobile apps. React also allows us to create reusable UI components.

Node.js:

Node.js is a platform built on Chrome's JavaScript runtime for easily building fast and scalable network applications. Node.js uses an event-driven, non-blocking I/O model that makes it lightweight and efficient, perfect for data-intensive real-time applications that run across distributed devices.

React Native:

React Native is an open-source JavaScript framework, designed for building apps on multiple platforms like iOS, Android, and also web applications, utilizing the very same code base. It is based on React, and it brings all its glory to mobile app development.

2.3 Sequence of Operation

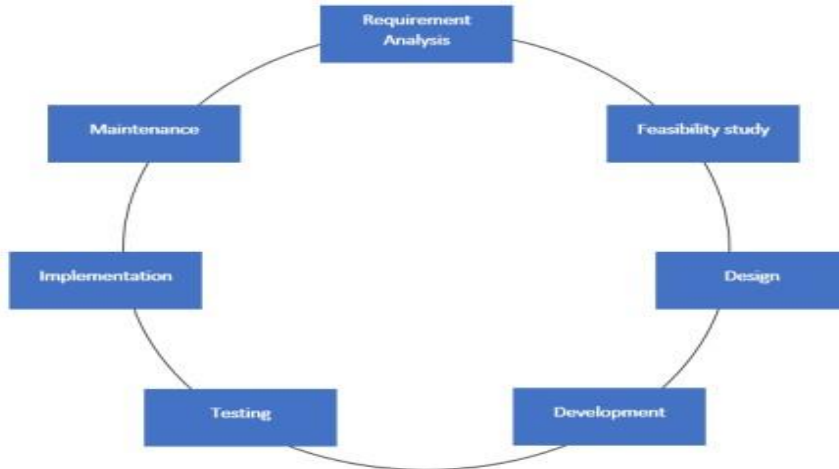


Figure 2. Sequence of Operation

2.4 Stages of Production

Planning

Planning for the quality assurance requirements and identification of the risks associated with the project is also done in the planning stage. The outcome of the technical feasibility study is to define the various technical approaches that can be followed to implement the project successfully with minimum risks.

In this third phase, the system and software design documents are prepared as per the requirement specification document. This helps define overall system architecture. This design phase serves as input for the next phase of the model.

There are two kinds of design documents developed in this phase:

High-Level Design (HLD)

- Brief description and name of each module
- An outline about the functionality of every module
- Interface relationship and dependencies between modules
- Database tables identified along with their key elements

Low-Level Design (LLD)

- Functional logic of the modules

- Database tables, which include type and size
- Complete detail of the interface
- Addresses all types of dependency issues
- Listing of error messages
- Complete input and outputs for every module

Implementation / coding

Once the system design phase is over, the next phase is coding. In this phase, developers start to build the entire system by writing code using the chosen programming language. In the coding phase, tasks are divided into units or modules and assigned to the various developers. It is the longest phase of the Software Development Life Cycle process. In this phase, developers need to follow certain predefined coding guidelines.

Testing

Once the software is complete, it is deployed in the testing environment. The testing team starts testing the functionality of the entire system. This is done to verify that the entire application works according to the customer requirement.

Deployment

Once the software testing phase is over and no bugs or errors left in the system then the final deployment process starts. Based on the feedback given by the project manager, the final software is released and checked for deployment issues if any.

- Bug fixing – bugs are reported because of some scenarios which are not tested at all
- Upgrade – Upgrading the application to the newer versions of the Software
- Enhancement – Adding some new features into the existing software

CHAPTER 3

INTRODUCTION TO PROJECT

3.1 Project Summary:

Electronic Trial Master File (eTMF) An electronic trial master file is a specialized content management system used to manage clinical documents; collection of essential documents such as IEC Approved Protocol, Information Boucher (IB), CRF, ICD, CV, Insurance Certificate, etc., across the life cycle of a clinical trial – conducting of a clinical trial to be reconstructed .

Methods of Capturing the data clinical trials.

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What EDC Gives:

- eTMF Process Management and Workflow of the Activity Wise Management
- In an eTMF,

3.2 Purpose:

- The purpose of the ETMF project is to create a decentralized document management ecosystem that provides a secure and efficient way for individuals and organizations to manage and organize their documents, data, and workflows.
- The purpose of a ETMF project can vary depending on the specific project in question.
- Currently, many document management systems are centralized and rely on a trusted third party to manage and secure data. However, this approach can be vulnerable to security breaches, data loss, and censorship.
- ETMF aims to solve these issues by providing a decentralized alternative that uses blockchain technology to ensure the security and immutability of data. By using smart contracts and a decentralized network of nodes, DoQstack can provide a more secure and transparent system for managing documents.
- In addition, the protocol aims to provide interoperability between various dApps, allowing users to seamlessly transfer data and workflows between different applications. This can help streamline the document management process and reduce the need for multiple systems.
- Overall, the purpose of the ETMF project is to create a more secure, efficient, and accessible document management ecosystem that empowers individuals and organizations to manage their data in a decentralized and user-friendly way.

These objectives in this project.

- i** Decentralization: ETMF aims to provide a decentralized alternative to centralized document management systems by using ETMF technology to ensure the security and immutability of data.
- ii** Interoperability: The protocol aims to provide interoperability between various dApps, allowing users to seamlessly transfer data and workflows between different applications.
- iii** Usability: ETMF aims to create a user-friendly interface that simplifies the document management process for both individuals and organizations.

3.3 Scope:

The scope of the ETMF project is focused on creating a decentralized protocol and ecosystem for document management, data organization, and workflow automation.

The protocol aims to provide a secure and transparent system for managing documents, with features such as access control, audit trails, and versioning. Users can store, share, and collaborate on documents with others in a decentralized and trustless manner.

In addition to document management, ETMF also aims to provide tools for data organization and workflow automation. This can include features such as data tagging, categorization, and integration with external systems such as email or project management tools.

3.4 Tools and Technology:

3.4.1 Java:

- Java was created at [Sun Microsystems, Inc.](#), where James Gosling led a team of researchers in an effort to create a new language that would allow consumer electronic devices to communicate with each other. Work on the language began in 1991, and before long the team's focus changed to a new [niche](#), the [World Wide Web](#). Java was first released in 1995, and Java's ability to provide interactivity and multimedia showed that it was particularly well suited for the Web. React Native was built based on React – a JavaScript library, which was already hugely popular when the mobile framework was released.

3.4.2 JavaScript:

- JavaScript (js) is a light-weight object-oriented programming language which is used by several websites for scripting the webpages.
- It is an interpreted, full-fledged programming language that enables dynamic interactivity on websites when applied to an HTML document.
- It was introduced in the year 1995 for adding programs to the webpages in the Netscape Navigator browser. Since then, it has been adopted by all other graphical web browsers.

3.4.3 Visual Studio Code:

- Visual Studio Code is a freeware source-code editor for Windows, Linux and macOS. Features include for debugging, Syntax highlighting, intelligent code completion and snippets and embedded git.

3.4.4 Firebase:

- Firebase is a platform developed by Google for creating mobile and web applications. Provide built in function and libraries to integrate with react native and easy to manage data with a good user interface.

3.4.4 Sql:

- Microsoft SQL Server is a relational database management system developed by Microsoft. As a database server, it is a software product with the primary function of storing and retrieving data as requested by other software applications—which may run either on the same computer or on another computer across a network (including the Internet)

CHAPTER 4

PROJECT MANAGEMENT

4.1 Project Planning:

4.1.1 Project Planning:

- Project planning is a subset of project management that relates to the use of schedules like Gantt charts to plan and report progress within a project setting.
- The project scope is defined first, followed by the best methods for completing it.
- The goals of the project have been established. Following this, the durations for the various jobs that must be completed are calculated.
- A work breakdown structure is used to list and organize the tasks that must be done.
- Various aspects of a project, including project management, are routinely coordinated using project planning.

4.1.2 Project Scheduling:

- Project scheduling is the culmination of a planning process that is an important part of software project management.
- A project management road map is created when scheduling is combined with estimation methodologies and risk analysis.
- The beginning point for scheduling is the process composition. The features of the project are used to adapt a task set that is suited for the job at hand.
- The important project path, a timeline chart, and other project data are all generated using the task network.

4.2 Project development approach:

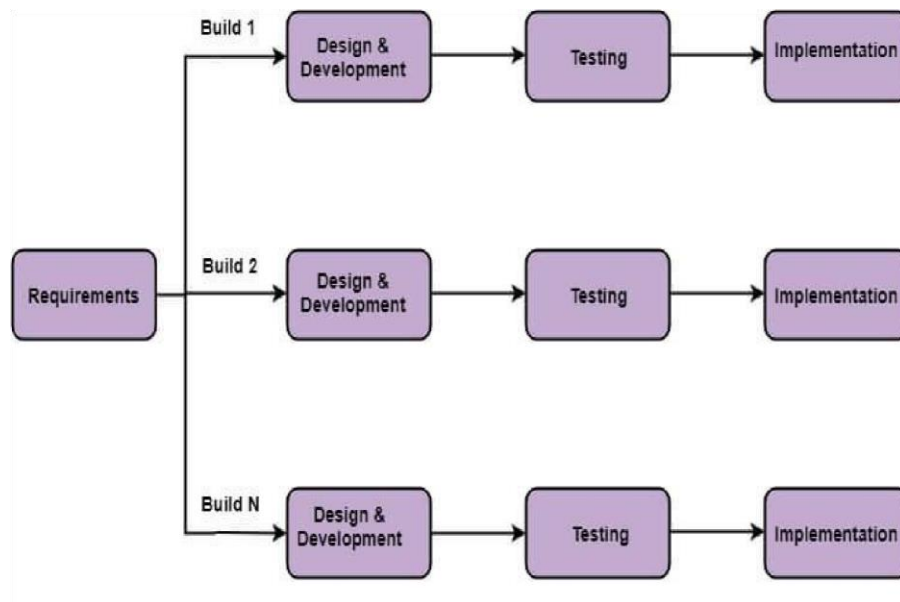


Figure 3. The incremental software process model

The following are the phases of the incremental model:

- **Requirement analysis:** The product analysis expertise identifies the requirements in the first phase of the incremental model. The requirement analysis team also understands the system's functional requirements. This phase is critical for developing software using the incremental methodology.
- **Design & Development:** The design of the system functionality and the development technique are completed successfully in this phase of the Incremental model of SDLC. The incremental model employs a style and development phase when software creates new functionality.

- **Testing:** The testing step of the incremental approach examines the performance of each current function as well as new capabilities. Various approaches are utilized to test the behavior of each task throughout the testing phase.
- **Implementation:** The coding phase of the development system is enabled by the implementation phase. It entails the final code that was created throughout the designing and development process, as well as the testing of the functionality.

Incremental model is used when there are below possibilities:

- When the requirements are more stringent.
- A project's development takes a long time.
- When the software crew is under-skilled or under-trained.
- When a customer requests a speedy delivery of a product.
- You might start by creating prioritized requirements.

Table 1. Project plan

Activity	Start Date	End Date
Preliminary Investigation	26/01/2023	02/02/2023
Requirement Analysis	03/02/2023	15/02/2023
Designing	16/02/2023	27/02/2023
Implementation	27/02/2023	30/03/2023
Testing	31/03/2023	15/04/2023
Report	16/04/2023	22/04/2023

4.3 Milestone and Deliverables:

- In this project, I went through step by step, first I learnt JavaScript then React native.

- After that I started designing an authentication module.
- After completing it I started with the design of the User module. Then I design a quiz module.
- After completing the Quiz module in user, I started the admin module design.
- Along with that I manage databases in firebase.
- After that I got changes in requirements based on that I changed my project, so that I got a real scenario of the professional life of a software engineer.

Table 2. Milestones and Deliverables

Software Process Activity	Milestones
Project Plan	Project Schedule
Requirement Collection	User requirements
Data Flow Analysis	System Flow
Design <ol style="list-style-type: none"> 1. Database Design 2. User Interface Design 3. System Design 	System Design Document
Implementation <ol style="list-style-type: none"> 1. Code for giving security 2. Code for reports 	Access Reports
Testing	Setting validation and error message

4.4 Roles and Responsibilities:

1. Preliminary studies
2. Requirement Analysis
3. DB Design
4. Coding
5. Testing

CHAPTER 5

SYSTEM REQUIREMENT STUDY

5.1 User Characteristics:

This application is related to two sorts of users.

1. Admin:

- Admin can create the project
- Manage the website
- Admin can assign the users

2. Client:

- Client can upload the files
- Client can give the rights to the team

3. IT User:

- Keep track of User Profile.
- Make Changes if necessary

5.2 Hardware and Software requirements:

5.2.1 Hardware Requirements:

- RAM: 4.0 GB
- Processor: Intel core i3 CPU @ 3.4GHz
- System type: 32-bit Operating System
- Input Device: Mouse, Keyboard

5.2.2 Software Requirements:

- Operating System : Windows, Mac
- Make Changes if necessary

5.2 Assumption and Constraint:

- It is assumed that the user has an Active AWS account and the user has some basic knowledge of Jenkins.
- Users must be familiar with the cloud terminologies that are related to DevOps.

5.3.1 Regulatory Policies:

- Regulatory policies or mandates limit an individual's or an agency's discretion or otherwise compel particular sorts of behavior.
- When good behavior can be simply defined and bad behavior can be easily regulated and punished by fines and punishments, these policies are regarded to be most effective.

5.3.2 Hardware Limitation:

- The portal's seamless operation is mostly determined by the hardware's speed, followed by the internet's speed.
- When it comes to hardware, it is always a good idea to stay current. If the user is still utilizing a CPU with a low MHz or a RAM of less than 128Mb, the hardware constraint will occur.
- This will reduce the portal's overall functionality, as well as waste a lot of time, energy, and resources.

CHAPTER 6 SYSTEM ANALYSIS

6.1. Study of Current System and Requirement of this System:

- System analysis is the process of analyzing the requirements and specifications of a system, identifying potential problems or areas for improvement, and designing a solution that meets the needs of the stakeholders.
- In the ETMF project, system analysis would involve evaluating the requirements and specifications of the decentralized document management ecosystem, identifying potential issues or inefficiencies, and designing a solution that meets the needs of users and stakeholders.
- The first step in system analysis would be to identify the requirements of the system. This would involve gathering input from stakeholders such as users, developers, and other interested parties to determine what features and capabilities the system should have.
- Once the requirements have been identified, the next step would be to analyze the current system to identify any potential issues or inefficiencies. This could involve evaluating the performance, security, and usability of the current system, as well as identifying any areas for improvement.
- Based on the requirements and analysis, a solution would then be designed that meets the needs of the stakeholders. This could involve changes to the system architecture, the introduction of new features or capabilities, or other modifications to improve the system's performance, security, or usability.
- Throughout the system analysis process, it is important to consider factors such as scalability, interoperability, and incentivization, which are key objectives of the ETMF project. This can help ensure that the solution is efficient manner.

6.2. Operational Feasibility:

- The operational feasibility of a given system is a measure of how successfully it addresses problems.
- This system is solving all the problems given by the company.
- This system meets all the requirement criteria that the app should have to enhance user experience.

6.3. Technical Feasibility:

- The formal process of determining whether it is technically possible to manufacture a product or service is known as technical feasibility.
- Conduct a preliminary feasibility analysis for production.
- We also conduct a preliminary development assessment.
- Calculate the cost of an engineering prototype.

6.3.1 Functional Requirements:

Authorization:

- Document Storage: The system should allow users to store and manage documents in a decentralized manner, with features such as access control, versioning, and audit trails.
- Document Collaboration: The system should enable users to collaborate on documents with others in a trustless and secure way.
- Data Organization: The system should provide tools for tagging, categorizing, and searching documents and data.
- Workflow Automation: The system should allow users to create and automate workflows, such as approval processes or task assignments.
- Interoperability: The system should be designed to integrate with other dApps and blockchain networks, allowing for seamless data transfer and workflow management.

6.3.2 Non-Functional Requirements:

- **Security:** The system should provide a high level of security, with features such as data encryption, access control, and audit trails to prevent unauthorized access or tampering.
- **Scalability:** The system should be designed to handle a large number of users and documents, with the ability to scale as the network grows.
- **Usability:** The system should be user-friendly and intuitive, with a simple and intuitive interface that makes it easy to manage documents and workflows.
- **Performance:** The system should be designed to perform efficiently, with fast load times and minimal latency.
- **Reliability:** The system should be designed to be reliable and available, with minimal downtime or disruptions to users.

6.4. Schedule Feasibility:

Schedule feasibility refers to whether or not there is enough time to execute the project aspect in question:

- The project's schedule
- The deadline by which the project must be finished
- Period of reporting

6.5. Economic feasibility:

- Economic feasibility is a measure of a project's or solution's cost effectiveness.
- The benefits from the project should exceed or be at least equivalent to the cost of development before the system can be declared economically feasible.

6.6. Function of the System:

Admin side:

1. Admin can create the project
2. Admin can give rights to the users
3. Admin can track the all profiles

4. Admin can assign the users
5. create the users
6. Three time login

User side:

1. Create the project
2. Upload the files
3. Assign the user
4. Assign node rights to the user
5. Logout
6. Three time login
7. Create review approve the project
8. Change the password
9. Create the node structure
10. Do the e signature

6.7. Use-Case:

- A use case is a collection of steps in software and systems engineering that define interactions between actors and systems in order to achieve a goal.
- A human, an external system, or time can be the actor.
- Use cases are utilized at a higher level in systems engineering than they are in software engineering, and they frequently represent missions or stakeholder goals.

- The detailed requirements can then be expressed as contractual declarations or in Systems Modeling Language.
- Use cases have been widely employed in modern software engineering for the past two decades as a key requirement technique.
- Use case driven development is a crucial feature of process models and frameworks, and because of its iterative and evolutionary nature, it's a strong fit for agile development.

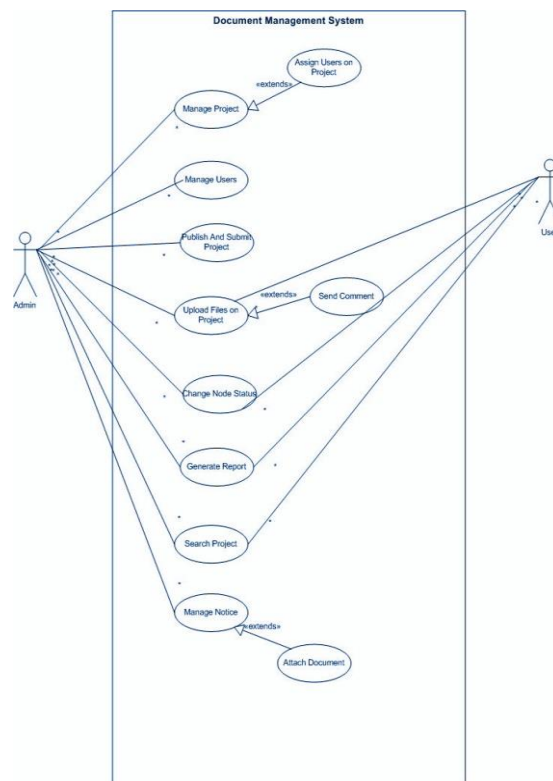


Figure 4. Use case diagram

6.8. Activity Diagram:

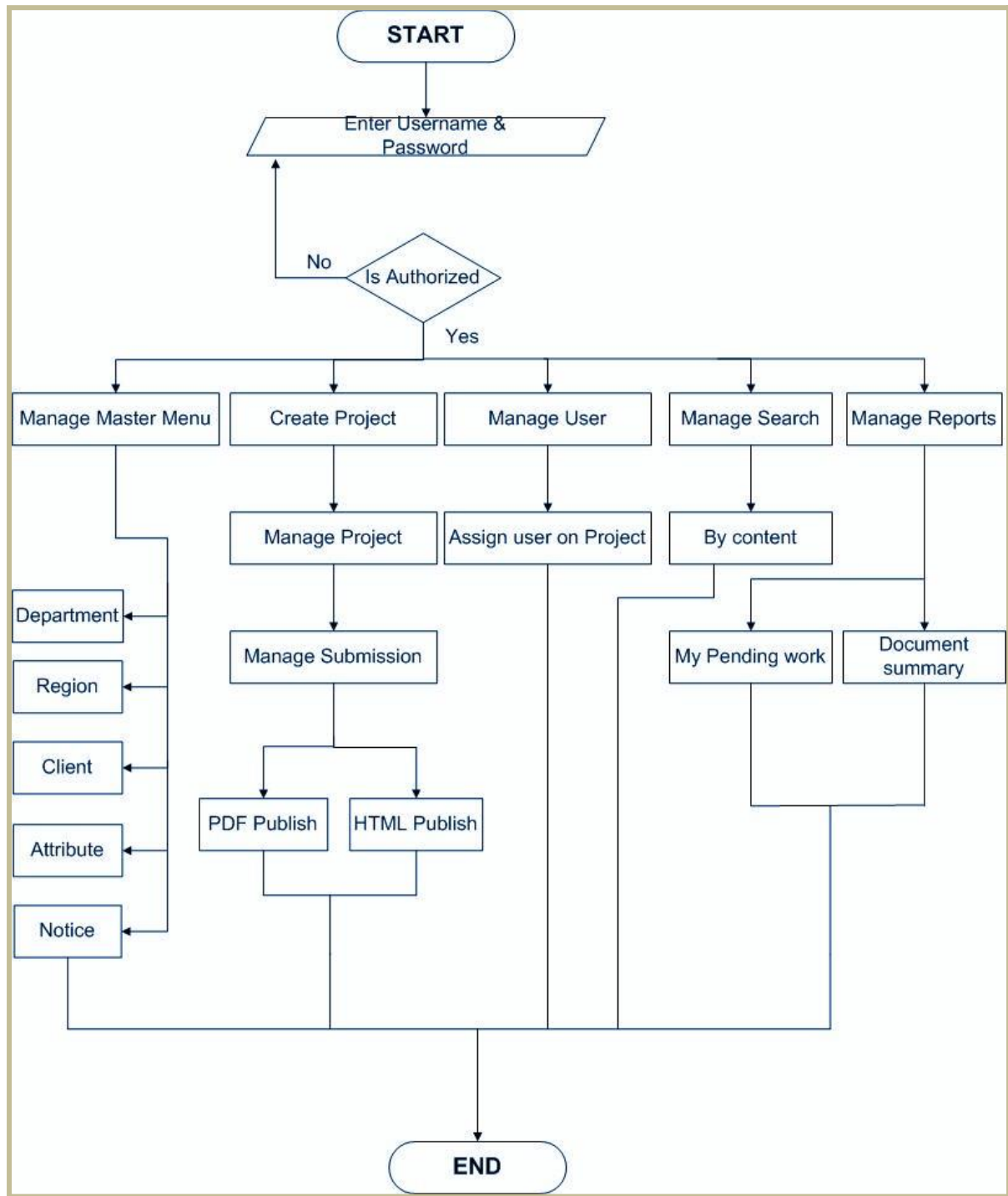


Figure 5. Activity diagram for user

6.10. Data Modelling:

6.10.1 E-R Diagram:

- An entity–relationship model (ER model) is a data model used in software engineering to describe the data or information parts of a business domain or its process requirements in an abstract way that can be implemented in a database like a relational database.
- Entities and the relationships that can exist between them, as well as databases, are the core components of ER models. An entity–relationship model is a method of describing and modeling a business process in a systematic manner.
- The process is represented as a set of components (entities) connected by relationships that explain the dependencies and requirements between them, such as: one building can be partitioned into zero or more apartments, but each apartment can only be found in one building.
- Entities can have a number of different properties (attributes) that define them. Entity–relationship diagrams are diagrams that are used to graphically describe these entities, properties, and relationships.

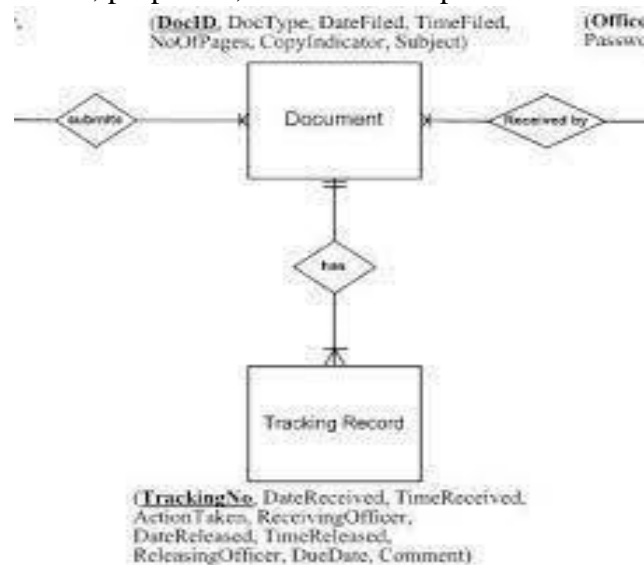


Figure 8. E-R diagram

6.10.2 Class Diagram:

- A class diagram in the Unified Modeling Language (UML) is a form of static structural diagram used in software engineering to depict the structure of a system by displaying the system's classes, properties, operations (or methods), and interactions between objects.
- The class diagram is an essential component of object-oriented modeling.
- It is used for both overall conceptual modeling of the application's architecture and detailed modeling of the models' translation into programming code.

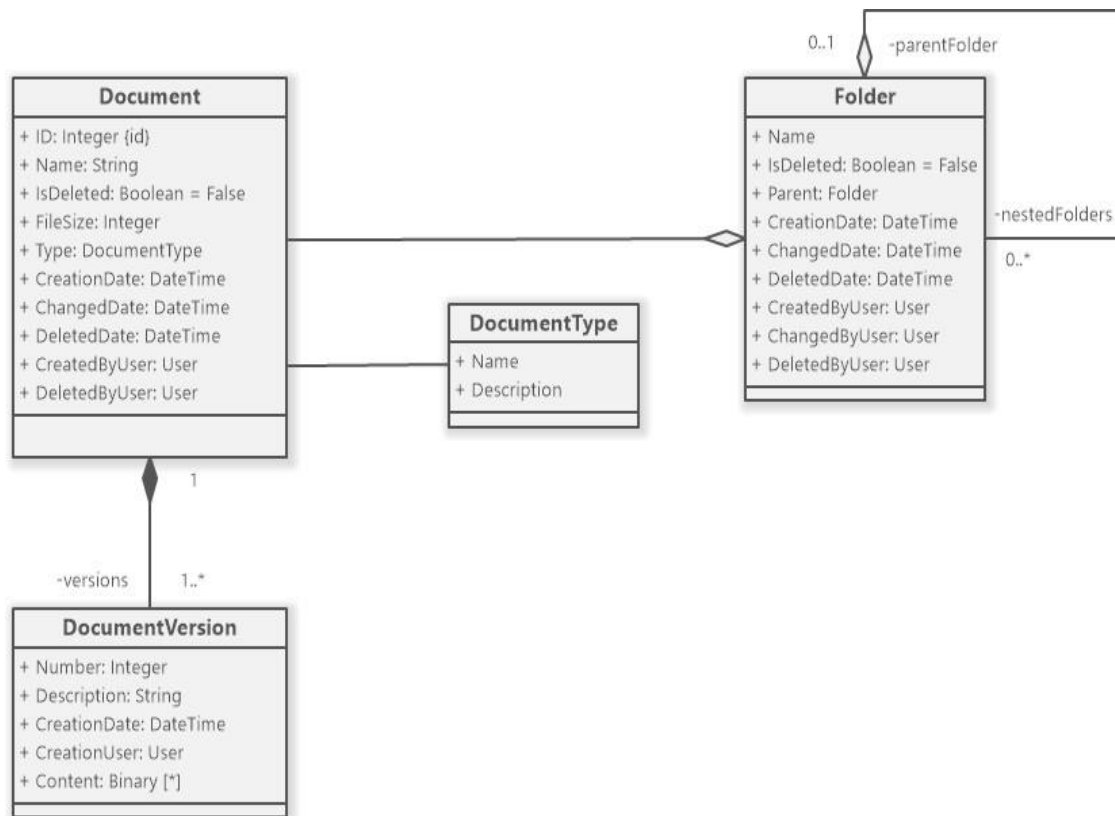


Figure 9. Class diagram

6.11 Modules and Their Description of System:

The following are the four primary modules:

Authorization:

- Phone number sign-In used for authentication using firebase.
- The already registered number will not be able to sign up again
- After successful verification of the mobile number the user has to provide some personal information like name, email, phone number (non-editable), address, etc.
- Validation of phone number and OTP.

Admin Dashboard:

- List of quizzes listed on admin dashboard
- Admin can change the status of the quiz from active to inactive and vice-versa.
- Admin can check the quiz result.
- Graph analysis.

User Dashboard:

- List of quizzes listed on the user dashboard.
- Only an active quiz can be taken by the user.
- Can take a quiz for one time only.
- Can check the result of previous quizzes.

Quiz:

- Users cannot take the same quiz again.
- Users can change the question to previous or next.
- Users can quit the quiz anytime.
- A timer will be shown in the quiz after a specific time quiz will be submitted automatically.

CHAPTER 8

IMPLEMENTATION PLANNING AND DETAILS

8.1. User Base:

The environment will allow a user to access the system from anywhere. Each user can attend the quizzes which are available in application with admin permission and they can see the results of attempted quizzes. This all functionality can be used from anywhere and they can access from anytime and many numbers of users can access this application only they require network connectivity to start the quiz and the permission required from admin.

8.2. User Interface:

The user needs to add a phone number and OTP to securely login in the application. If the user is first time in application, then they need to add the register details like full name, email and address. If the user is admin, then he/she can manage the quizzes of the application. He/she can manage the quiz student wise. Admin can see the results of student and graph analysis. After work is done admin can log out anytime. If the admin is a student, then the user can attempt the quiz which is activated by the admin. After that user can see the result of quizzes with attempts and after work is done admin can log out anytime. So, this is the main user interface of the portal.

8.3. Functional components:

In React Native are JavaScript functions that render a React element. They can accept a single argument which is an object containing component properties. They can also use state and lifecycle behavior with hooks.

8.4. Naming Conventions:

- The names of folders and subfolders should always begin with small letters, and the files that belong to the folders should always be written in pascal case. The term "Pascal Case" derives from software development and can be used to denote any compound word with the first letter capitalized.
- We use the path-based component naming method to name the components, which involves naming the component according to its relative path to the folder components or to the app. A component that may be found in components/common/Button. Button.js would be the name of the js file. The component name should be written in capital letters.
- We don't need to repeat the name if the file is in a folder with the same name. That is, UserForm would be titled instead of UserFormForm in components/user/form/Form.js.
- Include all of the controls from the same module in a single import and terminate with a semicolon. Between two imports, there should be no space.

CHAPTER 9

TESTING

Testing is a procedure for demonstrating the program's correctness. Testing is required to demonstrate completeness, improve software quality, and give maintenance assistance. As a result, some testing standards are required to reduce testing costs and time. Testing software takes place throughout the coding process and is the final check of setups, design, and coding. We can determine whether the configuration that has been developed is studied or not based on how the software reacts to these tests. All components of an application are tested, because failing to do so leads to a slew of bugs once the software is in use.

9.1. Testing Plan:

The main goal of the test plan is to include all the details related to testing such as what to test, when to test, how to test and who will be the tester. Test plans are often not updated but if there is some new feature or change introduced then it has to be updated accordingly.

9.2. Testing Strategy:

A test strategy is a diagram that outlines the software development cycle's testing technique. It was intended to provide project managers, testers, and developers with information about some of the most important aspects of the testing process. This comprises the testing objective, new function testing methodologies, total project duration and resources, and the testing environment.

9.3. Testing Methods:

Branch Testing: Each branch of application that is a corporate dealing solution is working correctly and navigation takes place easily.

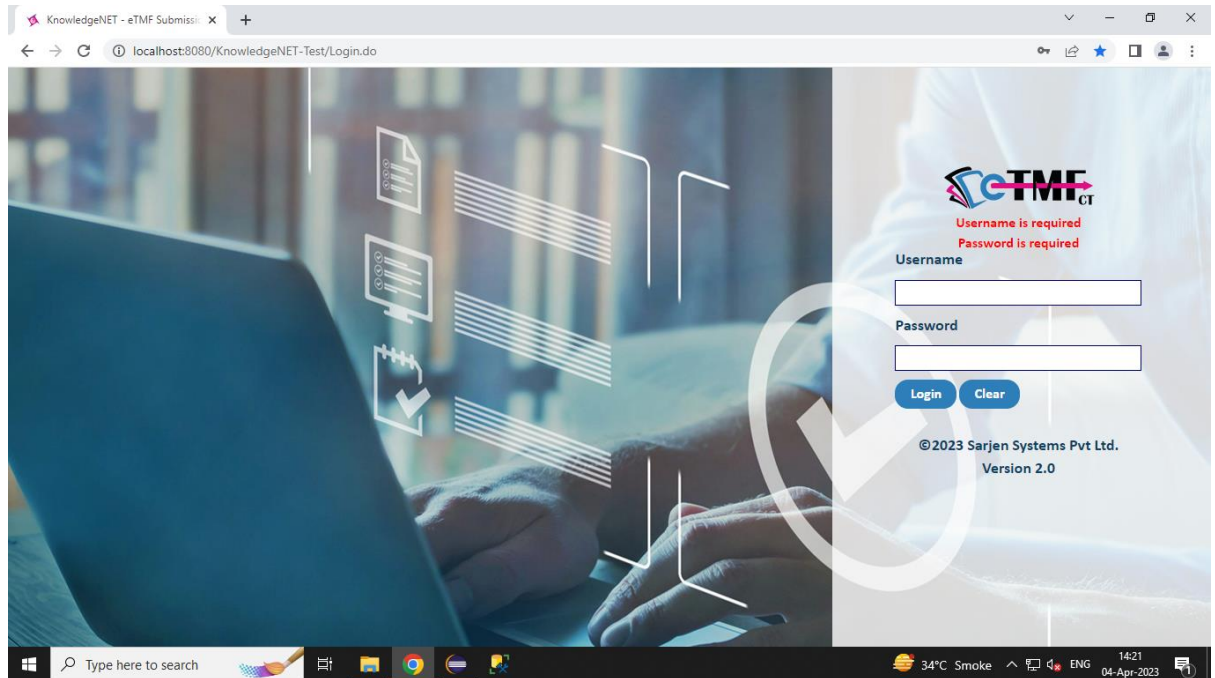
Bottom-up Testing: We tested each part separately and then integrated them into appropriate modules and testing is done also at module level and at the end each and every module are integrated with each other for complete functionality of the system. Entire system is then tested by many users to find out bugs.

System Work Performance Testing: System work performance testing is done by many users for appropriate working of applications and to remove problems that may possibly be faced by the user.

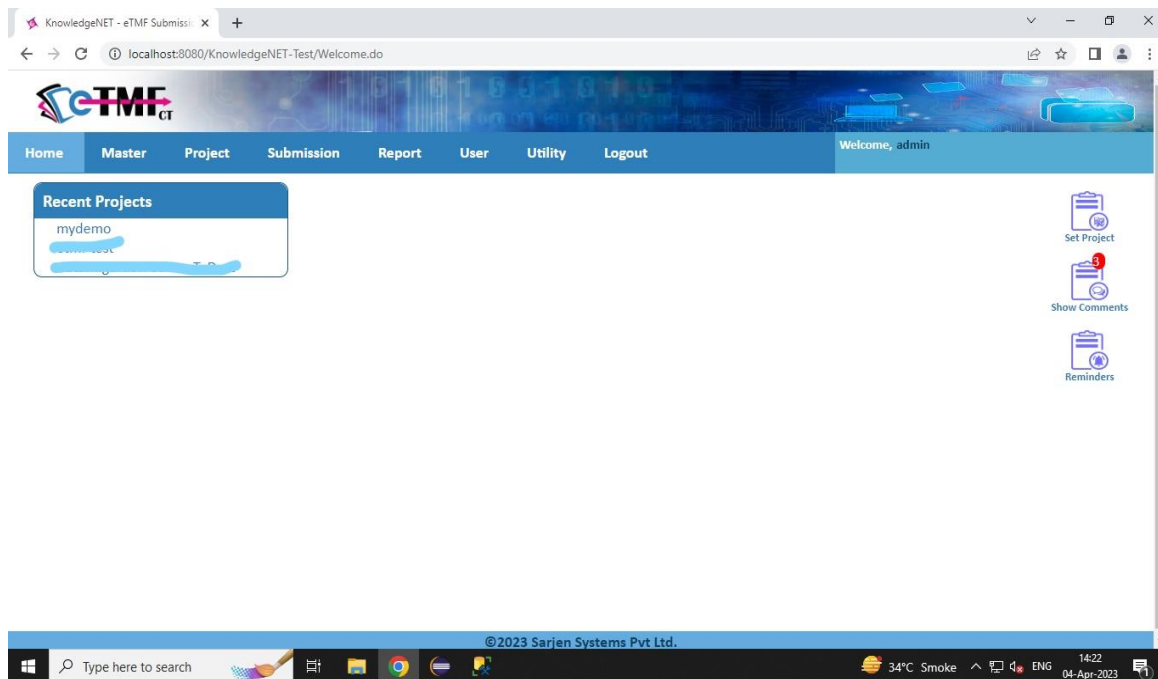
CHAPTER 10

SCREENSHOTS

10.1. login Module:



10.2. Home page Module:



Team ID-297275

10.3. Project page Module:

The screenshot displays the 'Create Project' form within the KnowledgeNET - eTMF Submission system. The form is titled 'Create Project' and is located under the 'Project' tab in the navigation menu. The form contains several input fields and dropdown menus for project configuration:

- Project Name:** A text input field.
- Template Name:** A dropdown menu with 'Select Template' as the placeholder.
- Publish Type:** A dropdown menu with 'Select Type' as the placeholder.
- Region:** A dropdown menu with 'Select Region' as the placeholder.
- Department:** A dropdown menu with 'Select Department' as the placeholder.
- Client:** A dropdown menu with 'Select Client' as the placeholder.
- Project Type:** A dropdown menu with 'Select Project Type' as the placeholder.
- Reason for Change:** A text input field.
- Default Admin:** A dropdown menu with 'admin' as the selected value.
- Copy User Rights:** Radio buttons for 'Yes' (selected) and 'No'.

At the bottom of the form, there are two buttons: 'Create Project' and 'Advance Search'. The footer of the page indicates '©2023 Sarjen Systems Pvt Ltd.' and the system status shows '34°C Smoke' and '14:23 04-Apr-2023'.

10.4. Password page Module:

The screenshot displays the 'Change Password' form within the KnowledgeNET - eTMF Submission system. The form is titled 'Change Password' and is located under the 'Utility' tab in the navigation menu. The form contains several input fields and a 'Change' button:

- Current Password:** A text input field.
- New Password:** A text input field.
- Retype New Password:** A text input field.

At the bottom of the form, there is a 'Change' button. To the right of the input fields, there are several checkboxes for password requirements:

- ☐ Special Characters
- ☐ Lowercase (Minimum 1)
- ☐ Uppercase (Minimum 1)
- ☐ Number (Minimum 1)
- ☐ At least 8 characters
- ☐ Passwords Match

The footer of the page indicates '©2023 Sarjen Systems Pvt Ltd.' and the system status shows '34°C Smoke' and '14:24 04-Apr-2023'.

10.5. Master page Module:

The screenshot displays the 'Client Master' module in the KnowledgeNET - eTMF Submission system. The interface includes a navigation bar with links: Home, Master, Project, Submission, Report, User, Utility, and Logout. The user is logged in as 'admin'.

Client Master

Client Name
 Add

Show **10** entries Search:

#	Client Name	Status	Action done on	Revert	Audit Trail
1	Remark	InActivate	30-Jun-2022 12:36 IST(+05:30 GMT)		
2	Sarjen	InActivate	30-Jun-2022 12:36 IST(+05:30 GMT)		
3	Sarjen Systems Pvt. Ltd.	Activate	30-Jun-2022 12:36 IST(+05:30 GMT)		
4	sspl1	InActivate	30-Jun-2022 12:36 IST(+05:30 GMT)		
5	test3	New	06-Mar-2023 16:01 IST(+05:30 GMT)		
6	test9	New	14-Mar-2023 13:04 IST(+05:30 GMT)		

Showing 1 to 6 of 6 entries First Previous 1 Next Last

10.6. Submission page Module:

The screenshot displays the 'PDF Publish' module in the KnowledgeNET - eTMF Submission system. The interface includes a navigation bar with links: Home, Master, Project, Submission, Report, User, Utility, and Logout. The user is logged in as 'admin'.

PDF Publish

Project Name

PDF Documents List For : mydemo

#	Header	Footer	Shrink	#	Artifact/SubArtifact	File Name	User Detail	Action done on
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	1.1.2 Trial Master File Plan(admin,Medical Writing,Res)	TECHNICAL_PROGRAMS.pdf	admin	28-Mar-2023 16:23 IST(+05:30 GMT)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2	1.1.1.1 Trial Master File Plan Signature Page	Trial-Master-File-Plan-Signature-Page.pdf	admin	24-Mar-2023 15:39 IST(+05:30 GMT)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3	1.1.1.2 TMF Index	TMF-index.pdf	admin	24-Mar-2023 16:57 IST(+05:30 GMT)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4	1.1.2.1 Project Management Plan Signature Page	Project-Management-Plan-Signature-Page.pdf	admin	21-Mar-2023 10:23 IST(+05:30 GMT)

☒ Generate TOC ☒ Generate Bookmark ☐ Add Page Header ☒ Add Page Footer ☒ Add Cover Pages

Header Settings

☒ Input Header Text Header Text Line 1: Header Text Line 2: Left:

☐ Add Logo Select Logo: Right:

☒ Add Node Title Right:

☒ Add Line

Footer Settings

☒ Add Page Number 1,2,3... Center:

☒ Input Footer Text Left:

☒ Add Line

Cover Page Settings

Product Name: Font Size: Font Style: Font Name:

KnowledgeNET - eTMF Submissi... x +

localhost8080/KnowledgeNET-Test/PublishProject.do

Footer Settings

☒ Add Page Number 1,2,3... --Center--

☒ Input Footer Text --Left--

☒ Add Line

Cover Page Settings

Product Name: --Font Size-- --Font Style-- --Font Name--

Submitted By: --Font Size-- --Font Style-- --Font Name--

Submitted To: --Font Size-- --Font Style-- --Font Name--

TOC Settings

☒ Module Wise TOC

☒ Module Wise Page Numbering

☒ Add Page Number 1,2,3... --Font Size--

Publish And Submission Detail

Sequence No. 0000

Submission Mode --Select--

Submission Info.

Date Of Submission (YYYY/MM/DD)

Project Detail

Project Name mydemo

Project Type DMS

Client Name Sarjen Systems Pvt. Ltd.

©2023 Sarjen Systems Pvt Ltd.

Type here to search

34°C Smoke ENG 14:27 04-Apr-2023

10.7. reports page Module:

KnowledgeNET - eTMF Submissi... x +

localhost8080/KnowledgeNET-Test/Welcome.do

TMF CT

Home Master Project Submission **Report** User Utility Logout Welcome, admin

Recent Projects

- mydemo
- etmf-test
- DataMigartion-SourceToDest

Section Wise Report

- Department Level eTMF Report
- Project Node History
- Comment History
- Assigned Users On Project
- Assigned Users On Project History
- Attribute Audit Trail
- Doc Summary
- My Pending Work
- Project Snapshot
- Assigned Users On Artifact History
- Artifact/SubArtifact Active-InActive History

Set Project

Show Comments

Reminders

localhost8080/KnowledgeNET-Test/Welcome.do#

©2023 Sarjen Systems Pvt Ltd.

Type here to search

34°C Smoke ENG 14:30 04-Apr-2023

10.8. reports page Module:

Home	Masters	Projects	Documents	Publish	Reports	Assign	Utility	Logout	Welcome test Session 29:42	Last Login 18-Apr-2023 09:29 AM
------	---------	----------	-----------	---------	---------	--------	---------	--------	-------------------------------	---------------------------------

Project: test-12-0.5		Approved: 0.00%		Name: User Requirement Specification-1	
Client: test					
Project Type: eCSV					
Search Document					
<ul style="list-style-type: none">GAMP-Category III<ul style="list-style-type: none">User-Requirement-Specification<ul style="list-style-type: none">Edited.pdf - [knet, Yes]User-Requirement-Specification-1.pdf - [knet, Yes]User-Requirement-Specification-5.pdf - [knet, Yes]Gxp-Assessment-or-Initial-Impact-AssessmentValidation-PlanRisk-AssessmentFunctional-Risk-AssessmentUser-Acceptance-TestingTraining-RecordsRole-specific-access-or-User-access-privilegesIQOQ ProtocolOQ Script					
		<div>Edit Project</div> <div>Edit Unit DetailAssign RightsAudit Trail</div> <div>Add Reference Value</div> <div>Clientknet</div> <div>Type of SignatureDigital</div> <div>Reason for Change</div> <div>SaveAudit Trail</div> <div>IterateSelect ActivityGo</div>			

CHAPTER 11

LIMITATIONS

11.1. Limitations of current System:

- Limited Information: The provided information about the project is limited.
- Usability and User Experience: If the platform's interface is not intuitive, user-friendly, or aligned with user needs, it could impact user adoption, satisfaction, and overall project success.
- Scalability and Performance: If the platform lacks the ability to handle large volumes of documents or concurrent users, or if it has suboptimal performance, it could impact its effectiveness in meeting user needs and expectations.

11.2. Enhancement:

- I will try to create a digital Signature Module to let users sign the document with a touchpad.
- As the technology emerges, I'll upgrade system security features.

CHAPTER 12 CONCLUSION

In conclusion, the ETMF project is a decentralized protocol and ecosystem for document management, data organization, and workflow automation. The project aims to provide a comprehensive solution that meets the needs of users and stakeholders, with features such as access control, audit trails, versioning, and collaboration.

The success of the ETMF project depends on careful analysis of the requirements and specifications of the system, as well as the design and implementation of a solution that meets the functional and non-functional requirements. System analysis plays a critical role in this process, by identifying potential issues or inefficiencies and designing a solution that meets the needs of users and stakeholders.

Overall, the ETMF project has the potential to revolutionize document management and workflow automation, providing a secure, efficient, and decentralized solution for users around the world. With careful planning, analysis, and implementation, the ETMFteam can create a system that meets the needs of users and stakeholders, while advancing the adoption of blockchain technology in new and innovative ways.

CHAPTER 13

REFERENCES

- <https://www.oracle.com/technetwork/java/index.html>
- <https://docs.oracle.com/en/java/index.html>
- <https://www.w3schools.com/>
- <https://api.jquery.com/>
- <http://www.mysql.com/>