Appendix 2: Software Requirements Specification

Consultancy for Scoping of a Continental Regulatory Information Management System Solution and Information Sharing Platform for the Member States in the African Union

To:
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Submitted by:

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Table of Contents

List of Tables

List of Figures

1 Introduction

1.1 Purpose

The purpose of this document is to present a detailed description of the Regulatory Information Management System (R-MIS). It will explain the purpose and features of the system, the interfaces of the system, what the system will do, the constraints under which it must operate and how the system will react to external stimuli. This document is intended for both the stakeholders and the developers of the system and will be proposed to the African Union (AU) for its approval.

To achieve this, an integrated continental Information Management System (IMS) will have to be developed for the continent, by connecting Regional IMS (R-MIS) where they exist, ensuring interoperability. This will be an important means of ensuring speedy access to medical products that are safe, efficacious and of assured quality to the African population as well as information on the same. The proposed continent-wide integrated IMS should provide online and real-time availability of medicine regulation information and support workflow management, where possible.

1.2 Project Scope

Project separated to two main web systems:

1. Online system for NMRA stakeholders providing information and services. The Portal consists of the following modules: Premise Module, Product Module, GMP Module, Import and Export Module, Finance Module, Content Module

2. Management Information System–This is the core system of the IMS implementation automating all processing including handling logical processing for the Portal system. MIS consists of the following modules: Premise module, Product module, GMP module, Import and Export module, Inspection module, Finance module, Document Library module, Report module, Administration module.

1.3 Intended Audience and Reading Suggestions

Section 1 of this document should be read by everyone. This section gives the reader all the information needed to read the rest of the document as well as a general overview of the problem, the solution and describes how the solution will benefit the company.

Section 2 of this document should be read by everyone. This section gives a detailed textual description of the system, describes how the system might tie into already existing systems, lists the functionalities that will exist in the system, depicts the types of users of the system, describes general constraints and indicates the assumptions and dependencies.

Section 3 of this document should be read by the system designer's, implementers and maintainers in its entirety. For those who would like more information on a specific functionality can consult this section to get more information on it. This section contains a structured and detailed explanation of all functionalities, the

external interfaces to the system, performance requirements, design constraints, quality attributes and other requirements.

Table 1-1: Document Readers and Their Recommended Reading

Reader Type	Recommended Reading
User	Section 1 (all), 2 (all)
Manager	Section 1 (all), 2 (all)
Requirement Engineer	Section 1 (all), 2 (all), 3(all), 4(all)
System Designer	Section 1 (all), 2 (all), 3(all), 4(all)
Implementor	Section 1 (all), 2 (all), 3(selective), 4(all)
System Tester	Section 1 (all), 2 (all), 3(all), 4(all)
System Maintainer	Section 1 (all), 2 (all), 3(selective), 4(all)

2 Overall Description

2.1 Product Functions

Below is a list of all functions that can be found in the system with a description of the function and its priority. The priorities range from 1 to 3, with 1 being the highest priority and 3 being the lowest.

Table 2-1: Function's Priorities Range

Priority	Detail
1	Must have
2	Should have
3	Nice to have

Table 2-2: Product Functions

ID	Function	Description	Priority
1	Premise License Registration	The system shall allow Actors to submit new premise license registration applications	1
2	Premise License Renewal	The system shall allow Actors to submit new premise license renewal applications	1
3	Premise License Variation	The system shall allow Actors to submit new premise license variation applications	1
4	Premise License Withdrawal	The system shall allow Actors to submit new premise license withdrawal applications	1
5	Premise Price Setup	The system shall allow Actors to setup price for applications	1
6	Premise Licensing Period Setup	The system shall allow Actors to setup new premise license period setup for applications	1
7	Premise Invoice Expiry Setup	The system shall allow Actors to setup invoice expiry	1
8	Product License Retention	The system shall allow Actors to submit product license retention applications	1
9	Product License Variation	The system shall allow Actors to submit new product license variation applications	1
10	Product License Withdrawal	The system shall allow Actors to submit new product license withdrawal applications	1
11	Product Clinical Trial	The system shall allow Actors to submit application for clinical trial	1
12	Product Survey	The system shall allow Actors to submit product survey	1
13	Product Promotion	The system shall allow Actors to submit product promotion applications	1
14	Product Price Setup	The system shall allow Actors to submit new product license price for applications	1
15	Product Licensing Period Setup	The system shall allow Actors to setup product license period for applications	1
16	Product Invoice Expiry Setup	The system shall allow Actors to setup invoice expiry for applications	1
17	Import Permit	The system shall allow Actors to import permit	1
18	Export Permit	The system shall allow Actors to export permit	1
19	Import License Registration	The system shall allow Actors to import license registration	1
20	Import License Renewal	The system shall allow Actors to import license renewal	1
21	Export License Registration	The system shall allow Actors to export license registration	1
22	Export License Renewal	The system shall allow Actors to export license renewal	1
23	Import Permit Registration	The system shall allow Actors to import license registration	1

24	Export Permit Registration	The system shall allow Actors to export license registration	1
25	Import/Export License Registration	The system shall allow Actors to import/export license registration	1
26	Import/Export License Renewal	The system shall allow Actors to import/export license renewal	1
27	import/export Price Setup	The system shall allow Actors to import/export price setup	1
28	Import and Export Licensing Period Setup	The system shall allow Actors to import/export exporting licensing period setup	1
29	Import and Export Invoice Expiry Setup	The system shall allow Actors to import/export exporting invoice expiry setup	1
30	GMP License Registration	The system shall allow Actors to register GMP license	1
31	GMP License Renewal	The system shall allow Actors to renew GMP license	1
32	GMP Inspection Assignment	The system shall allow Actors for GNP inspection assignment	1
33	Premise Inspection Assignment	The system shall allow Actors to premise inspection assignment	1
34	Premise Inspection	The system shall allow Actors to premise inspection	1
35	Premise Inspection Approval	The system shall allow Actors to premise inspection approval	1
36	Premise Inspection Admin		1
37	POE Inspection Application	The system shall allow Actors to POE inspection Application	1
38	POE Inspection Approval	The system shall allow Actors to POE inspection approval	1
39	Payment (submission)	The system shall allow Actors to submit payments	1
40	Invoicing (auto generation)	The system shall allow Invoicing (auto generation)	1
41	Pricing (setup)	The system shall allow pricing setup	1
42	Currency Setup		1
43	Exchange Rate Setup	The system shall allow Actors to setup exchange rate	1

2.2 User Classes and Characteristics (Actors)

Table 2-3: System Actors

Actor	Description
General Public	all the people who are not members of a particular organization or who do not have any special type of permissions
Manufacturers	a person or company that makes goods for sale and has special permissions to access.
Importers	a person or organization that brings goods or services into a country from abroad for sale and has special permissions to access.
Exporters	a person, country, or company that sends goods or services to another country for sale.
Inspectors	an official employed to ensure that official regulations are obeyed, especially in public services.
Assessors	a person who evaluates the quality of a person or thing and calculates or estimates the price or value of something
Finance	the management of money, especially by companies or organization and has special permission on the system
Management	the administration of an organization
Laboratory Technicians	the backbone of a scientific research lab. Their work is almost entirely laboratory-based, and technicians may work alone or as part of a team of scientific staff. They can work in most areas of science including health and manufacturing.

2.3 Operating Environment

The application will operate at web browsers on windows, Linux (GUI), android or any other operating system has GUI and connection to the internet

2.4 Design and Implementation Constraints

- The MIS shall be designed with a Service Oriented Architecture (SOA).
- The MIS shall build so that it can follow Representational State Transfer (REST).
- The MIS must be designed with Modal-View-Controller (MVC) architecture.
- The MIS must use open source programming technology.
- The MIS code shall build on Test Driven Development (TDD)

2.5 User Documentation

The MIS shall have a hardcopy user guide that explains all the functions.
The MIS shall have an online user guide that explains the functions of the System

2.6 Assumptions and Dependencies

- The MIS system shall maintain unique user identification for every person who will use the system.

- The MIS system shall maintain a password for every unique user identification on the system.
- The MIS system shall allow a user three attempts to enter their user ID and password (and select the domain, where appropriate) before that session is ended.
- When the user has failed to enter their user ID and password correctly, the MIS system shall only allow the user three attempts to log in again after a system administrator has authorized it.
- The MIS system shall allow roles that allow people to read the database.
- The MIS system shall allow roles that allow people to add to the database.
- The MIS system shall allow roles that allow people to change the database.
- The MIS system shall allow roles that allow people to delete from the database.
- The MIS system shall allow for system administrator roles.
- The MIS system shall allow users to have multiple roles.
- The MIS system shall allow for system administrator roles.
- The MIS system shall allow for system monitoring roles.

3 Specific Requirements: Functional Requirements (Use Cases)

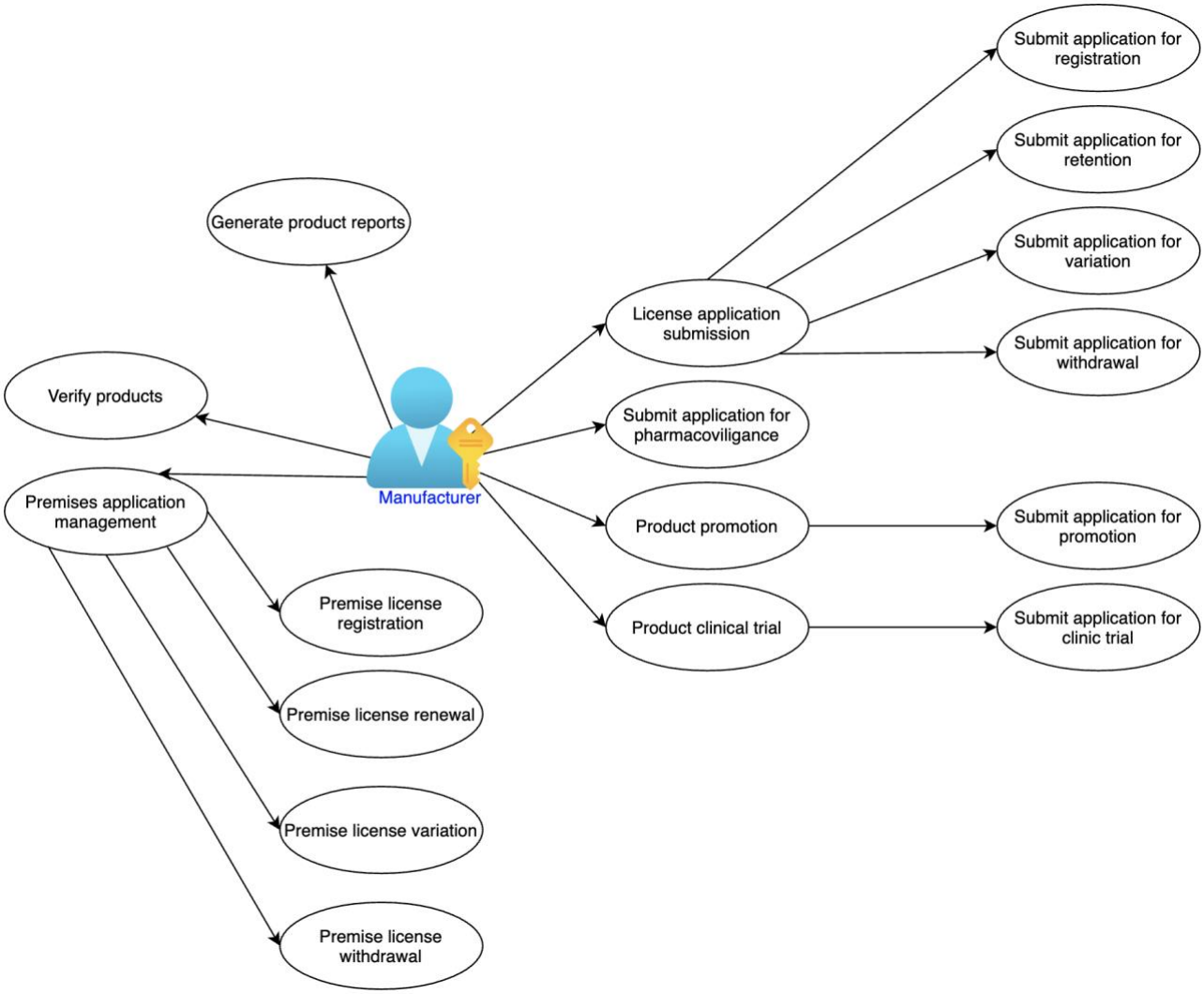

Figure 3-1: Manufacturer User Case

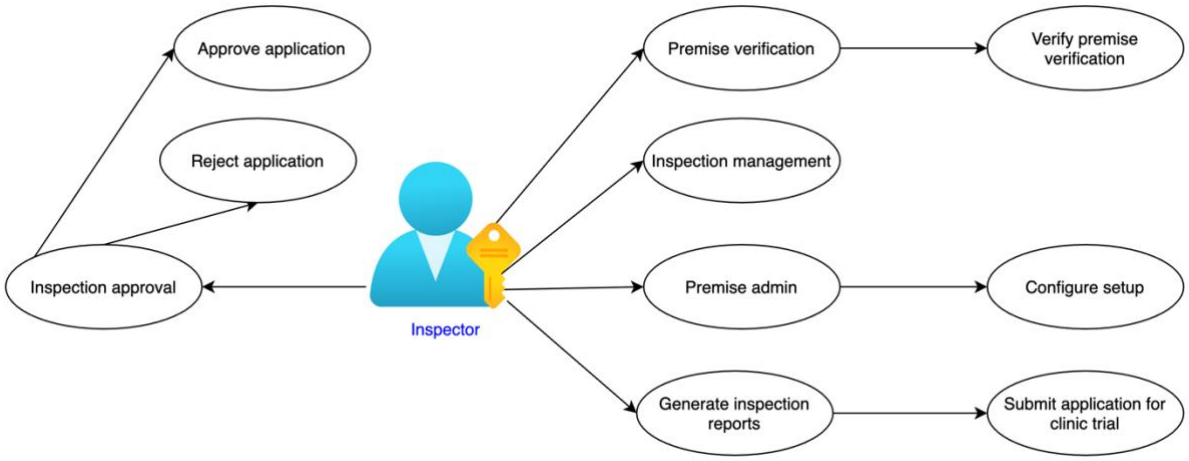

Figure 3-2: Inspector Use Case

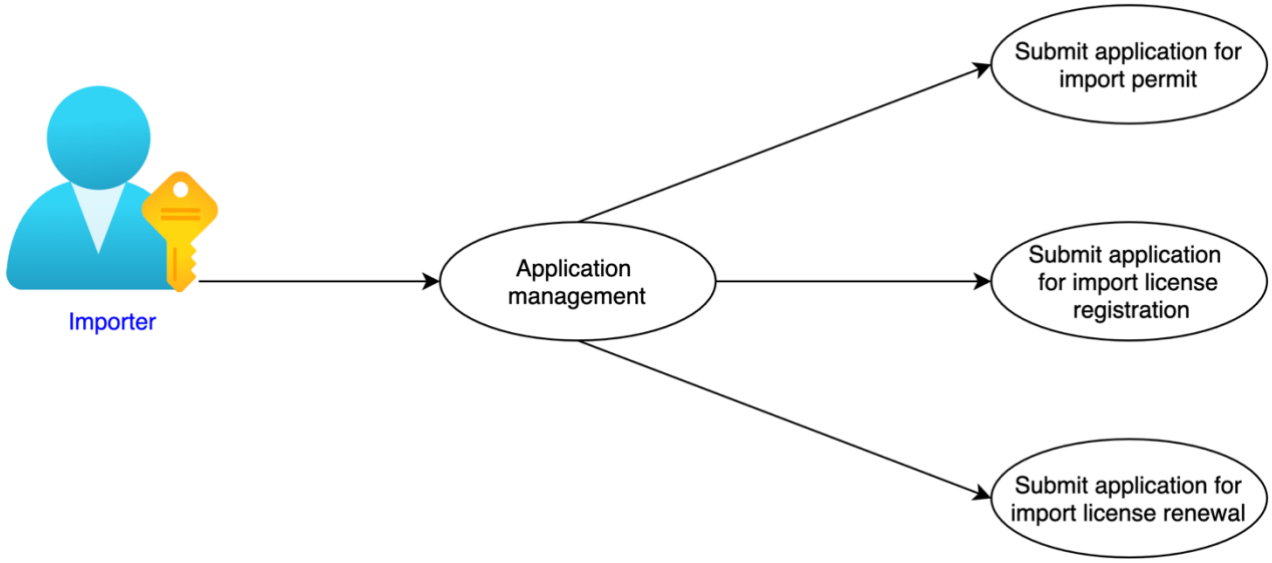

Figure 3-3: Importer User Case

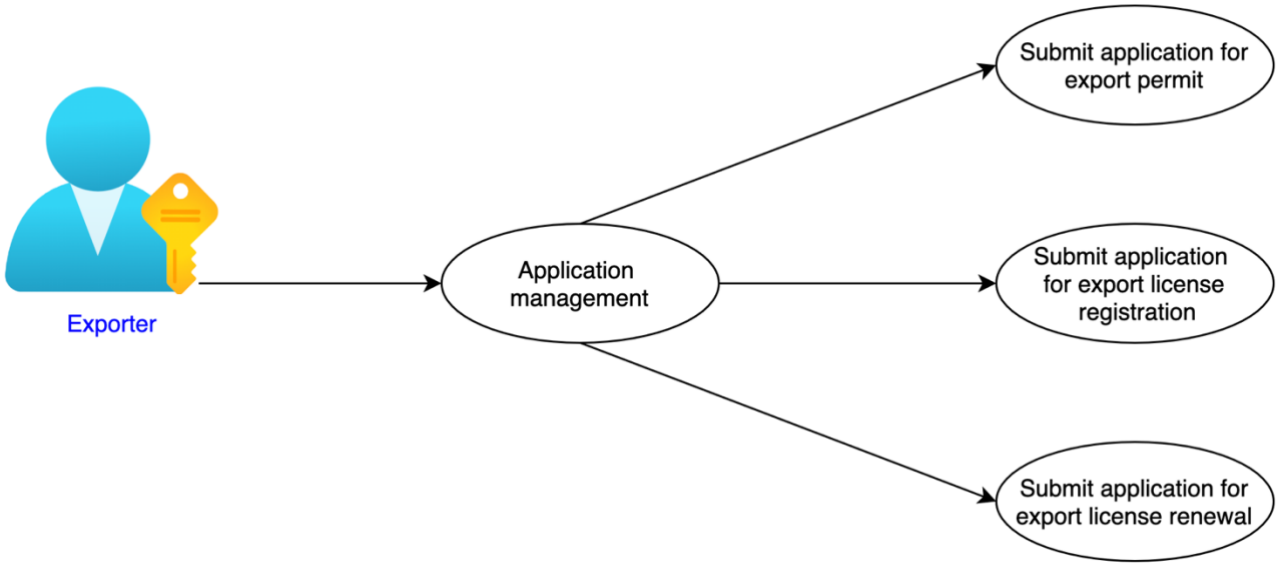

Figure 3-4: Exporter Use Case

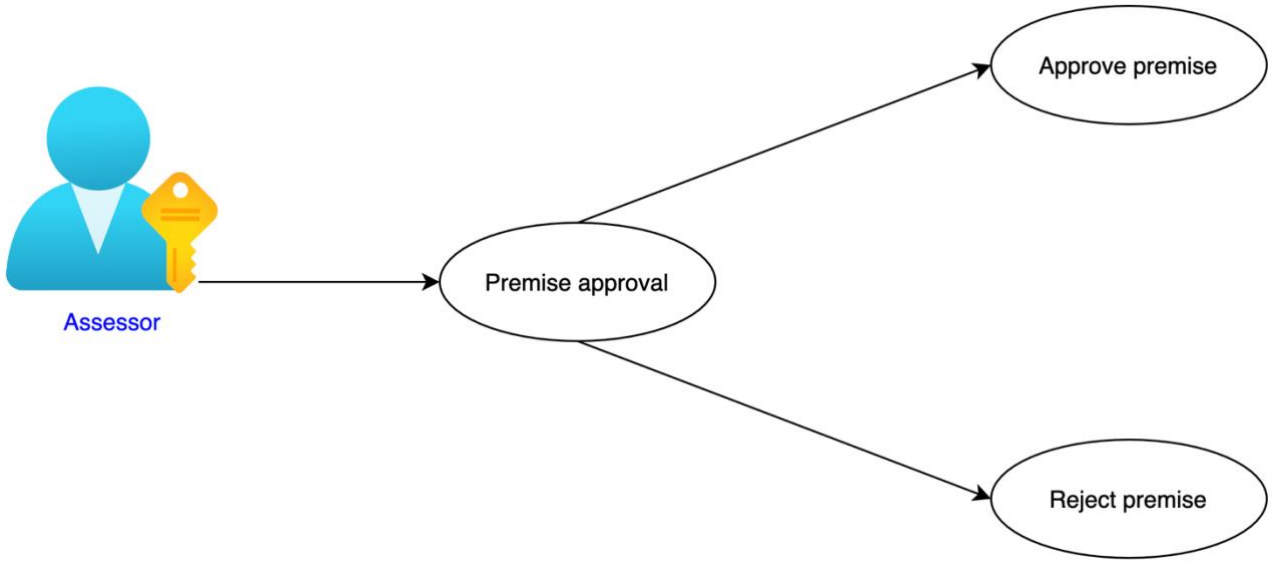

Figure 3-5: Assessor Use Case

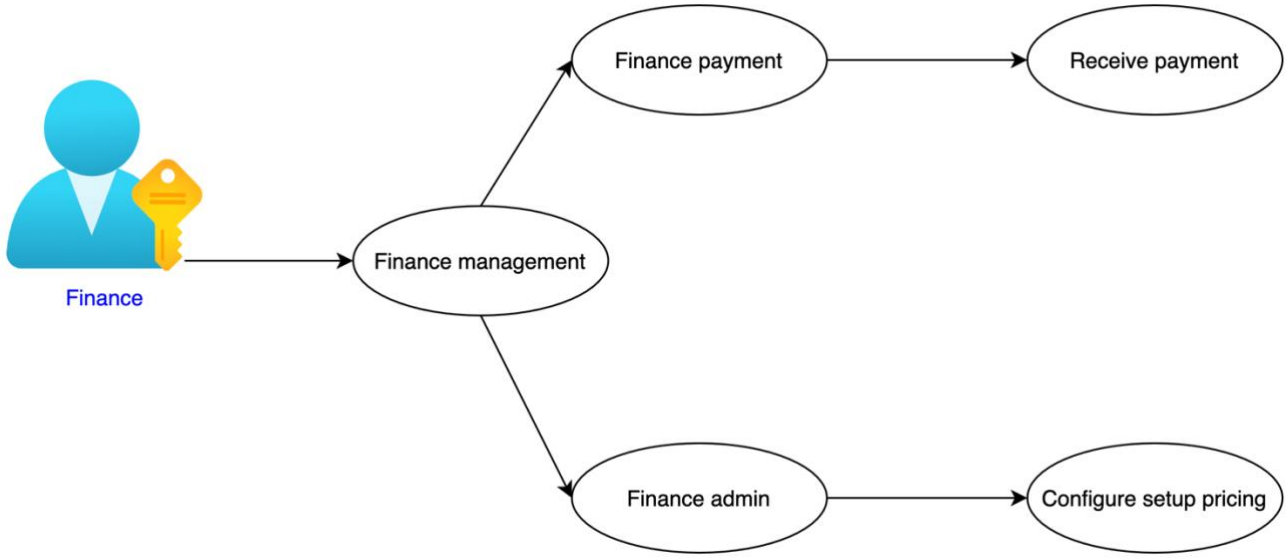

Figure 3-6: Finance Use Case

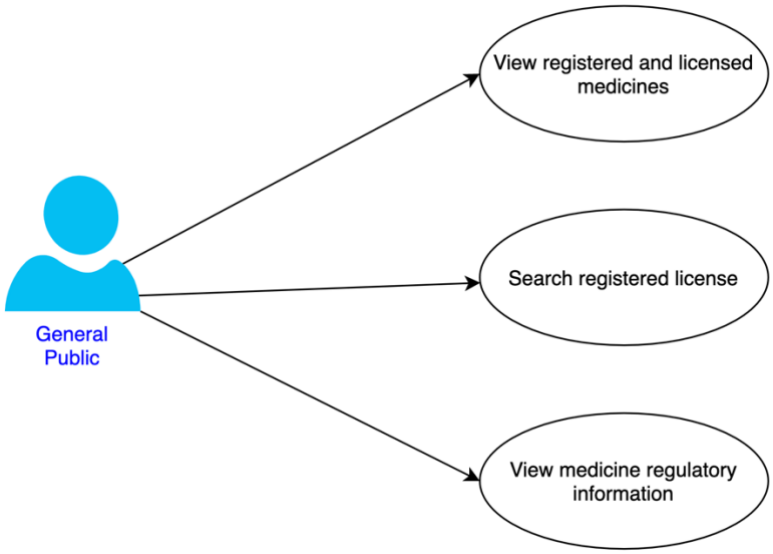

Figure 3-7: General Public Use Case

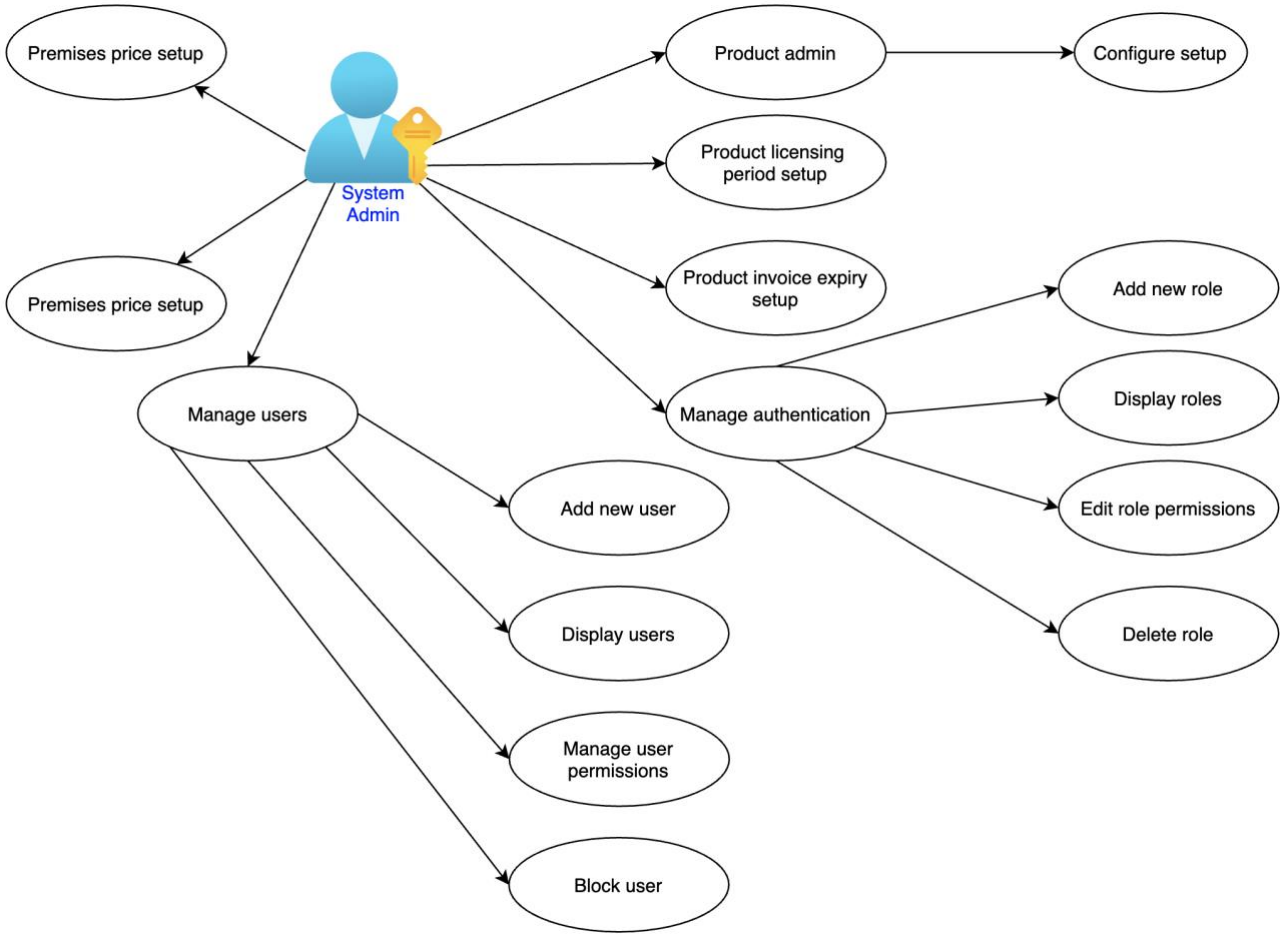

Figure 3-8: System Administrator Use Case

3.1 Premise licenses

3.1.1 Premise license registration

Table 3-1: Functional Requirements for Use Case Premise License Registration

ID	1
Name	Premise License Registration
Description	The system shall allow Actors to submit new premise license registration applications
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in
Inputs	● Premise Type ● Supervising Pharmacist ● Quality Control Pharmacist ● Authorization Letter from Sr. Pharmacist Attachment ● Product Category ● Product Classification ● Building Plan Attachments ● Distance. Nearest Pharmacist ● Premise License Duration ● Premise Directors ● Premise Staff
Flow of Events	
Basic Path	1. Open add Premise License Registration page 2. Choose Premise Type 3. Enter the required info 4. Attach the required documents 5. Enter premise information 6. Click add button
Alternative Paths	
Post-Conditions	● New application has been added
[Outputs]	● Invoice shall be printed and sent by email ● Application Verification Rejection Letter ● Suitability of Premise Rejection Letter ● Suitability of Premise License ● Premise License Registration Rejection Letter ● Premise License
[Constraint(s)]	● Must be able to complete in less than 2 s
Related Use Cases	
Used Use Cases	Submit Premise License Registration use case
Extending Use Cases	Submit Premise License Registration extends from license application submission use case

Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.1.2 Premise License Renewal

Table 3-2: Functional Requirements for Use Case Premise License Renewal

ID	2
Name	Premise License Renewal
Description	The system shall allow Actors to submit premise license renewal Application
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in
Inputs	• Previous License No • Premise License Duration
Flow of Events	
Basic Path	1. Open add Premise License renewal application page. 2. Choose Premise Previous License No. 3. Enter premise license duration. 4. Click the add button.
Alternative Paths	
Post-Conditions	• New application has been added
[Outputs]	• Invoice shall be printed and sent by email • Premise License • Premise License Renewal Rejection Letter
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Premise License Renewal
Extending Use Cases	Premise license submissions
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.1.3 Premise License Variation

Table 3-3: Functional Requirements for Use Case Premise License Variation

ID	3
Name	Premise License Variation
Description	The system shall allow Actors to submit premise license variation Application
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in
Inputs	• License No • Supervising Pharmacist • Quality Control Pharmacist • Authorization Letter from Sr. Pharmacist Attachment • Product Category • Product Classification • Building Plan Attachment • Distance. Nearest Pharmacist • Premise Directors • Premise Staff
Flow of Events	
Basic Path	1. Open add premise license variation application page. 2. Enter premise data. 3. Attach required files. 4. Click the add button.
Alternative Paths	
Post-Conditions	• New application has been added
[Outputs]	• Invoice shall be printed and sent by email • Premise License • Premise License Variation Rejection Letter
[Constraint(s)]	Must be able to complete in less than 50 ms
Related Use Cases	
Used Use Cases	Premise license submissions
Extending Use Cases	
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.1.4 Premise Price Setup

Table 3-4: Functional Requirements for Use Case Premise Price Setup

ID	4
Name	Premise Price Setup
Description	The system shall allow Actors to submit premise price setup application
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in
Inputs	• Premise Category • Registration Fee • Duration • Duration Type
Flow of Events	
Basic Path	1. Open premise price setup page. 2.Choose the premise category 3. Choose the process type: premise registration, premise renewal, premise alteration. 4.Enter Process Type fee, 5. Enter Duration information. 6. Click the Save button.
Alternative Paths	
Post-Conditions	
[Outputs]	
[Constraint(s)]	Must be able to complete in less than 50 ms
Related Use Cases	
Used Use Cases	Premise license submissions
Extending Use Cases	
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.1.5 Premise licensing period setup

Table 3-5: Functional Requirements for Use Case Premise Licensing Period Setup

ID	5
Name	premise licensing period setup
Description	The system shall allow Actors to licensing periods
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	
Inputs	● Premise Category ● Duration ● Duration Type
Flow of Events	
Basic Path	1. Open premise licensing period setup page. 2.Choose the premise category 3. Enter Duration information. 4. Click the Save button.
Alternative Paths	
Post-Conditions	
[Outputs]	● Suitability of Premise License ● Suitability of Premise Rejection Letter ● invoice
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Premise license submissions
Extending Use Cases	
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.1.6 Premise invoice expiry setup

Table 3-6: Functional Requirements for Use Case Premise Invoice Expiry Setup

ID	6
Name	Premise Licensing Period Setup
Description	The system shall allow Actors to setup premise licensing period
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Previous License No • Premise License Duration
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Setup invoice expiry
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Premise license submissions
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.2 Product licenses

3.2.1 Register New Product

3.2.1.1 Add Product details

Table 3-7: Functional Requirements for Use Case Add Product Details

ID	7
Name	Add product details
Description	The system shall allow Actors to register product licensing and adding product details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Application Number ● Date of submission of the dossier ● Product category ● Type of the medicinal product application ● Proprietary Name: ● International Nonproprietary Name (INN) of the Active Pharmaceutical Ingredient (API): ● Strength of Active Pharmaceutical Ingredient (API) per unit dosage form:
Flow of Events	
Basic Path	1. Open product licensing registration page. 2. Choose the product details tab. 3. Enter product information. 4. Click the Save button
Alternative Paths	
Post-Conditions	
[Outputs]	1. Product details saved 2. Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Register new product
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	4.1.1 Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.2 Add Applicant Info

Table 3-8: Functional Requirements for Use Case Add Applicant Info

ID	8
Name	Add Applicant Info
Description	The system shall allow Actors to register product licensing and applicant information
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	Applicant type (Individual) • Name • physical address • postal address • Telephone: • Telefax: • E-Mail: (Company) • Name: • Country: • address • Telephone: • Telefax: • E-Mail:
Flow of Events	
Basic Path	• Open product licensing registration page. • Choose the Applicant Info tab. • Enter applicant type: individual/company • Enter the details of applicant info • Click save
Alternative Paths	
Post-Conditions	
[Outputs]	• Product Info saved • Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Add applicant Info
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.3 Add Dosage Form

Table 3-9: Functional Requirements for Use Case Add Dosage Form

ID	9
Name	Add Dosage Form
Description	The system shall allow Actors to register product licensing and dosage form
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Package size ● Visual description
Flow of Events	
Basic Path	● Open product licensing registration page. ● Choose the Applicant Info tab. ● Enter applicant type: individual/company ● Enter the details of applicant info ● Click save
Alternative Paths	
Post-Conditions	
[Outputs]	● Product Info saved ● Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.4 Add Shelf Life

Table 3-10: Functional Requirements for Use Case Product License Registration /Add Shelf Life

ID	10
Name	Add shelf life
Description	The system shall allow Actors to register product licensing and add shelf life details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Proposed shelf life (in months): • Proposed shelf life (after reconstitution or dilution): • Proposed shelf life (after first opening container): • Proposed Storage Conditions • Proposed storage conditions after first opening • Other sister medicinal products registered or applied for registration
Flow of Events	
Basic Path	• Open product licensing registration page. • Choose the shelf life tab. • Enter shelf life inputs • Click save
Alternative Paths	
Post-Conditions	
[Outputs]	• Shelf life saved • Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	Register new product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.5 Add Marketing Authorization

Table 3-11: Functional Requirements for Use Case Product License Registration/Add Marketing Authorization

ID	11
Name	Add Marketing Authorization
Description	The system shall allow Actors to register product licensing and add Marketing Authorization details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Product Name ● Strength ● Marketing authorization number(s): ● Indication ● Is applied for Marketing Authorization of medicinal product containing the same active substance ○ Yes ■ Product Name ■ Strength ■ Indication ■ pharmaceutical form ○ No ■ None ● Is Product Marketing Authorization in the country of origin registered? ○ Registered ■ Date of authorization ■ Proprietary name: ■ Authorization number: ○ Not registered Explain the reason: ● Withdrawn ■ Date of withdrawal (dd-mm-Manufacturer): ■ Proprietary name: ■ Reason for withdrawal: ● Refused ■ Date of refusal ■ Country

	■ Reason for Refusal: ■ Suspended/revoked ■ Country ■ Date of suspension/revocation ■ Reason for suspension
Flow of Events	
Basic Path	● Open product licensing registration page. ● Choose the Marketing Authorization tab. ● Enter Authorization inputs ● Fill authorization answers ● Click save button
Alternative Paths	
Post-Conditions	
[Outputs]	● Authorizations saved ● Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.6 Add Manufacturers (FFP)

Table 3-12: Functional Requirements for Use Case Product License Registration/Add Manufactures

ID	12
Name	Add Manufacturers (FFP)
Description	The system shall allow Actors to register product licensing and add Marketing Authorization details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Name ● Company ● Address ● Country ● Telephone ● Telefax ● E-Mail
Flow of Events	
Basic Path	● Open product licensing registration page. ● Choose the Manufacturers (FFP) tab. ● Enter Manufacturers inputs ● Click save button
Alternative Paths	
Post-Conditions	
[Outputs]	● Manufacturers (FFP) saved ● New record will be added ● Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.7 Add Manufacturers (API)

Table 3-13: Functional Requirements for Use Case Product License Registration/ Add Manufactures

ID	13
Name	Add Marketing Authorization
Description	The system shall allow Actors to register product licensing and add Marketing Authorization details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Name • Company • Address • Country • Telephone • Telefax • E-Mail
Flow of Events	
Basic Path	• Open product licensing registration page. • Choose the Manufacturers (API) tab. • Enter Manufacturers inputs • Click save button
Alternative Paths	
Post-Conditions	
[Outputs]	• Manufacturers (API) saved • New record will be added • Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.8 Add Brokers and suppliers

Table 3-14: Functional Requirements for Use Case Product License Registration/Add Brokers And Suppliers

ID	14
Name	Add Brokers and suppliers
Description	The system shall allow Actors to register product licensing and add Brokers and suppliers' details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Name ● Company ● Address ● Country ● Telephone ● Telefax ● E-Mail
Flow of Events	
Basic Path	● Open product licensing registration page. ● Choose the Brokers/suppliers tab. ● Enter Brokers/suppliers inputs ● Click save button
Alternative Paths	
Post-Conditions	
[Outputs]	● New record saved ● New record will be added ● Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.9 Add Medicinal Product

Table 3-15: Functional Requirements for Use Case Product License Registration/Add Medicinal Product

ID	15
Name	Add Medicinal Product
Description	The system shall allow Actors to register product licensing and add Marketing Authorization details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Name of active ingredient(s) • Quantity /dosage unit • Unit of measure • Reference/monograph standard
Flow of Events	
Basic Path	• Open product licensing registration page. • Choose the medicinal product tab. • Enter medicinal product inputs • Click save button
Alternative Paths	
Post-Conditions	
[Outputs]	• New record will be added • Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.1.10 Add Contract Organization

Table 3-16: Functional Requirements for Use Case Product License Registration/Add Contract Organization

ID	16
Name	Add Marketing Authorization
Description	The system shall allow Actors to register product licensing and add Marketing Authorization details
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Name • Company • Address • Country • Telephone • Telefax • E-Mail
Flow of Events	
Basic Path	• Open product licensing registration page. • Choose the Manufacturers (API) tab. • Enter Manufacturers inputs • Click save button
Alternative Paths	
Post-Conditions	
[Outputs]	• Contract Research Organization saved • New record will be added • Move to the next step
[Constraint(s)]	
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	3.2.1 Register New Product
Related Screenshots	Add Product License registration
Source(s)	Application for Registration of Medicinal Product (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.2 Product license retention

Table 3-17: Functional Requirements for Use Case Product License Retention

ID	17
Name	product license retention
Description	The system shall allow Actors to retention product's licensing
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Product License No • Product Licensing Duration
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Product License Retention Rejection Letter
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Product license submissions
Extending Use Cases	No use case extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.2.3 Product License Variation

Table 3-18: Functional Requirements for Use Case Product License Variation

ID	18
Name	Premise Licensing Period Setup
Description	The system shall allow Actors to setup premise licensing period
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	Product License No
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	• Product License Variation Rejection Letter • Invoice
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Product license variation
Extending Use Cases	No xtended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.2.4 Product License Withdrawal

Table 3-19: Functional Requirements for Use Case Product License Withdrawal

ID	19
Name	Product License Withdrawal
Description	The system shall allow Actors to withdraw premise licensing
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Product License No • Withdrawal Reason • Related Attachments
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	• Product License Withdrawal Rejection Letter • Product License Withdrawal Acceptance Letter
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Product license withdrawal
Extending Use Cases	No use cases extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.2.5 Product Clinical Trial

3.2.5.1 Add List of Submissions

Table 3-20: Functional Requirements for Use Case Product Clinical Trial/Add List of Submissions

ID	20
Name	Add list of submissions
Description	The system shall allow Actors to add list of submissions while adding product clinical trial
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Covering letter • Application Form • General investigational plan • Capacity building plans • Overall Summary of th • Signed and approved protocol • Participant Information Leaflet (PIL), Informed Consent Forms (English and Swahili versions) and any other information • Declarations by Principal investigator, Co/Sub investigators and Monitor(s) • Joint declaration by Sponsor (or representative) and National Principal Investigator • Certified copy of insurance policy cover of study participants • Ethical clearance certificate/copy of acknowledgement from NIMR (Parallel submission) • Curriculum vitae (CVs) of investigator(s) • Blank Case Report Forms (CRFs) • Serious Adverse Events reporting form to be used in the study • Nonclinical Overall Summary (Hard copy and in MS Word) • Clinical Study Reports • Investigator's Brochure (IB) • Prescribing information sheets • Quality Overall Summary – Chemical Entities (Hard copy and in MS Word) • Certificate of GMP for manufacture of the Investigational products • Certificate of GMP manufacture of the Placebo/Comparator (if applicable) • Trial product Mockup labels and package Insert/s for other trial medicines • Letters of Access authorizing TFDA to Drug master Files, Site Reference Files

	● Full, legible copies of key, peer-reviewed published articles supporting the application ● Investigational Medicinal product dossier ● Chemistry, manufacturing and quality control data of active ingredient and finished product/dosage form ● Pharmacology and toxicology data
Flow of Events	
Basic Path	1. Open product clinical trial page. 2. Choose list summations tab. 3. Select and upload available documents or files. 4. Click the Save button
Alternative Paths	
Post-Conditions	List of submissions has been saved
[Outputs]	Move to the next step
[Constraints(s)]	
Related Use Cases	
Used Use Cases	Product clinical trial application
Extending Use Cases	No use cases extended
Related Screenshots	4.1.3 Product clinical trial
Source(s)	Application Form for a New Clinical Trial (url:https://Manufacturer.tmda.go.tz/publications/28)

3.2.5.2 Add Administrative Details

Table 3-21: Functional Requirements for Use Case Product Clinical Trial/Add Administrative Details

ID	21
Name	Add Administrative Details
Description	The system shall allow Actors to add administrative details while adding product clinical trial
Priority	1
Status	Detailed description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Title of the Study: ● Protocol Number/Identification: ● Version number ● Date of final protocol: ● Applicant: Sponsor: ● Local contact person: ● National principal investigator ● International principal investigator ● Monitor: Study coordinator:
Flow of Events	
Basic Path	1. Open product clinical trial page. 2. Choose add administrative tab. 3. Enter the required information. 4. Click the Save button
Alternative Paths	
Post-Conditions	Administrative data should be saved
[Outputs]	Move to the next step
[Constraints(s)]	
Related Use Cases	
Used Use Cases	Product clinical trial application
Extending Use Cases	
Related Screenshots	4.1.3 Product clinical trial
Source(s)	Application Form for a New Clinical Trial (URL:https://Manufacturer.tmda.go.tz/publications/28)

3.2.5.3 Add Investigational Product

Table 3-22: Functional Requirements for Use Case Product Clinical Trial/Add Administrative Details/Add Investigational Products

ID	22
Name	Add investigational product
Description	
Priority	1
Status	Detailed description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Investigational Products ○ Investigator product ○ Description ○ Is locally sourced ○ Registration No. ○ date of registration ● Comparator product ○ comparator product ○ Description ○ Is locally sourced ○ Registration No. ○ date of registration ● Concomitant medication ○ concomitant medication ○ Description ○ Is locally sourced ○ Registration No. ○ date of registration ● Other info ○ Details of packaging ○ storage conditions ○ shelf-life of IMP ○ Registration status of IMP
Flow of Events	
Basic Path	1. Open product clinical trial page. 2. Choose Investigation product tab. 3. Enter the required inputs. 4. Click the Save button
Alternative Paths	
Post-Conditions	Investigational products will be saved
[Outputs]	Move to the next step
[Constraints(s)]	

Related Use Cases	
Used Use Cases	Product clinical trial application
Extending Use Cases	
Related Screenshots	4.1.3 Product clinical trial
Source(s)	Application Form for a New Clinical Trial (url:https://Manufacturer.tmda.go.tz/publications/28)

3.2.5.4 Add Investigators and trial sites

Table 3-23: Functional Requirements for Use Case Product Clinical Trial/ Add Investigators/Trial Sites

ID	23
Name	Add Investigators and trial sites
Description	
Priority	1
Status	Detailed description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Investigators ○ Personal info ▪ Name ▪ Address ▪ Tel ▪ Mobile ▪ Fax ▪ Email ○ Current workload of investigator ▪ Number of studies currently undertaken by investigators as principal ▪ Total number of patients represented by these study ▪ Time-commitments of researcher ● Details of Trial Site ○ General Info ▪ Name of site ▪ physical address ▪ Phone ▪ contact person ▪ Mobile ○ Capacity of Trial Site ▪ Number of staffs ▪ Site facilities ▪ emergency facility ▪ other relevant infrastructure

Flow of Events	
Basic Path	5. Open product clinical trial page. 6. Choose Investigation product tab. 7. Enter the required inputs. 8. Click the Save button
Alternative Paths	
Post-Conditions	Investigational products will be saved
[Outputs]	Move to the next step
[Constraints(s)]	
Related Use Cases	
Used Use Cases	Product clinical trial application
Extending Use Cases	
Related Screenshots	4.1.3 Product clinical trial
Source(s)	Application Form for a New Clinical Trial (url:https://Manufacturer.tmda.go.tz/publications/28)

3.2.5.5 Add other details

Table 3-24: Functional Requirements for Use Case Product Clinical Trial/ Add Other Details

ID	24
Name	Add other details
Description	
Priority	1
Status	Detailed description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Study participants ○ number of local participants ○ Total number of participants worldwide ○ Total enrolment in each local site/center ○ Volunteer base from which local participants will be drawn ○ Retrospective data ● Other details ○ Provide an explanation if the trial is to be conducted locally only and not in the host country of the applicant / sponsor: ○ Define Reg. Authorities which have: ▪ Submitted, approval has not yet been granted ● RA Name ● date of submission ▪ approved this trial ● RA Name

	● date of approval ▪ have rejected this trial ● RA Name ● reasons for the rejection ▪ suspended at any stage ● RA Name ● Details of and reasons
Flow of Events	
Basic Path	1. Open product clinical trial page. 2. Choose other details tab. 3. Enter the required inputs. 4. Click the Save button
Alternative Paths	
Post-Conditions	
[Outputs]	Other details data will be saved
[Constraints(s)]	
Related Use Cases	
Used Use Cases	Product clinical trial application
Extending Use Cases	
Related Screenshots	4.1.3 Product clinical trial
Source(s)	Application Form for a New Clinical Trial (url: https://Manufacturer.tmda.go.tz/publications/28)

3.2.5.6 Add Ethics documents

Table 3-25: Functional Requirements for Use Case Product Clinical Trial/Add Ethics Documents

ID	25
Name	Product Survey
Description	
Priority	1
Status	Detailed description
Actors	Manufacturer
Pre-Conditions	● Actor has been enrolled in the MIS system. ● Actor is not logged in ● Actor has permission
Inputs	● Ethics Committee responsible for each site, date of approval or date of application: ● Attach copy of response(s) positive or negative made by, and/or conditions required by Ethics Committee(s) if available] ● Details of capacity building component of the trial, if any:

	• Details of ICH-GCP training of investigators, monitors, study co-coordinators in terms of conducting this trial: • Detailed monitoring plan for each site: Attach as an Annex if necessary • Details of trial insurance: e.g. insurer, policy holder, policy number, insurance cover, period of validity • Details of possible conflict of interest of any person(s)/organization(s) who/which will be involved in the trial • Remuneration/compensation to be received by investigators, trial participants or others
Flow of Events	
Basic Path	1. Open product clinical trial page. 2. Choose Ethics tab. 3. Enter the required inputs. 4. Click the Save button
Alternative Paths	
Post-Conditions	
[Outputs]	Other details will be saved
[Constraints(s)]	
Related Use Cases	
Used Use Cases	Product clinical trial
Extending Use Cases	No use cases extended
Related Screenshots	4.1.3 Product clinical trial
Source(s)	Application Form for a New Clinical Trial (url:https://Manufacturer.tmda.go.tz/publications/28)

3.2.6 Product Survey

Table 3-26: Functional Requirements for Use Case Product Survey

ID	26
Name	Product Survey
Description	
Priority	1
Status	Incomplete Parts
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	
[Constraints(s)]	
Related Use Cases	
Used Use Cases	Product surey
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	No source available

3.2.7 Product Promotion

Table 3-27: Functional Requirements for Use Case Product Promotion

ID	27
Name	Product Promotion
Description	
Priority	1
Status	Detailed Description
Actors	Manufacturer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission

Inputs	• Applicant Particulars
	  ○ Name of applicant:
	  ○ Address
	  ○ contact Person

	○ E-mail ○ Tel ○ Fax ● Sponsor Particulars ○ Name of Sponsor ○ Address ○ Contact person: ○ E-mail ○ Tel ○ Fax ● Product Particulars ○ Distribution category ○ Product Name/s ○ Registration number ○ Name of registration holder ○ Active ingredient(s) and strengths of the product ● Attachments ○ A copy of the proposed advert ○ Current indications of use as indicated on Certificate of Registration (where applicable). ○ Copy of any research/surveys/data mentioned in advertisement ○ Copy of previous approval (If the advert is a reminder) ○ Current indications of use as indicated on Certificate of Registration (where applicable). ○ Application fee.
Flow of Events	
Basic Path	1. Open product promotion page. 2. Enter the required inputs. 3. Click the Save button
Alternative Paths	
Post-Conditions	Product promotion submitted
[Outputs]	● Product Promotion License ● Product Promotion Rejection Letter
[Constraints(s)]	
Related Use Cases	
Used Use Cases	License application submissions
Extending Use Cases	No extended use cases
Related Screenshots	4.1.2 Product promotion
Source(s)	Application Form for Approval of Promotional Materials (url: https://Manufacturer.tmda.go.tz/publications/23)

3.2.8 Product Price Setup

Table 3-28: Functional Requirements for Use Case Product Price Setup

ID	28
Name	Product Price Setup
Description	
Priority	1
Status	
Actors	System administrator
Pre-Conditions	
Inputs	• Product Category • Registration Fee • Duration • Duration Type
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Setup product price
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Product Price Setup
Extending Use Cases	No use cases extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.2.9 Product Licensing Period Setup

Table 3-29: Functional Requirements for Use Case Product Licensing Period Setup

ID	29
Name	Product Licensing Period Setup
Description	
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	
Inputs	• Product Category • Duration • Duration Type
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	• Setup product license period • invoice
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Product Licensing Period Setup
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.2.10 Product Invoice Expiry Setup

Table 3-30: Functional Requirements for Use Case Product Invoice Expiry Setup

ID	30
Name	Product Invoice Expiry Setup
Description	
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	
Inputs	• Product Category • Duration • Duration Type
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	
[Constraint(s)]	Setup Invoice Expiry
Related Use Cases	
Used Use Cases	No other use cases used
Extending Use Cases	No use cases extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3 Import and Export

3.3.1 Permit Import/Export

3.3.1.1 Import Permit Registration

Table 3-31: Functional Requirements for Use Case Import Permit Registration

ID	31
Name	Import Permit Registration
Description	
Priority	1
Status	
Actors	Importer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Premise License No • Product Category • Import Reason • Country of Origin • Import Invoice Particulars • Import Attachments
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	• Import Permit Import Permit Rejection Letter • Invoice
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Import permit registration
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.1.2 Export Permit Registration

Table 3-32: Functional Requirements for Use Case Export Permit Registration

ID	18
Name	Export Permit Registration
Description	
Priority	1
Status	
Actors	Exporter
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Premise License No • Product Category • Export Reason • Country of Export • Export Invoice Particulars • Export Attachments
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Export Permit Export Permit Rejection Letter Invoice
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Export permit registration
Extending Use Cases	No use case extended
Related Screenshots	
Source(s)	1 NDA IMS software design specification document 2 EAC IMS NMRA System Requirements

3.3.2 License Import/Export

3.3.2.1 Import License Registration

Table 3-33: Functional Requirements for Use Case Import License Registration

ID	32
Name	Import/Export License Registration
Description	
Priority	1
Status	Detailed Description
Actors	Importer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Premise License No • Product Category • License Duration
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	• Things that are true after the use case ends
[Outputs]	• Import license registration • Import License Registration Rejection Letter • Invoice
[Constraint(s)]	Must be able to complete in less than 50 ms
Related Use Cases	
Used Use Cases	Import license registration
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.2.2 Export License Registration

Table 3-34: Functional Requirements for Use Case Import/Export License Renewal

ID	20
Name	Export License Registration
Description	
Priority	1
Status	Detailed Description
Actors	Exporter
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Previous License No • License Duration
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	• Export License • Export License Registration Rejection Letter • Invoice
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Export license registration
Extending Use Cases	No use cases extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.2.3 Import License Renewal

Table 3-35: Functional Requirements for Use Case Import License Renewal

ID	21
Name	Import License Renewal
Description	
Priority	1
Status	Detailed Description
Actors	Importer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Previous License No • License Duration
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	• Import License Registration Renewal Letter • Invoice • Import License Registration renewal
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Import license renewal
Extending Use Cases	No extended use case
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.2.4 Export License Renewal

Table 3-36: Functional Requirements for Use Case Import/Export License Renewal

ID	22
Name	Export License Renewal
Description	
Priority	1
Status	Detailed Description
Actors	Exporter
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor is not logged in • Actor has permission
Inputs	• Previous License No • License Duration
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Export License Export License renewal rejection Letter
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Export License Renewal
Extending Use Cases	No use cases extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.3 Import/Export Price Setup

3.3.3.1 Import Price Setup

Table 3-37: Functional Requirements for Use Case Price Setup

ID	33
Name	Import Price Setup
Description	
Priority	1
Status	Detailed Description
Actors	Importer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor has permission
Inputs	• Permit Type • Invoice Value Percent • Product Category • Standard Fee
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Import Setup price
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Import Price Setup
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.4 Licensing Period Setup

3.3.4.1 Import Licensing Period

Table 3-38: Functional Requirements for Use Case Import and Export Licensing Period Setup

ID	34
Name	Import Licensing Period
Description	
Priority	1
Status	Detailed Description
Actors	Importer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor has permission
Inputs	• License Type • Duration • Duration Type
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Licensing period has been imported
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Import and Export Licensing Period
Extending Use Cases	No use cases extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.4.2 Export Licensing Period

Table 3-39: Functional Requirements for Use Case Import and Export Licensing Period Setup

ID	25
Name	Export Licensing Period
Description	
Priority	1
Status	Detailed Description
Actors	Exporter
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor has permission
Inputs	• License Type • Duration • Duration Type
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Export Licensing Period
Extending Use Cases	No use cases extended
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.5 Invoice Expiry Setup

3.3.5.1 Import Invoice Expiry Setup

Table 3-40: Functional Requirements for Use Case Import and Export Invoice Expiry Setup

ID	35
Name	Import and Export Invoice Expiry Setup
Description	
Priority	1
Status	Detailed Description
Actors	Importer
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor has permission
Inputs	• Invoice Type • Duration • Duration Type
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	Setup Invoice Expiry
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Application submissions
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.3.5.2 Export Invoice Expiry Setup

Table 3-41: Functional Requirements for Use Case Import and Export Invoice Expiry Setup

ID	27
Name	Import and Export Invoice Expiry Setup
Description	
Priority	1
Status	Detailed Description
Actors	Exporter
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor has permission
Inputs	• Invoice Type • Duration • Duration Type
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Application submissions
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.4 Document Library

3.4.1 Inputs/Output document

3.4.1.1 Add new document

Table 3-42: Functional Requirements for Use Case Add New Document

ID	36
Name	Add new document
Description	
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	• Actor has been enrolled in the MIS system. • Actor has permission
Inputs	• Date created • Created By • Document Owner • Document Type • Document Reference No • Document Name • Document Description
Flow of Events	
Basic Path	
Alternative Paths	
Post-Conditions	
[Outputs]	New document saved
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Application submissions
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	• NDA IMS software design specification document • EAC IMS NMRA System Requirements

3.5 System administration

3.5.1 Manage users

3.5.1.1 Add New User

Table 3-43: Functional Requirement for Use case Add New User

ID	37
Name	Add new user
Description	System shall allow administrator to add new user
Priority	1
Status	Detailed Description
Actors	system administrator
Pre-Conditions	User has privilege to add new user
Inputs	1. Full Name 2. email 3. phone 4. Mobile 5. Mobile2 6. Image 7. Username 8. password
Flow of Events	
Basic Path	1. Open add user page 2. Enter user information 3. Enter username 4. Enter user password 5. Confirm user password 6. Click Add button
Alternative Paths	
Post-Conditions	- New user has account to the system and can sign in to access system
[Outputs]	-New user has been added
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Manage users
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	General use case

3.5.1.2 Display users

Table 3-44: Functional Requirement for Use Case Display Users

ID	38
Name	Display users
Description	System shall allow administrator to display users
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	User has privilege to display users
Inputs	No inputs
Flow of Events	
Basic Path	1. Open Display user's page 2. System shall display users' basic information
Alternative Paths	
Post-Conditions	-System shall display users list
[Outputs]	-New user has been added
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Manage users
Extending Use Cases	No extended use cases
Related Screenshots	
Source(s)	General use case

3.5.1.3 Manage User Permissions

Table 3-45: Functional Requirement for Use Case Manage Users' Permissions

ID	39
Name	Manage user permission
Description	The system shall allow administrator to manage user permission, User cannot access pages or actions he don't has permission on it
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	User has privilege to display users
Inputs	No inputs
Flow of Events	
Basic Path	1. Display all users 2. Click manage permission button for specific user 3. System open manage user permission page 4. Actor can change user role 5. User can check or uncheck permissions 6. Click Save button
Alternative Paths	
Post-Conditions	-The user permission has been changed
[Outputs]	-user permission has been changed
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Manage users
Extending Use Cases	No extended use case
Related Screenshots	
Source(s)	General use case

3.5.2 Manage Authentication

3.5.2.1 Add New Role

Table 3-46: Functional Requirements for Use Case Add New Role

ID	40
Name	Add New Role
Description	System shall allow administrator to add new role
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	User has privilege to add new role
Inputs	• role name • role permissions
Flow of Events	
Basic Path	1. Open add role page 2. Enter role name 3. Select role permissions 4. Click Add button
Alternative Paths	
Post-Conditions	
[Outputs]	New role added
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Manage Authentication
Extending Use Cases	No extended use case
Related Screenshots	
Source(s)	General use case

3.5.2.2 Display Roles

Table 3-47: Functional Requirements for Use Case Display Roles

ID	39
Name	Display Roles
Description	
Priority	1
Status	Detailed Description
Actors	System administrator
Pre-Conditions	User has privilege to add new role
Inputs	• role name • role permissions
Flow of Events	
Basic Path	1. Open add role page 2. Enter role name 3. Select role permissions 4. Click Add button
Alternative Paths	
Post-Conditions	System shall display all users in a role
[Outputs]	display all users in a role
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Manage authentication
Extending Use Cases	No uses cases extended
Related Screenshots	
Source(s)	General use case

3.5.2.3 . Edit Role Permissions

Table 3-48: Functional Requirement for Edit Role Permission Use Case

ID	42
Name	Edit Role permission
Description	The system shall allow administrator to edit role permission
Priority	1
Status	Detailed Description
Actors	system administrator
Pre-Conditions	User has privilege to manage user permission
Inputs	● Check or uncheck permissions
Flow of Events	
Basic Path	1. Display all users 2. Click manage permission button for specific user 3. System open manage user permission page 4. User can check or uncheck permissions 5. Click Save button 6. System will update users' permissions in this role according to updating permissions
Alternative Paths	
Post-Conditions	The user permission has been changed
[Outputs]	The user permission has been changed
[Constraint(s)]	
Related Use Cases	
Used Use Cases	Manage authentication
Extending Use Cases	
Related Screenshots	
Source(s)	General use case

4 External Interface Requirements

4.1 User Interfaces

4.1.1 Add Product License registration

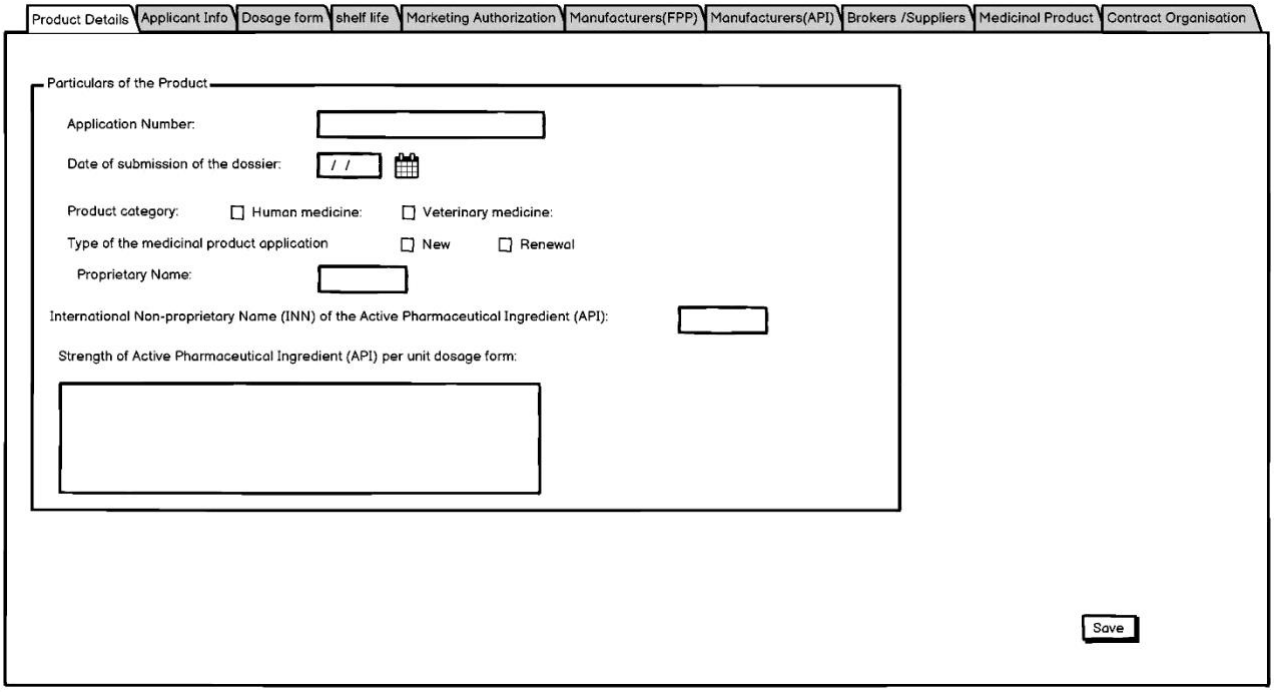

Figure 4-1: Product Licensing Registration/Add Product Details

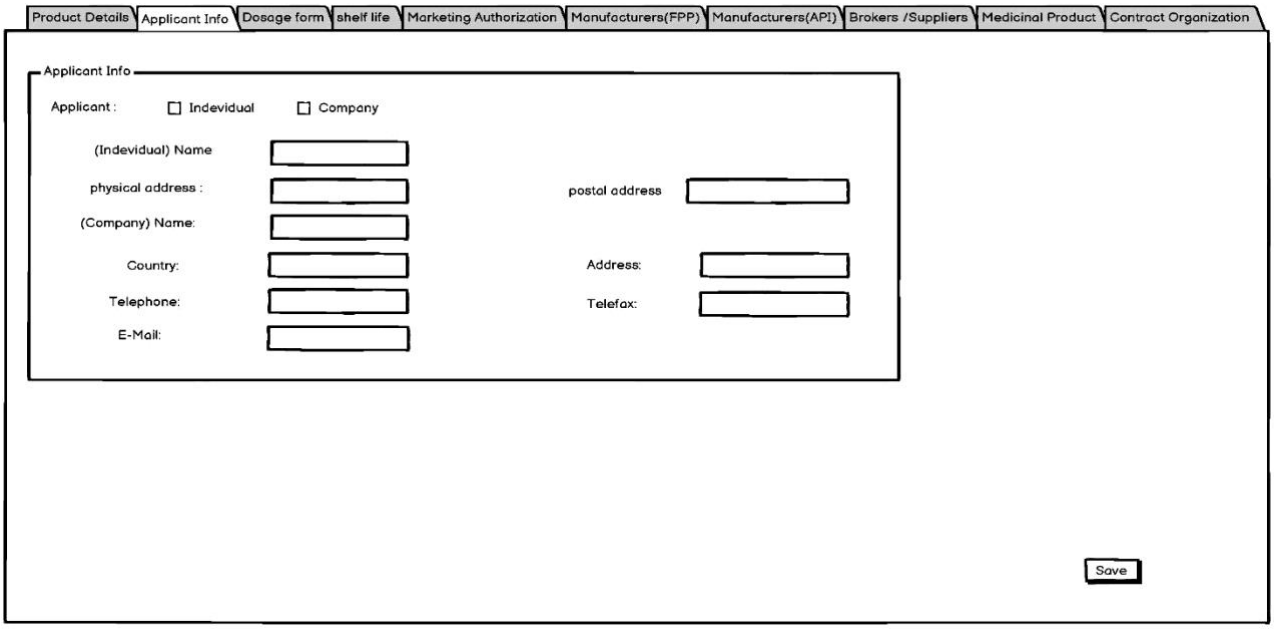

Figure 4-2: Product Licensing Registration/Add Product Details/Add Applicant Info

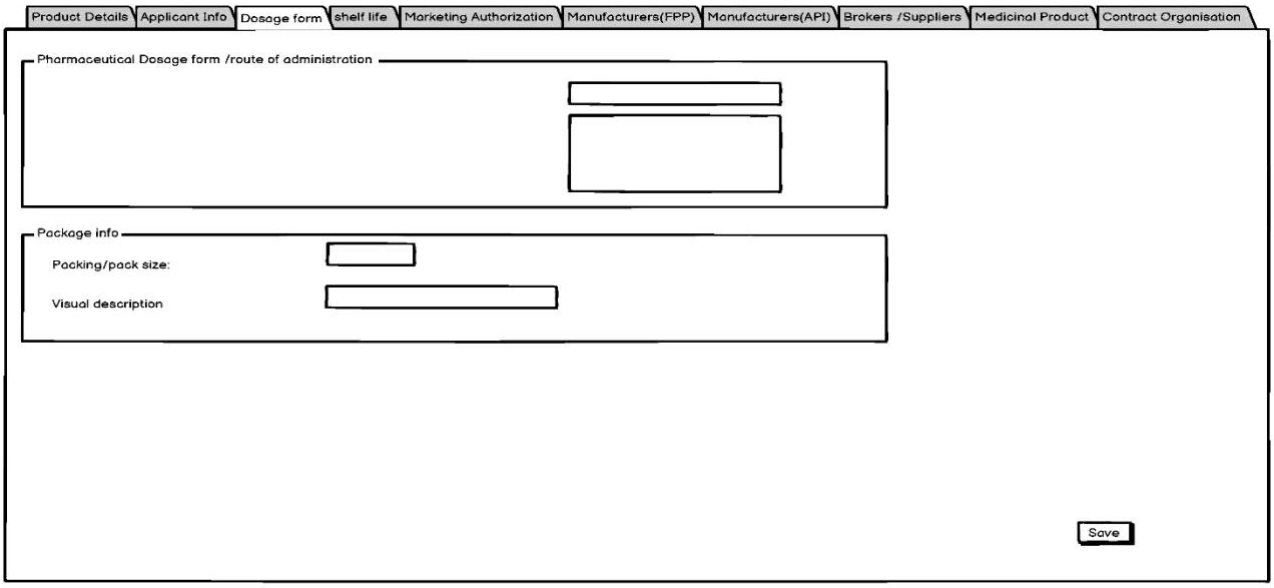

Figure 4-3: Product Licensing Registration/Add Product Details

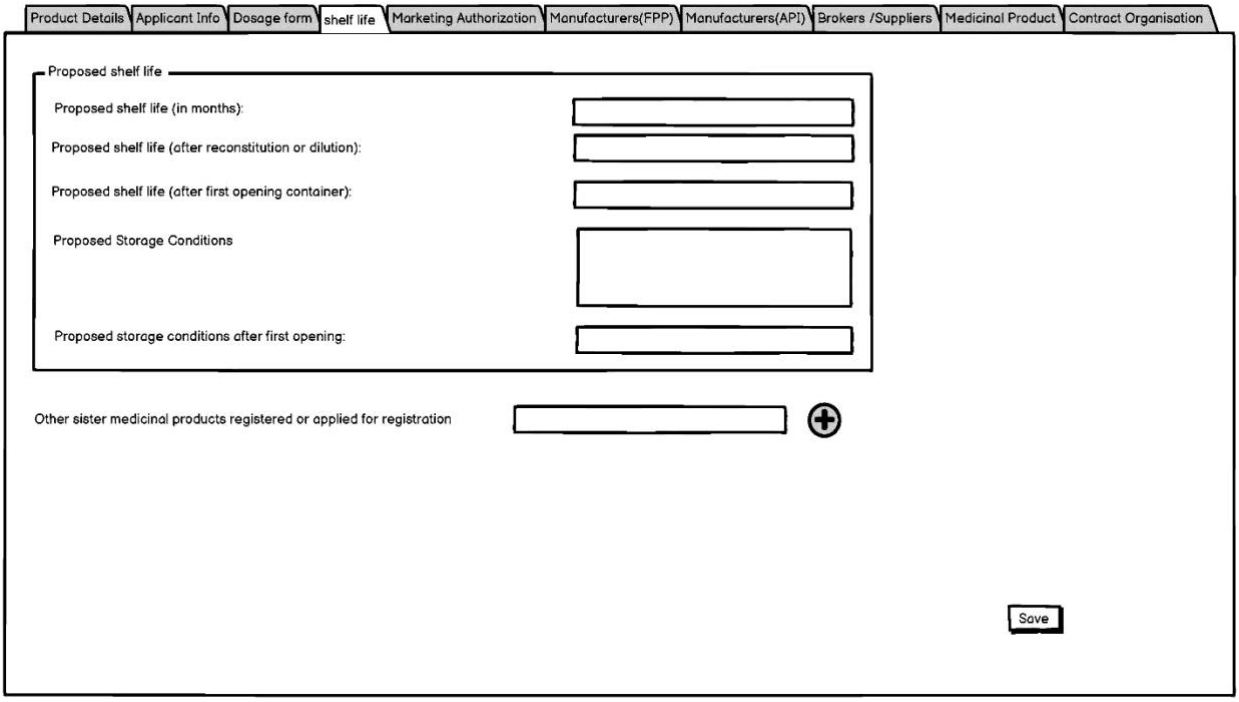

Figure 4-4: Product Licensing Registration/Add Shelf Life

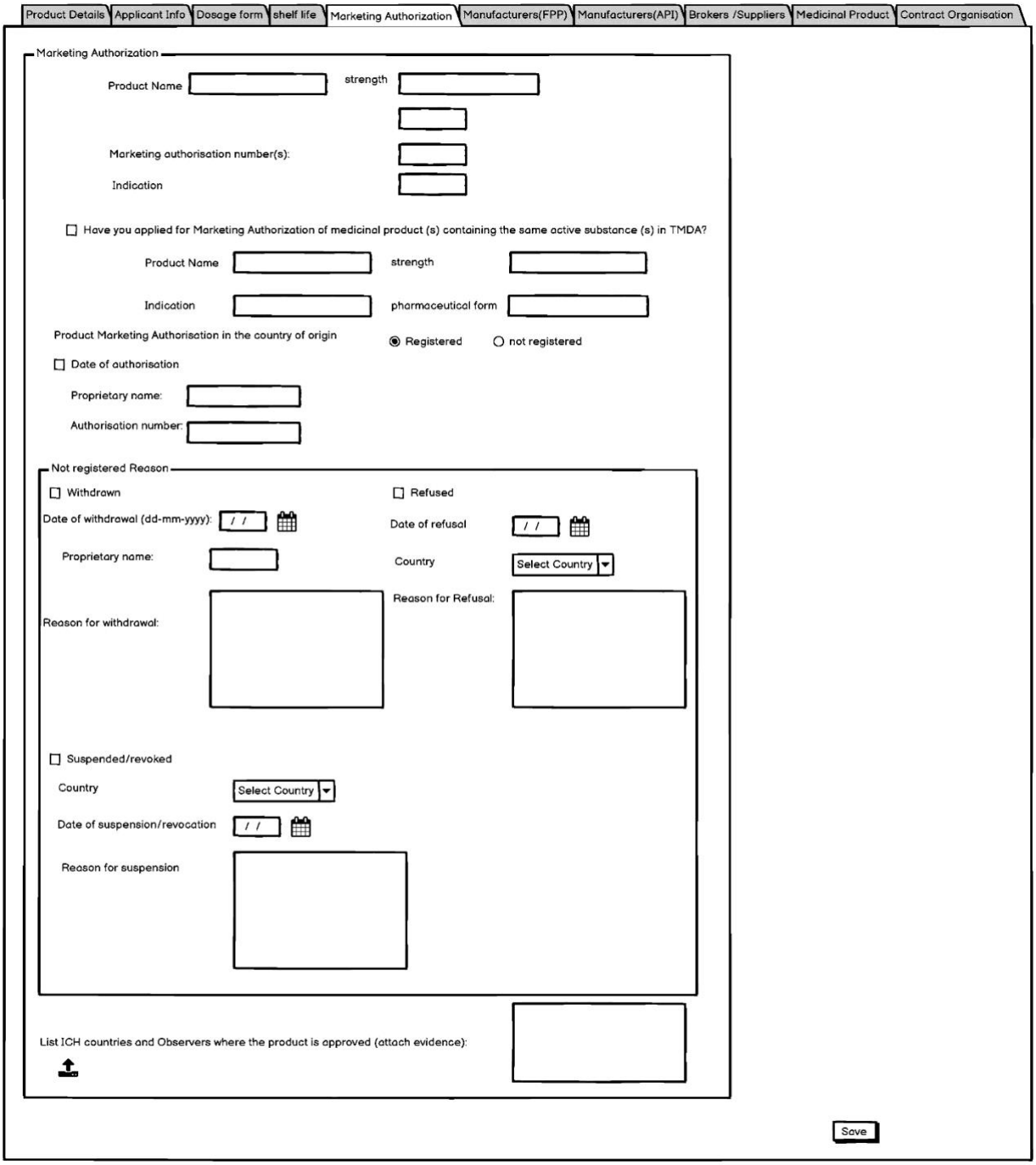

Figure 4-5: Product Licensing Registration/Add Marketing Authorization Details

Figure 4-6: Product Licensing Registration/Add Manufacturers (FPP)

Figure 4-7: Product Licensing Registration/Add Manufacturers (API)

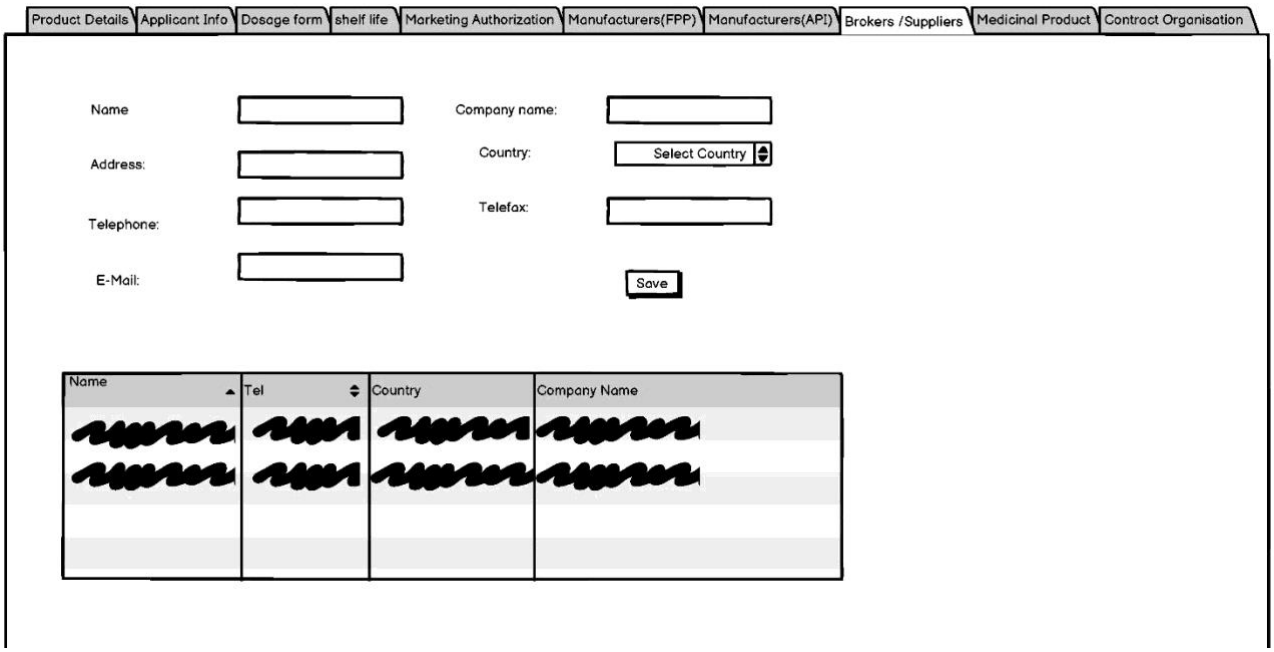

Figure 4-8: Product Licensing Registration/Add Brokers and Suppliers

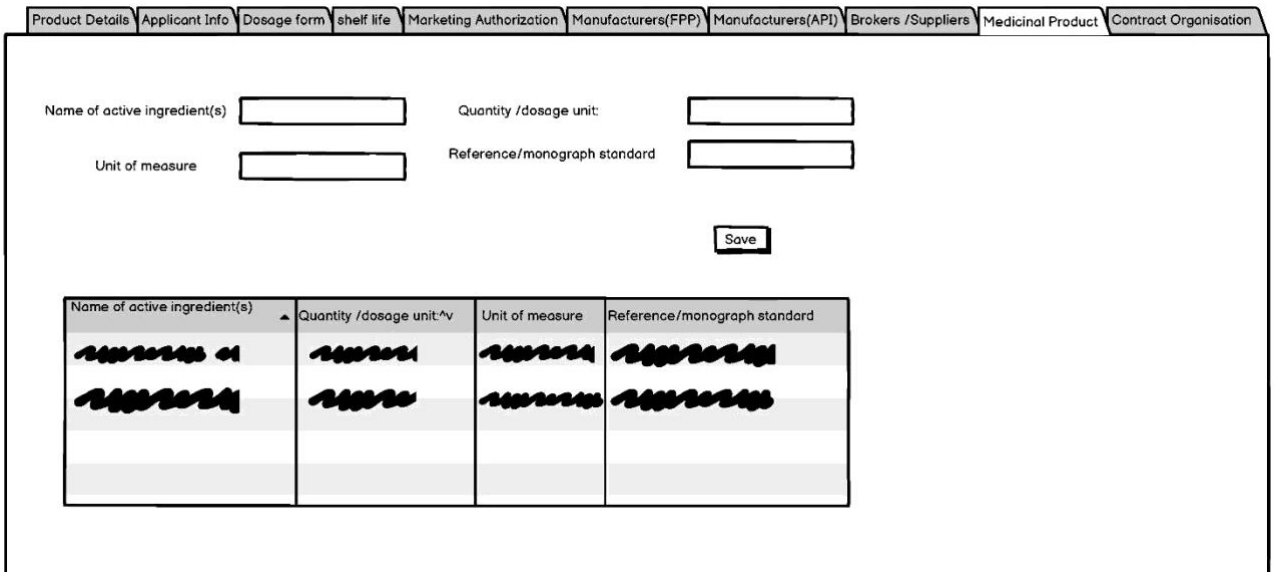

Figure 4-9: Product Licensing Registration/Add Medicinal Product

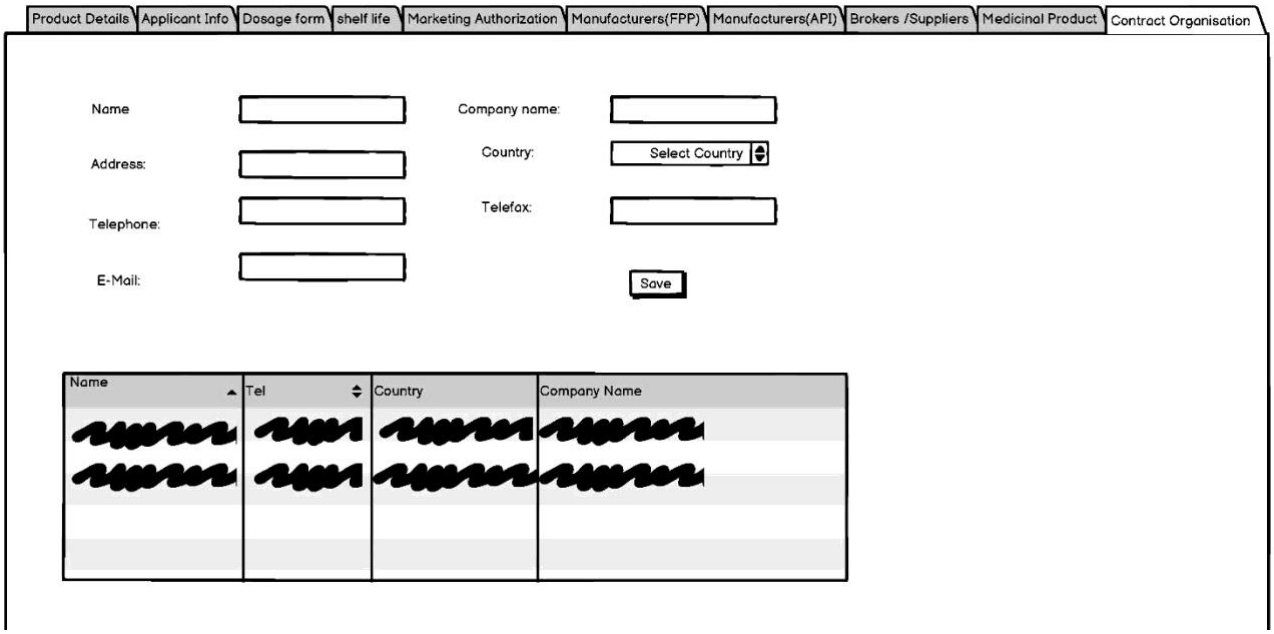

Figure 4-10: Product Licensing Registration/Add Contract Organization

4.1.2 Product promotion

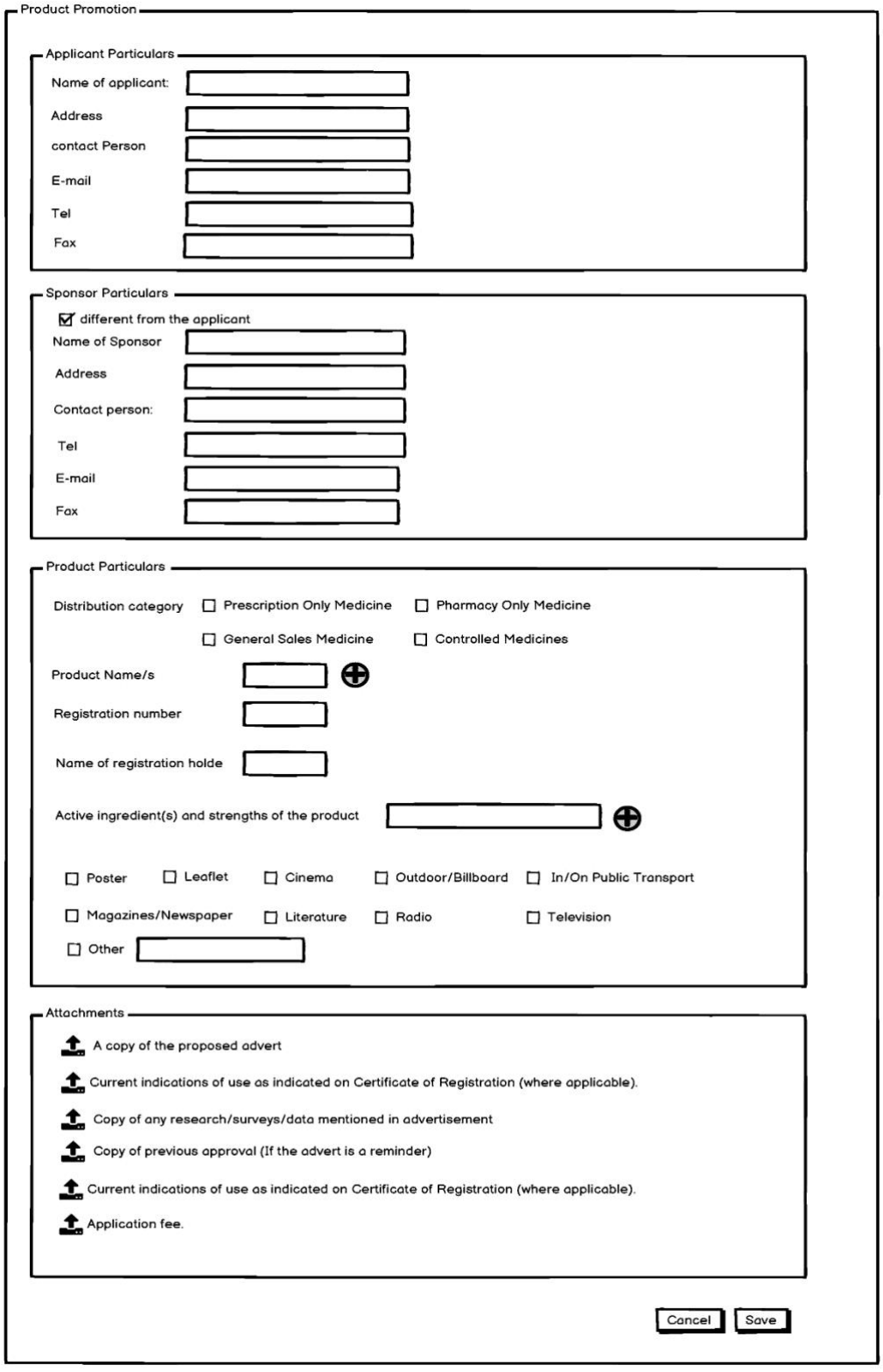

Figure 4-11: Product Promotion

4.1.3 Product clinical trial

Figure 4-12: Product Clinical Trial Introduction

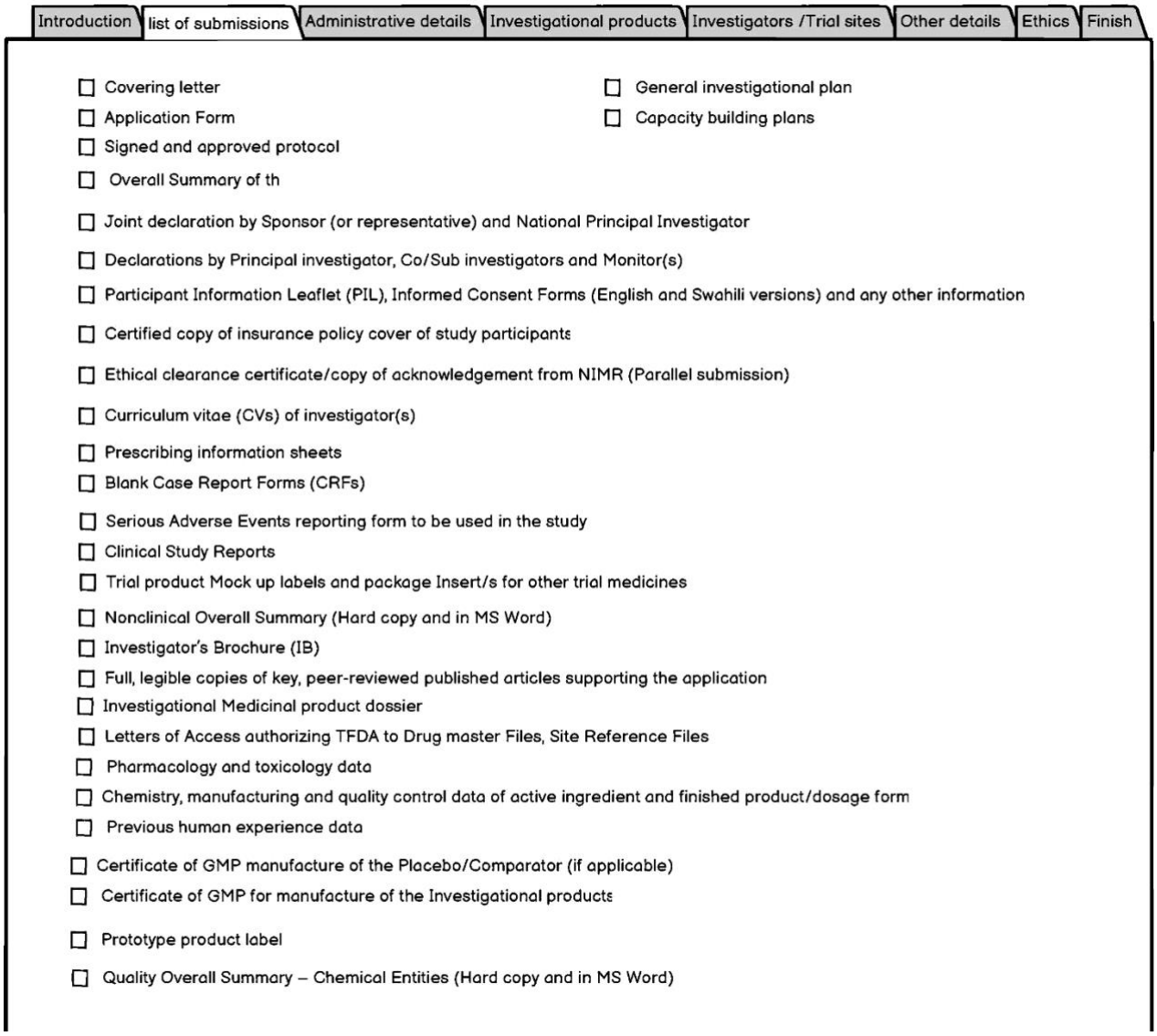

Figure 4-13: Product Clinical Trial/Add List of Submissions

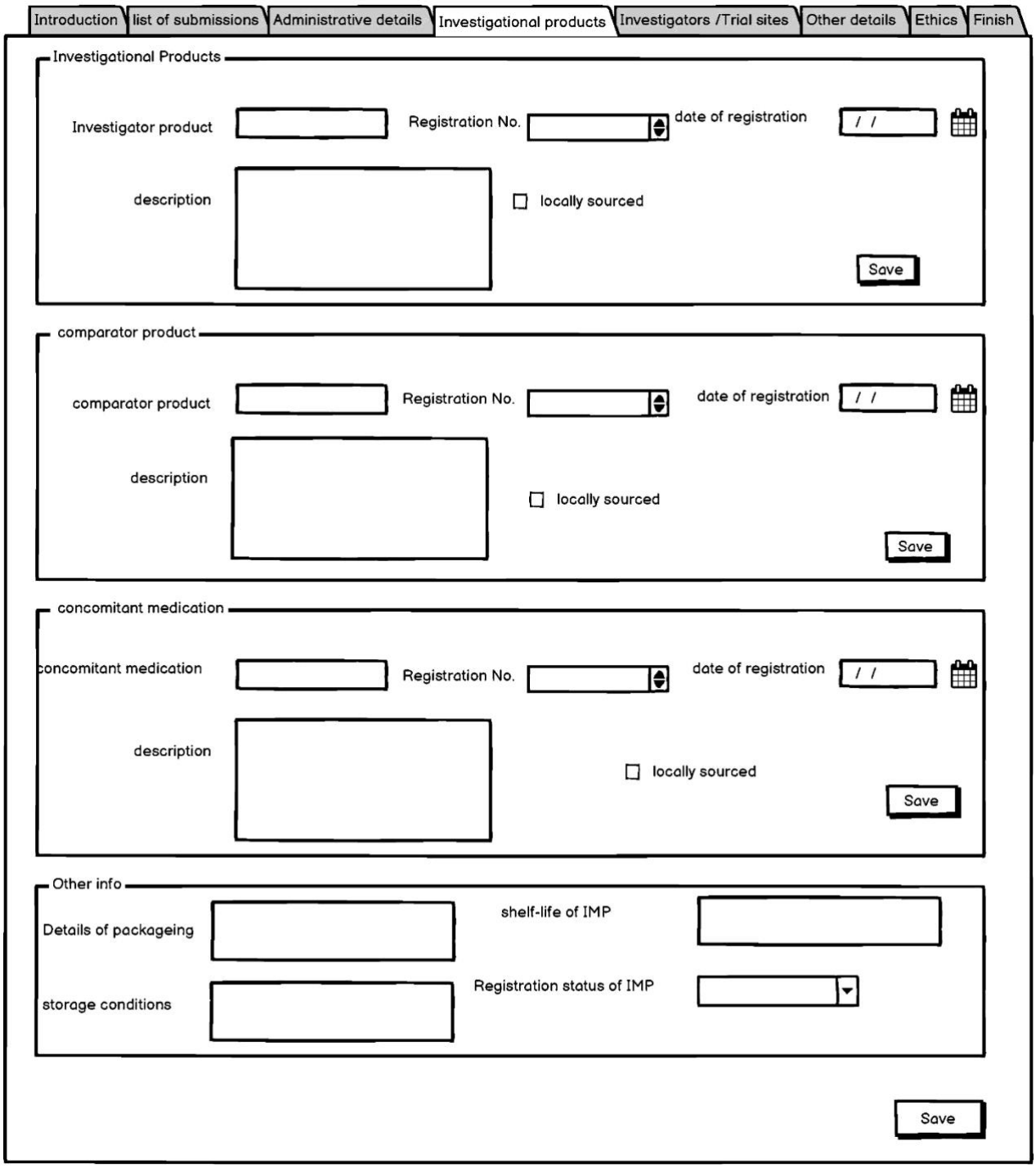

Figure 4-14: Product Clinical Trial/Investigational Products

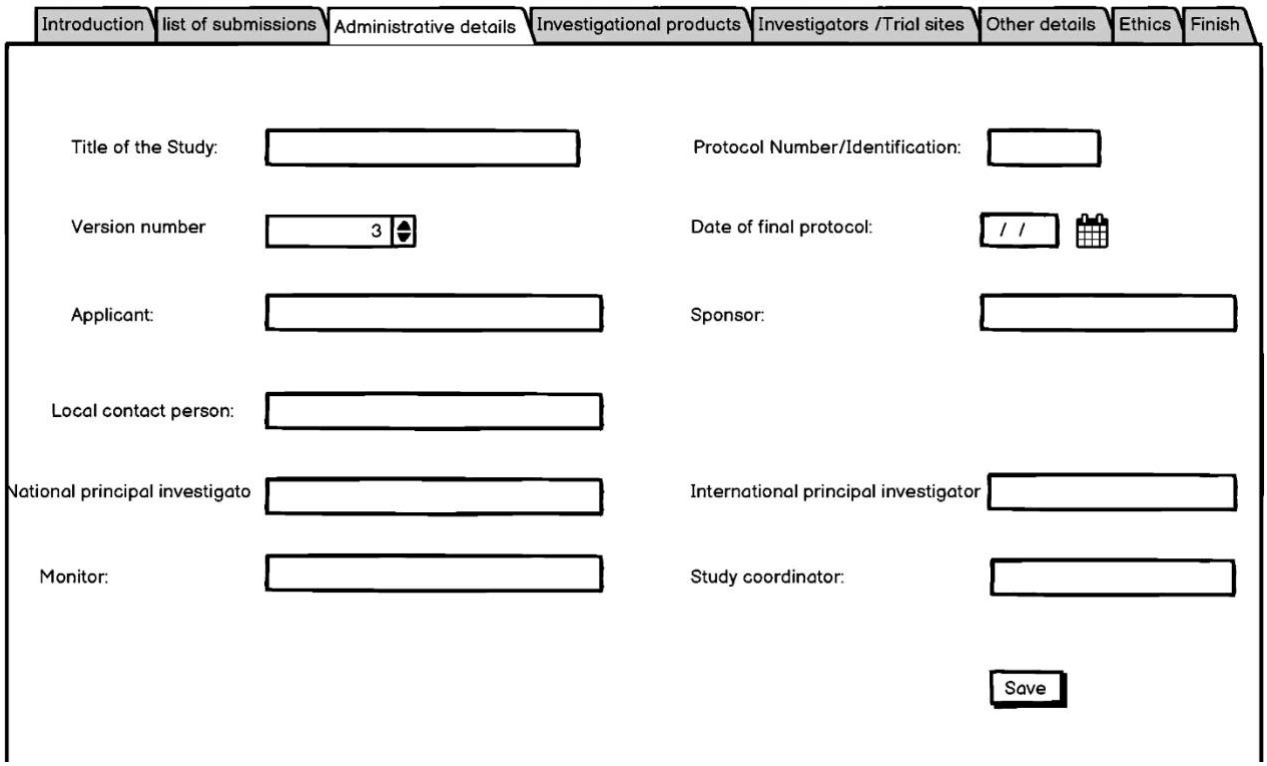

Figure 4-15: Product Clinic Trial/Add Administrative Details

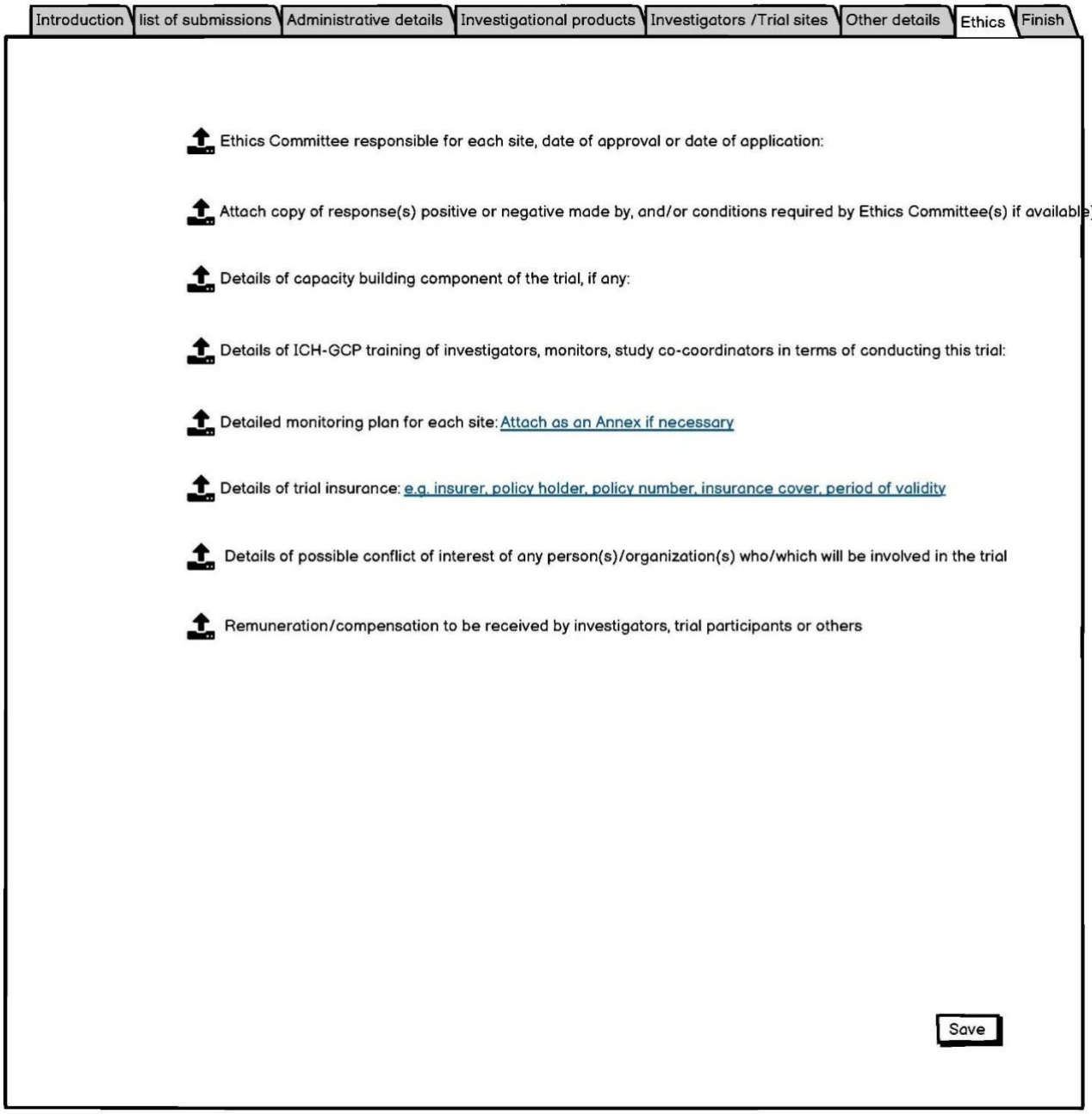

Figure 4-16: Product Clinical Trial/Add Ethics Document

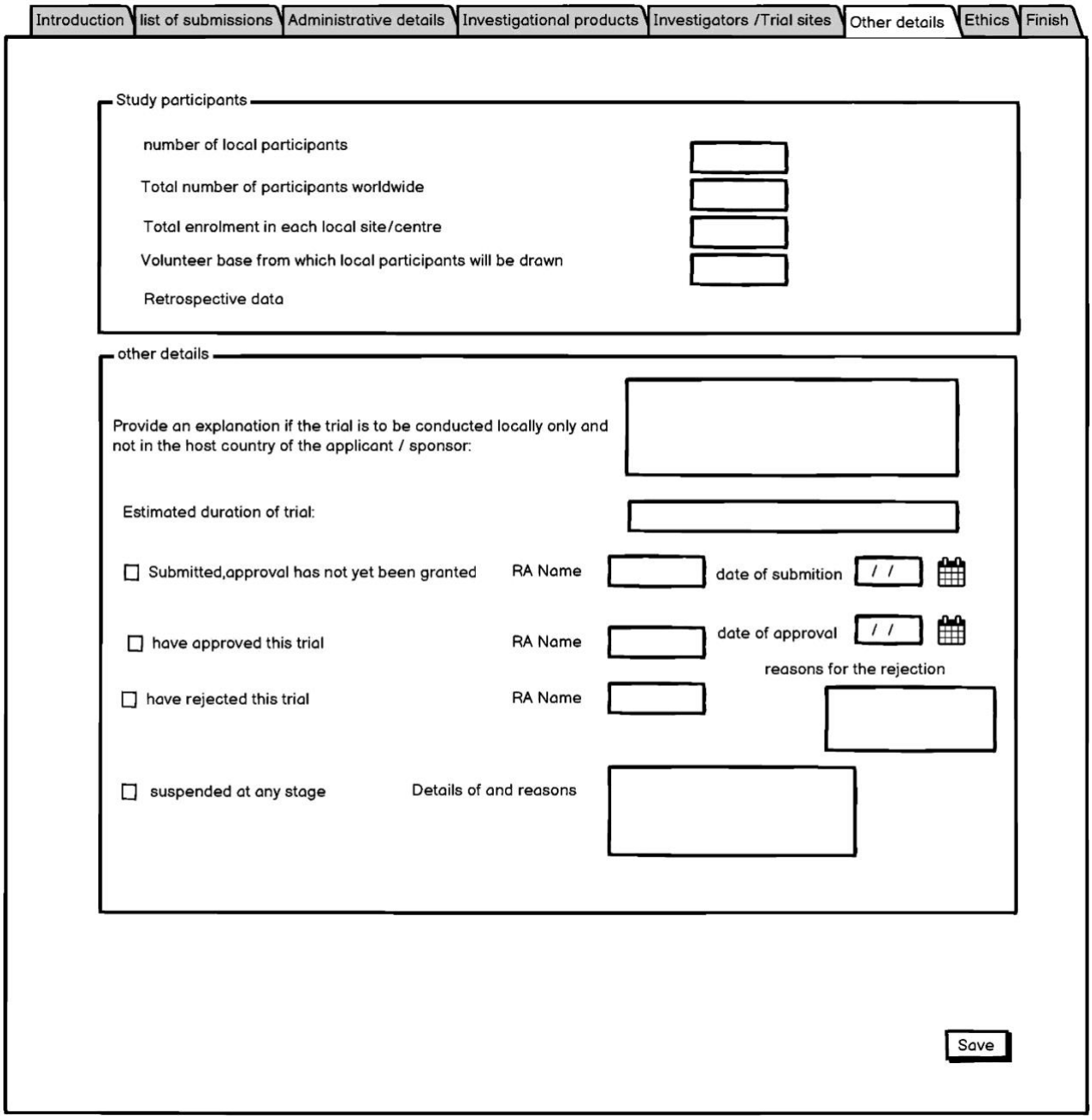

Figure 4-17: Product Clinical Trial/Other Details

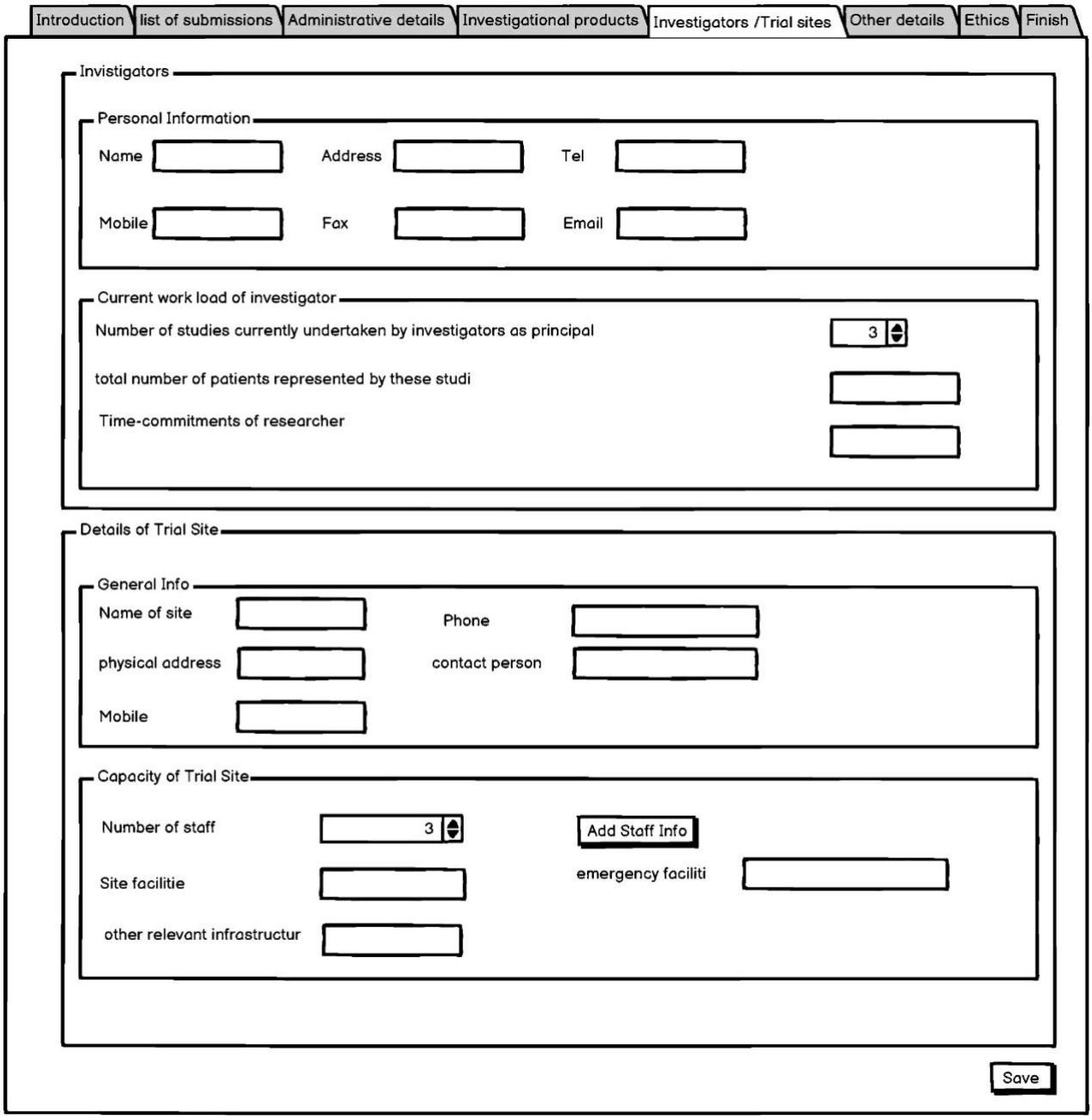

Figure 4-18: Product Clinical Trial/Add Investigators and Trial Sites

4.2 Hardware Interfaces

This section outlines the minimum recommended server specifications to be used for hosting the IMS. If the Partner NMRA is capable of installing superior specifications, they should do so. The specifications outlined below have taken into account ability of IMS hardware resources to handle increasing usage and traffic to a minimum lifespan of 10 years.

The specifications have taken also into account the following

- Ability to of hardware and OS to handle growing traffic i.e. if IMS installation is scaled
- Adequate hardware resources to support failover environment

Table 4-1: Hardware Specifications

No	Server Name	Usage Description	Specifications
1	Primary Application Server	Host the NMRA Online Portal and NMRA MIS	Minimum 16GB RAM, x64 processor, 2.0GHZ, 4 CPU/Cores
2	Secondary Application Server	Supporting the Primary Application Server to support failover (clustering) Optional NMRA MIS can be hosted here	Minimum 16GB RAM, x64 processor, 2.0GHZ, 4 CPU/Cores
3	Primary Database Server	Host the IMS Master Database Server	Minimum 32GB RAM, x64 processor, 2.0GHZ, 8 CPU/Cores, 1TB Hard Drive
4	Secondary Database Server	Host the Slave Database Server and Database Backups	Minimum 32GB RAM, x64 processor, 2.0GHZ, 8 CPU/Cores, 1TB Hard Drive
5	UPS	Uninterruptible Power Supply Unit	Minimum 5kVa, Rack Mountable UPS, Quantity 2

4.3 Software Interfaces

Table 4-2: Software Interfaces

No	Software	Specifications
1	Operating System	Recommended Enterprise Linux Editions E.g. Red Hat, SUSE Or Unix
2	Antivirus	Linux Antivirus

4.4 Communications Interfaces

The NMRA information, functions and processes are of critical importance to enable achieve high standards of public safety. As such the environment where IMS shall be hosted and accessed is of critical importance.

The section below shall outline the network, internet and security requirements of IMS

- The NMRA shall have a Local Area Network (LAN) where NMRA MIS can be locally accessed with the premises
- NMRA MIS shall only accessed via a secure protocol HTTPS
- For regional NMRA offices, the NMRA shall have Wide Area Network or optionally provide a secure channel for NMRA MIS e.g. VPN
- NMRA Online Portal shall only be accessed via a secure protocol HTTPS over the public network
- The NMRA must provide secondary internet link with their ISP to ensure service delivery on the Online Portal
- The minimal internet bandwidth speeds must not be below 4MBS

5 Other Nonfunctional Requirements

5.1 Performance Requirements

- The MIS Search Function shall return the results within 4 seconds, 80% of the time.
- The MIS Search Function shall have a maximum of 500 records.
- The MIS Search Function shall have 40 average concurrent users.

5.2 Safety Requirements

- The MIS Weekly Backup shall be completed between 11 p.m. starting on Friday night and 6 a.m. on Monday.

5.3 Security Requirements

- The system shall embed security measures to ensure that the records present in the system are secure and no unauthorized personnel can access them.
- The application should protect user data by using username and password for login.
- The application should allow only the authorized people to access the application
- The domain will get an SSL Certificate that protects the domain to be published by hackers and get it to some secure level.
- on the database level security, the system will encrypt the password of each user and determine the user who has access to the database.

5.4 Software Quality Attributes

5.4.1 Availability

The MIS shall protect against denial of service (DOS).

5.4.2 Reliability

- The MIS will be available all the time, and there are no pages' crashes and freezes, and if an unexpected error there is an error page will appear and the reason will register on the error log and the correction will be provided.

- The MIS system shall be available 99.99% of the time. A failure of the MIS system shall occur when any of the following critical functions are not working:
- Security access to the system

5.4.3 Efficiency

The MIS Hosting System shall be hosted on cloud.

5.4.4 Effectiveness

The MIS process of every function must be in a separate page, so that the user can do the function directly not through many pages.

The MIS System Operating System shall operate 100% of records submitted.

5.4.5 Fault Tolerance

The MIS shall have all functions implemented as services within a service-oriented architecture to allow the system to operate in the event of one or more services failing.
The system must have Error handling features.

5.4.6 Privacy

MIS shall protect the privacy of individuals identified in a record in accordance with Federal Government Privacy policies.

5.4.7 Data Integrity

To prevent malicious corruption of the MIS, the system shall retain its data for 90 days after a designated user authorizes deletion of a record.
The MIS shall maintain data integrity by keeping backups of all updates to the database for every record transaction.

6 Other Requirements

Appendix A: Glossary

<Define all the terms necessary to properly interpret the SRS, including acronyms and abbreviations. You may wish to build a separate glossary that spans multiple projects or the entire organization, and just include terms specific to a single project in each SRS.>
<The following is a list of definitions, acronyms and abbreviations that will help you better understand the document.>

6.1.1 Definitions

Table 6-1: Definitions

6.1.2 Abbreviations

Table 6-2: Abbreviations

DB	Database
DBMS	Database Management System
DLFS	Document Library File Storage
EAC	East Africa Community
GUI	Graphical User Interface
HTML	Hypertext Markup Language
IMS	Information Management System
NMRA	National Medicine Regulatory Authority
SRD	Software Requirements Document
SRS	Software Requirements Specifications

6.1.3 Acronyms

Table 6-3 Acronyms

s/he	he/she