Software Requirements and Design Document

for

DrugDev

Prepared by:

Affan Ali 22i-1215
Abdul Majeed 22i-1216
Abdul Wasay 22i-0947

VoxaTech

Date Created: 26/11/2024

1. Introduction

1.1 Purpose

This document specifies the software requirements for DrugDev, aimed at accelerating the research and development of new drugs within the Pakistani pharmaceutical industry. DrugDev serves as an integrated platform to manage all stages of drug development, from ideation through regulatory approval and market launch.

1.2 Product Scope

DrugDev is an all-encompassing electronic record management system designed to streamline processes in the Pakistani pharmaceutical sector. It provides end-to-end support for drug development, significantly reducing the time and complexity involved in bringing new drugs to market.

1.3 Title

DrugDev: Streamlining Drug Development in Pakistan

1.4 Objectives

- Reduce

  R&D timelines for new drugs.

  - Provide

  a centralized platform for managing all stages of drug development.

  - Assist

  in regulatory approval processes with local (DRAP) and international bodies.

  - Enhance

data management automation to reduce errors and delays.

1.5 Problem Statement

The Pakistani pharmaceutical industry faces delays in drug market entry due to inefficient R&D cycles and fragmented regulatory management tools. DrugDev addresses these issues by offering a digital solution that integrates all aspects of drug development into a single platform, improving efficiency and compliance with regulatory standards.

2. Overall Description

2.1 Product Perspective

DrugDev is envisioned as a standalone product that integrates with existing systems within the pharmaceutical industry to provide a streamlined approach to drug development. It fits into the larger ecosystem of pharmaceutical R&D by interfacing with various regulatory and compliance systems.

2.2 Product Functions

- Management

  of clinical trials and regulatory submissions.

  - Automated

  data entry and management to reduce manual errors.

  - Comprehensive

  tracking of drug development stages from concept to market.

  - Support

  for compliance with local and international regulatory standards.

2.3 List of Use Cases

1. Submit new Idea
2. Review Idea
3. Idea Approval by C-Level
4. Idea Approval by M-Level
5. Track Idea
6. Prepare Regulatory Compliance
7. Approve Regulatory Compliance
8. Develop Sales Plan
9. Generate Sales Plan
10.

Manage Testing

11.

Review Testing

12.

Product Launch

2.4 Extended Use Cases

1. Submit New Idea (Idea Submission)

- Primary Actor: Idea Contributor
- Scope: DrugDev
- Level: User Goal
- Preconditions: Idea Contributor is registered in the system.
- Postconditions: Idea is successfully submitted and recorded in the system.
- Main Success Scenario:
    1. Idea Contributor logs into the system.
    2. Navigates to the idea submission form.
    3. Fills out the form and submits the idea.
    4. System acknowledges receipt and logs the submission.
- Extensions:
    - 4a. System rejects submission due to incomplete form:
        - System shows an error message.
        - Idea Contributor revises and resubmits the form.

2. Review

Idea (Idea Review)

- Primary Actor: Project Manager
- Scope: DrugDev
- Level: User Goal
- Preconditions: At least one idea has been

submitted.

- Postconditions: Ideas are reviewed and either approved for further development or rejected.
- Main Success Scenario:
    1. Project Manager logs into the system.
    2. Accesses the list of submitted ideas.
    3. Reviews each idea against set criteria.
    4. Makes decisions to approve or reject ideas.
- Extensions:
    - 4a. An idea requires more information:
    - Project Manager requests additional information from the Idea Contributor.
    - Continues review upon receiving additional information.

3. Idea

Approval by C-Level (Idea Approval)

- Primary Actor: Senior Management
- Scope: DrugDev
- Level: User Goal
- Preconditions: The idea has been reviewed by the Project Manager and marked as pending approval.
- Postconditions: Idea is either approved or rejected. Notifications are sent to relevant stakeholders.
- Main Success Scenario:
    1. Senior Management logs into the system.
    2. Navigates to the “Pending Idea Approvals” section.
    3. Reviews the details and evaluations of submitted ideas.
    4. Selects an idea to approve.
    5. Approves the idea within the system.
    6. System updates the idea status to “Approved”.
    7. Notifications are sent to the Project Manager and

Idea Contributor.

- Extensions:
    - 4a. If Senior Management rejects the idea:
        - Provides a reason for rejection.
        - System updates the idea status to “Rejected”.
    - Notifications with feedback are sent to the

Project Manager and Idea Contributor.

4. Idea

Approval by M-Level (Project Planning)

- Primary Actor: Project Manager
- Scope: DrugDev
- Level: User Goal
- Preconditions: Idea has been approved by Senior

Management. Project Manager has access to the system’s planning tools.

- Postconditions: A detailed project plan is created

and stored in the system. Relevant teams are assigned tasks and notified.

- Main Success Scenario:
    1. Project Manager logs into the system.
    2. Selects the approved idea to begin planning.
    3. Defines project scope and objectives.
    4. Breaks down the project into tasks and milestones.
    5. Assigns tasks to appropriate teams (R&D, QA,

    etc.).
    6. Sets deadlines and resource allocations.
    7. Reviews and finalizes the project plan.
    8. System saves the plan and sends notifications to

    assigned team members.

- Extensions:
    - 5a. If a team lacks available resources:
    - System alerts the Project Manager of resource

    constraints.

- Project Manager adjusts resource allocations or timelines.

5. Track Idea

- Primary Actor: Project Manager
- Scope: DrugDev
- Level: User Goal
- Preconditions: Idea has been submitted and recorded in the system.
- Postconditions: Status and progress of the idea are tracked and updated.
- Main Success Scenario:
    1. Project Manager logs into the system.
    2. Accesses the tracking module.
    3. Enters the tracking details for a specific idea.
    4. Reviews the progress and updates the status accordingly.
    5. System updates the records and optionally notifies the Idea Contributor.
- Extensions:
    - 4a. If the tracking information is incomplete or needs clarification:
        - Project Manager requests additional details from the Idea Contributor.
        - Updates the tracking record after receiving the necessary information.

6. Prepare Regulatory Compliance

- Primary Actor: Regulatory Affairs Specialist
- Scope: DrugDev

- Level: User Goal
- Preconditions: Idea has been approved; relevant

project details are available.

- Postconditions: Regulatory documentation is

prepared and ready for submission.

- Main Success Scenario:

1. Regulatory Affairs Specialist logs into the system.
2. Accesses the project details.
3. Gathers necessary information and prepares

required regulatory documents.

4. Reviews and verifies the completeness and accuracy

of the documents.

5. Saves the documents in the system for approval.

- Extensions:
  - 4a. If documentation is found incomplete:
  - Specialist is notified to provide the missing

information.

  - Specialist updates and resubmits the documentation.

7.

Approve Regulatory Compliance

- Primary Actor: Regulatory Affairs Specialist
- Scope: DrugDev
- Level: User Goal
- Preconditions: Regulatory documentation is

prepared.

- Postconditions: Documentation is approved and

ready for official submission.

- Main Success Scenario:

1. Regulatory Affairs Specialist reviews the prepared

documents.

2. Confirms adherence to all regulatory requirements.

3. Approves the documents within the system.
4. System records the approval and prepares for submission to regulatory bodies.

- Extensions:
  - 3a. If non-compliance is detected:
  - The Specialist rejects the documents and requests revisions.
  - Notifications are sent to relevant project members to correct the issues.

8.

Develop Sales Plan

- Primary Actor: Marketing Team
- Scope: DrugDev
- Level: User Goal
- Preconditions: Product development is nearing completion.
- Postconditions: A comprehensive sales plan is developed.
- Main Success Scenario:
  1. Marketing Team logs into the system.
  2. Accesses product information and target market data.
  3. Develops a sales strategy including pricing, distribution channels, and promotion plans.
  4. Reviews and finalizes the sales plan.
  5. System saves the plan and notifies the Sales and Project Management teams.
- Extensions:
  - 4a. If market conditions change:

- Marketing team updates the plan to reflect new conditions.
- Revises and resubmits the updated sales plan.

9.

Generate Sales Plan

- Primary Actor: Sales Team
- Scope: DrugDev
- Level: User Goal
- Preconditions: A developed sales plan exists.
- Postconditions: Detailed sales reports and implementation strategies are generated.
- Main Success Scenario:
    1. Sales Team logs into the system.
    2. Retrieves the finalized sales plan.
    3. Generates actionable tasks and assigns them to team members.
    4. Monitors the execution of the sales plan through the system.
    5. System generates reports on sales performance.
- Extensions:
    - 4a. If sales targets are not being met:
        - Sales Manager analyzes the reports.
        - Adjusts the sales strategies and updates the tasks.

10.

Manage Testing

- Primary Actor: Quality Assurance (QA) Team
- Scope: DrugDev
- Level: User Goal
- Preconditions: Product has reached the testing phase.
- Postconditions: All tests are conducted and

results are recorded.

- Main Success Scenario:
    1. QA Team logs into the system.
    2. Accesses the testing module.
    3. Conducts scheduled tests and records the outcomes.
    4. Reviews results for compliance with quality standards.
    5. Submits test results and any recommendations for improvements.
- Extensions:
    - 4a. If a test fails:
        - QA Team documents the failure and reasons.
        - Notifies the Development Team to make necessary adjustments.

11.

Review Testing

- Primary Actor: QA Team
- Scope: DrugDev
- Level: User Goal
- Preconditions: Testing has been completed.
- Postconditions: Test results are reviewed and finalized for compliance certification.
- Main Success Scenario:
    1. QA Team reviews the detailed reports from completed tests.
    2. Confirms whether each test meets the quality standards set.
    3. Approves the test results or requests re-testing if necessary.
    4. System updates the project status and notifies the

Project Manager.

- Extensions:
    - 3a. If re-testing is required:
        - QA Team schedules and conducts additional tests.
        - Results are updated in the system.

12.

Product Launch

- Primary Actor: Marketing Team
- Scope: DrugDev
- Level: User Goal
- Preconditions: Product is manufactured and marketing strategy is finalized.
- Postconditions: Product is launched and sales activities begin.
- Main Success Scenario:
    1. Marketing Team coordinates with the Sales and Manufacturing teams.
    2. Executes the launch according to the strategy (events, advertising, etc.).
    3. Monitors launch performance and gathers feedback.
    4. System logs launch activities and performance.
    5. Sales Team begins sales activities based on the launch.
- Extensions:
    - 4a. If there are issues during the launch (e.g., supply chain problems):
        - Marketing Team reports the issue to the Project Manager.
        - Project Manager coordinates with the Manufacturing Team to resolve the issue.

2.5 Use Case Diagram

3. Other Nonfunctional Requirements

3.1 Performance Requirements

DrugDev must support simultaneous use by up to 100 users without performance degradation, reflecting the high-demand environment of pharmaceutical R&D.

3.2 Safety Requirements

The system must ensure data integrity and accuracy, critical for regulatory compliance and patient safety during clinical trials.

3.3 Security Requirements

DrugDev must comply with national and international data protection regulations, ensuring that all patient and drug data is securely stored and transmitted.

3.4 Software Quality Attributes

- Reliability:

DrugDev must have an uptime of 99.9%.

- Usability:

Interface must be intuitive for users of varying technical skills.

- Maintainability:

Code should be well-documented and modular to facilitate updates.

3.5 Business Rules

- Only

authorized personnel can approve idea.

- All

data submissions must be audited and traceable.

3.6 Operating Environment

DrugDev will operate on standard hardware platforms and support integration with major databases and cloud services to ensure accessibility and scalability.

3.7 User Interfaces

The user interface will follow modern design principles, offering a responsive design compatible with desktop and mobile devices to accommodate the diverse needs of its users.

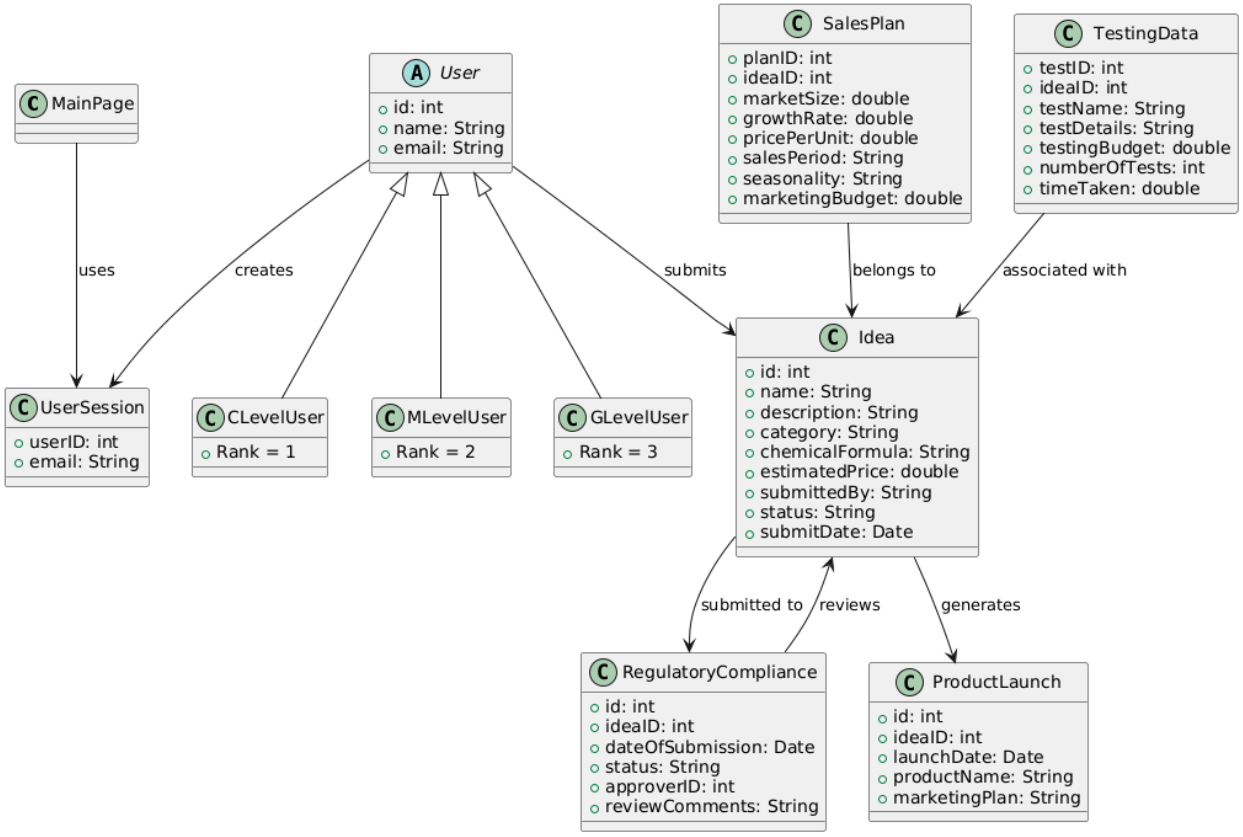
This

outline sets the groundwork for detailed development and further elaboration in

specific technical specifications and user interface designs as the project

progresses.

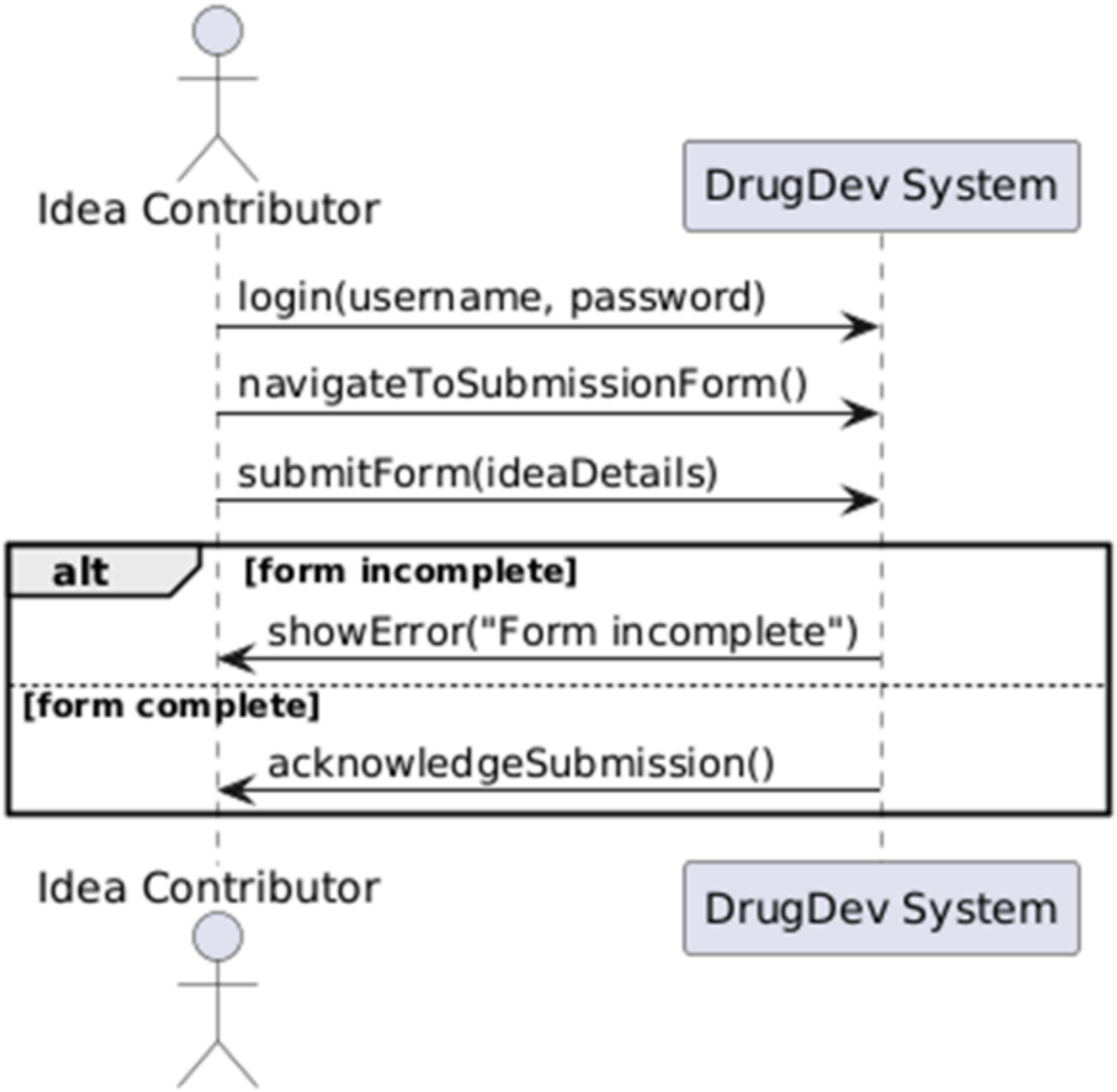
4. Domain Model



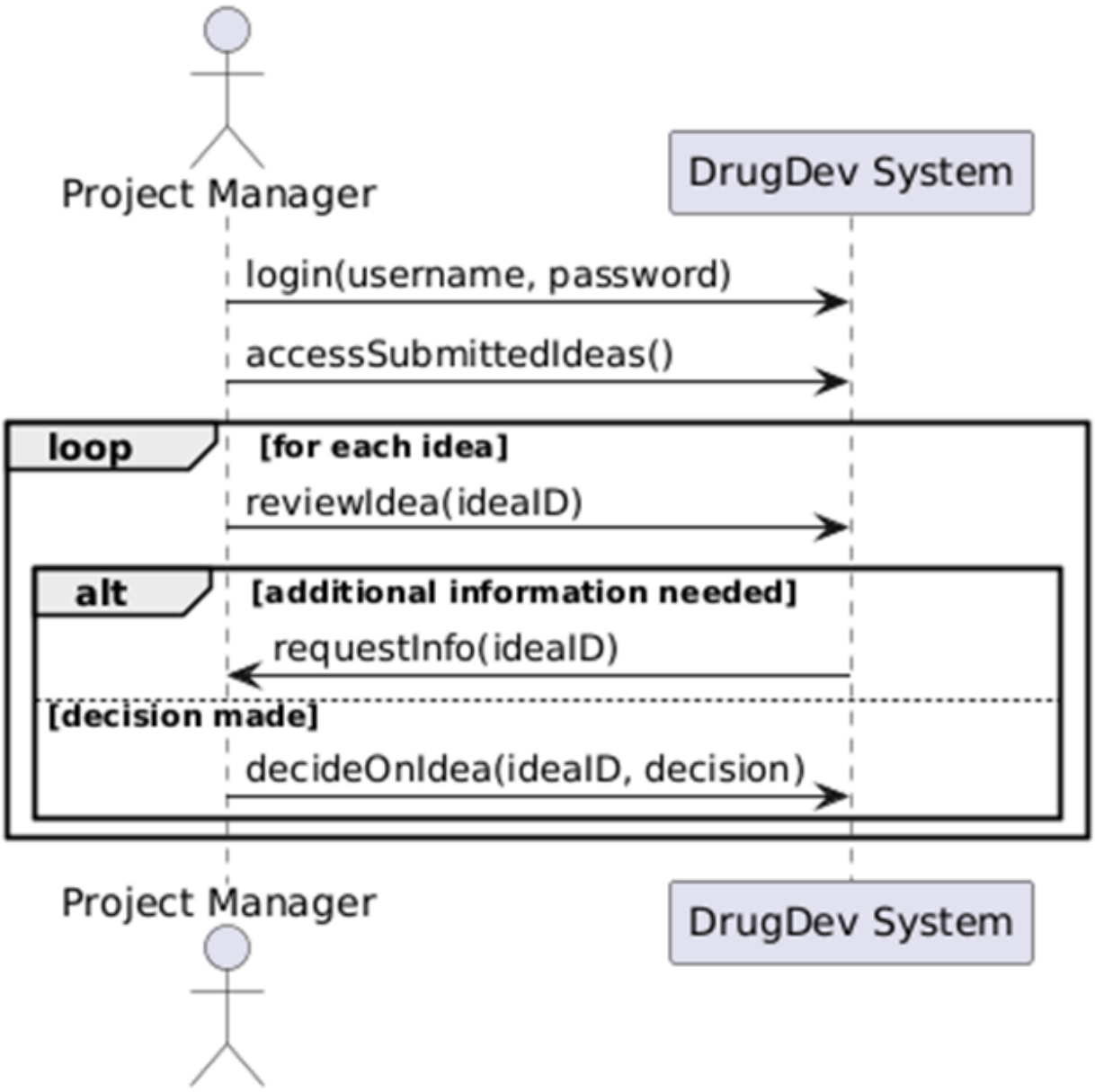
5. System Sequence Diagram

System Sequence Diagrams

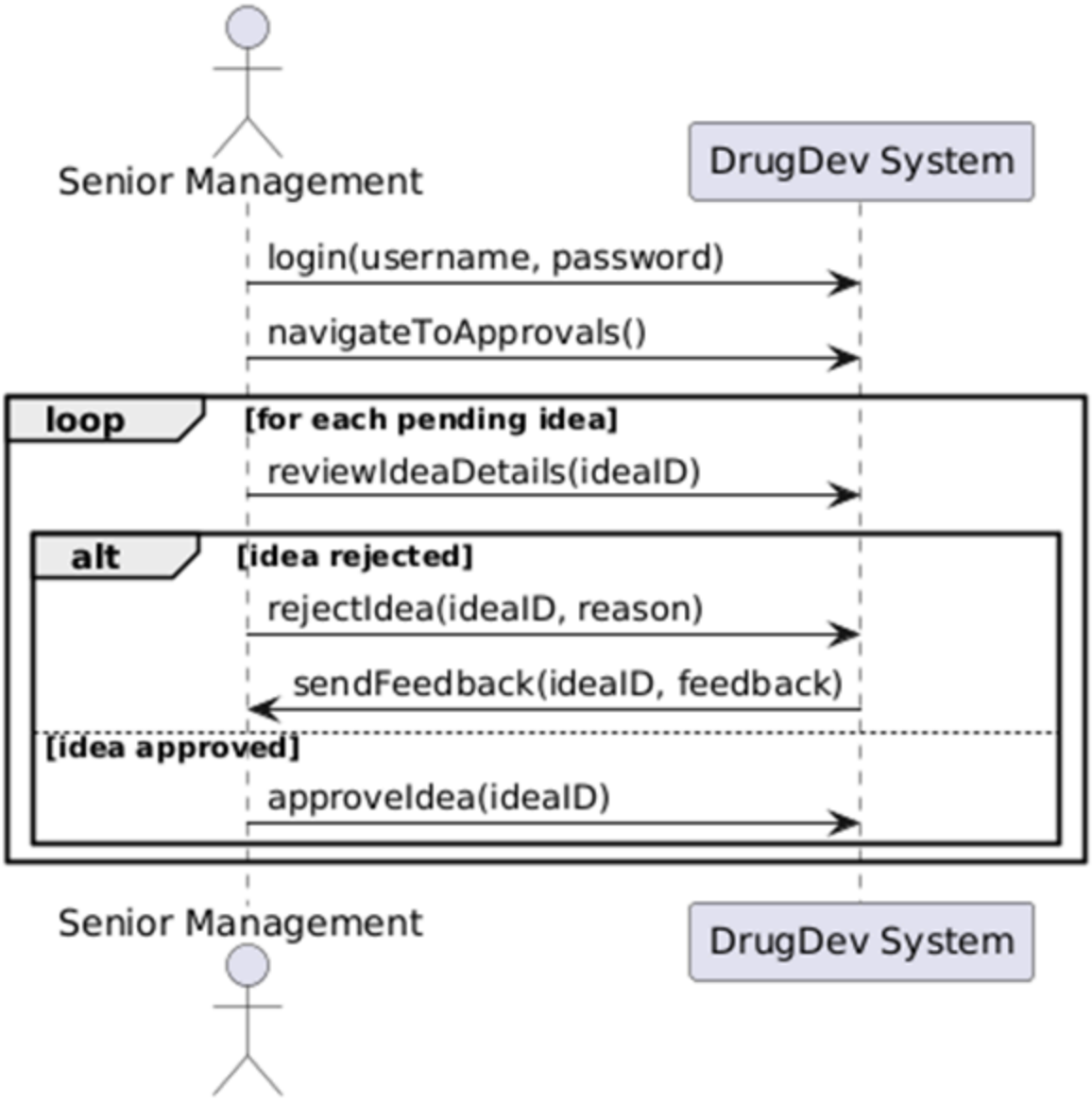
1. Idea Submission



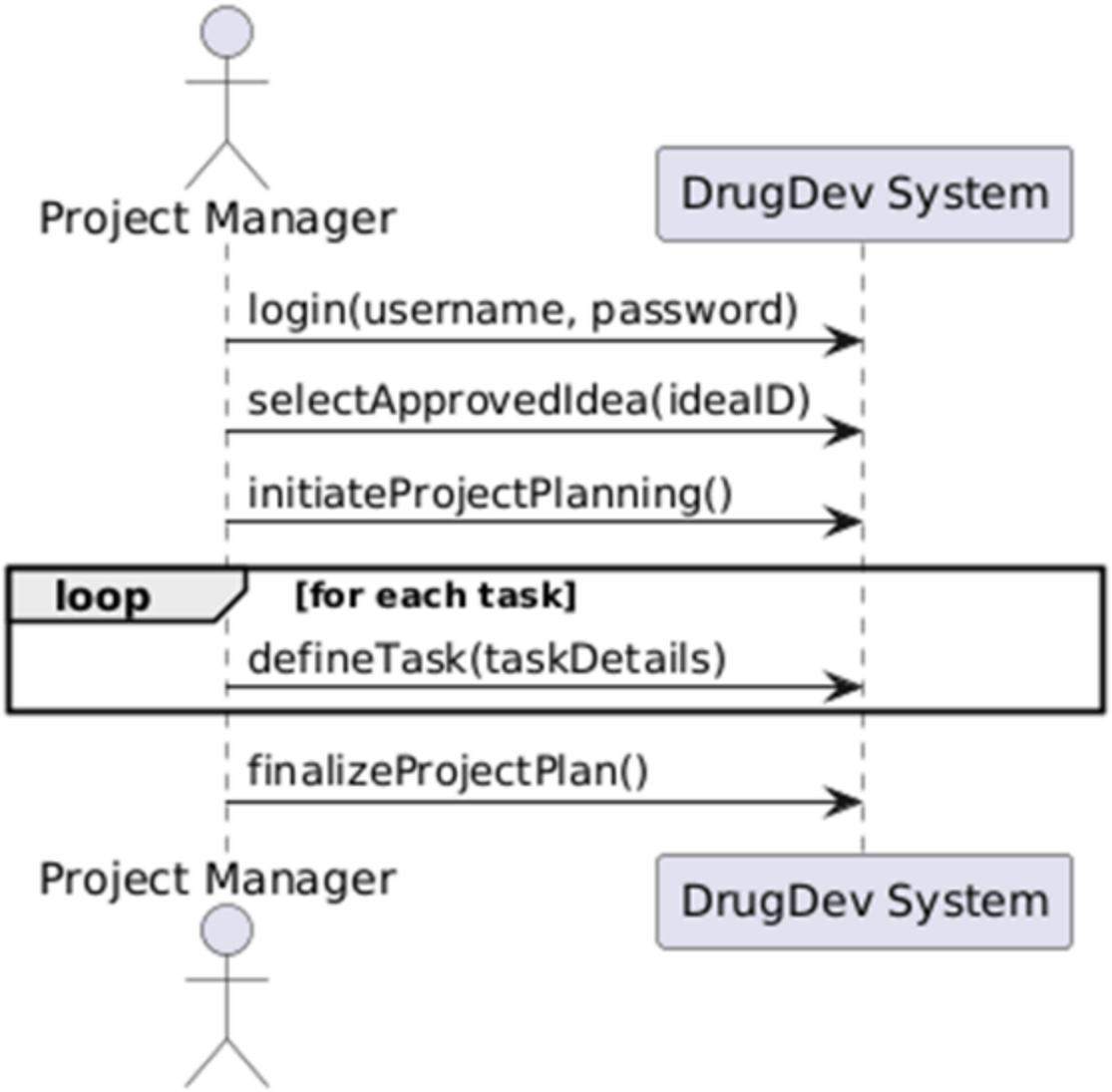
2. Idea Review



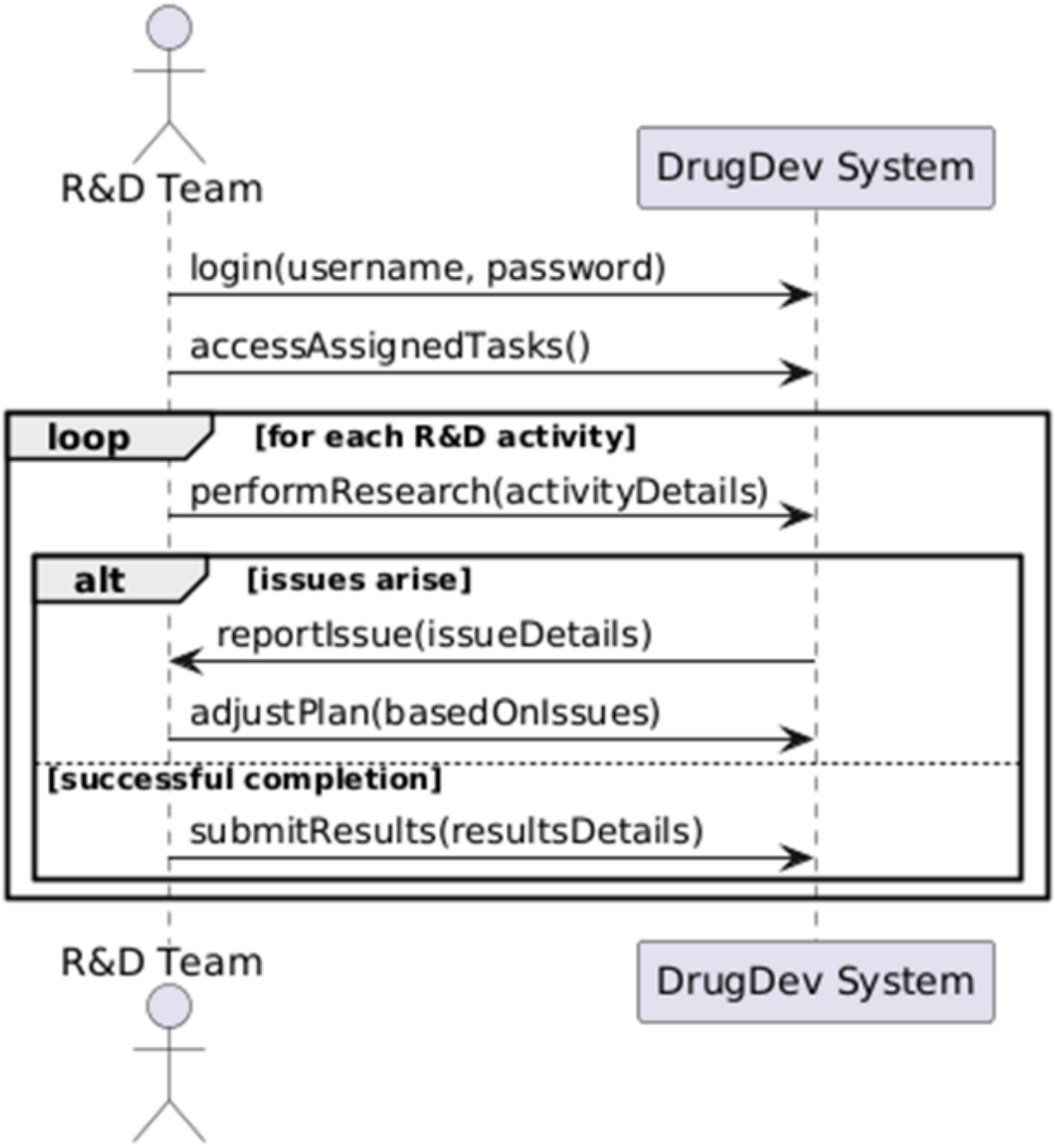
3. Idea Approval



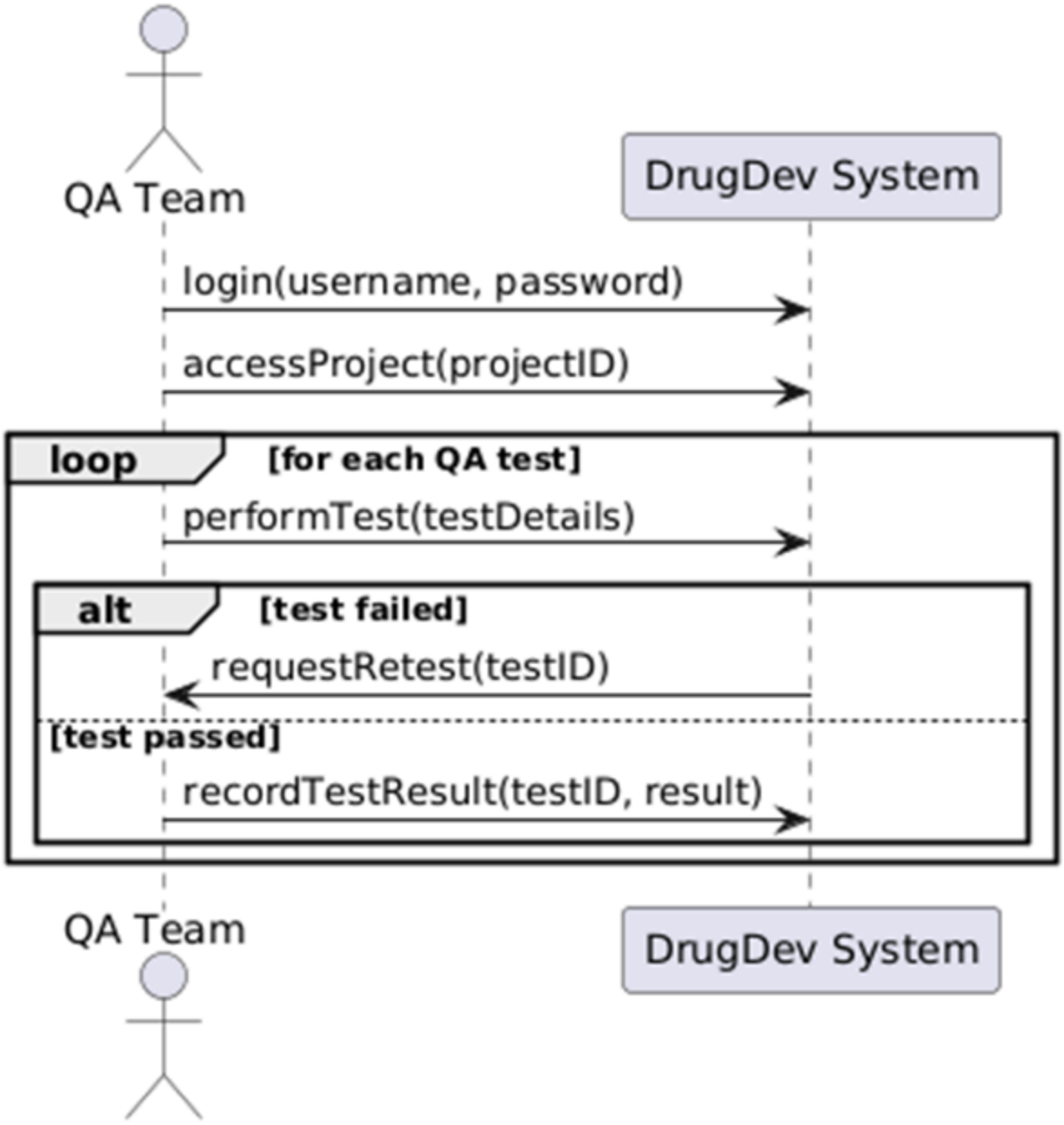
4. Project Planning



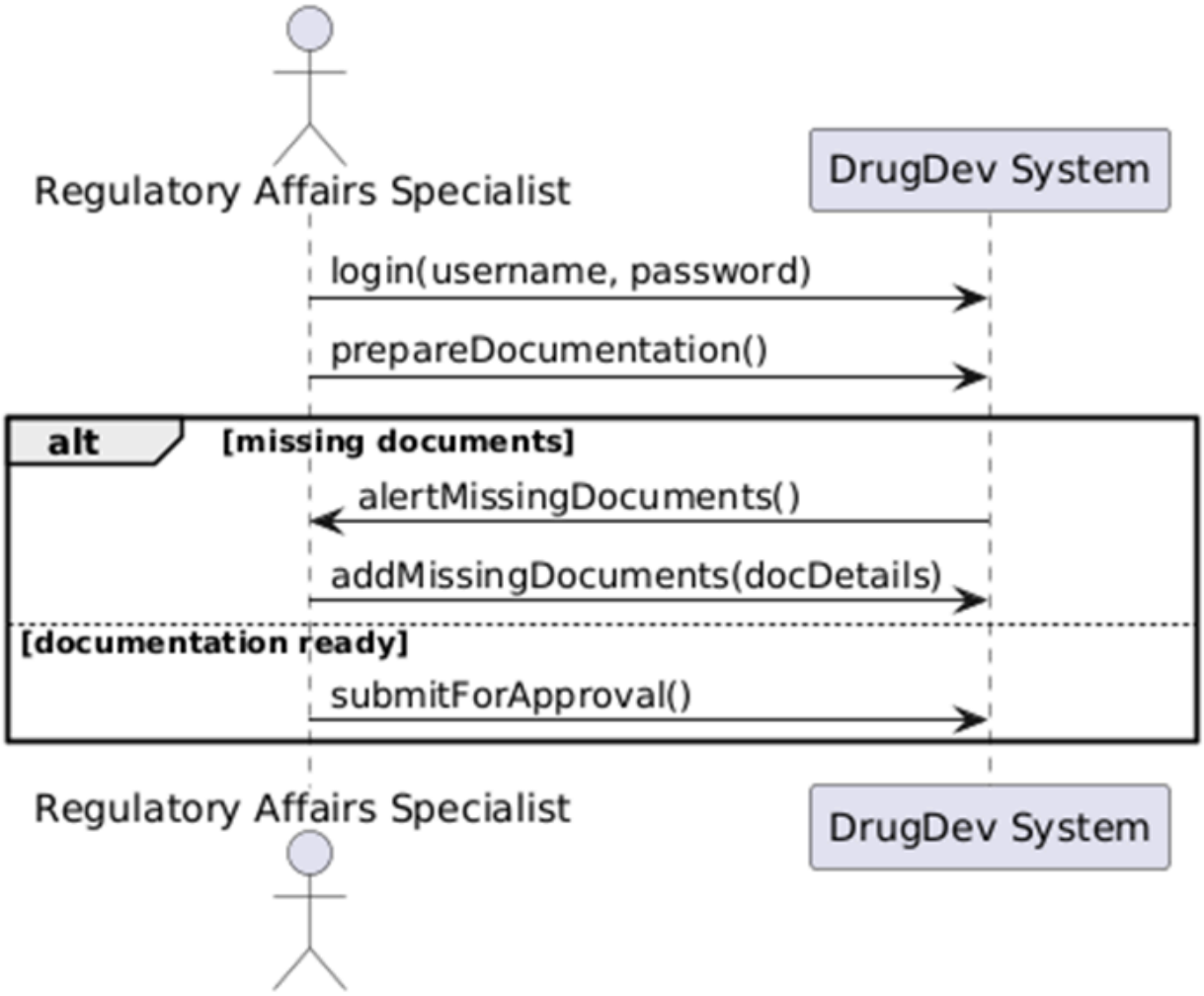
5. R&D Execution



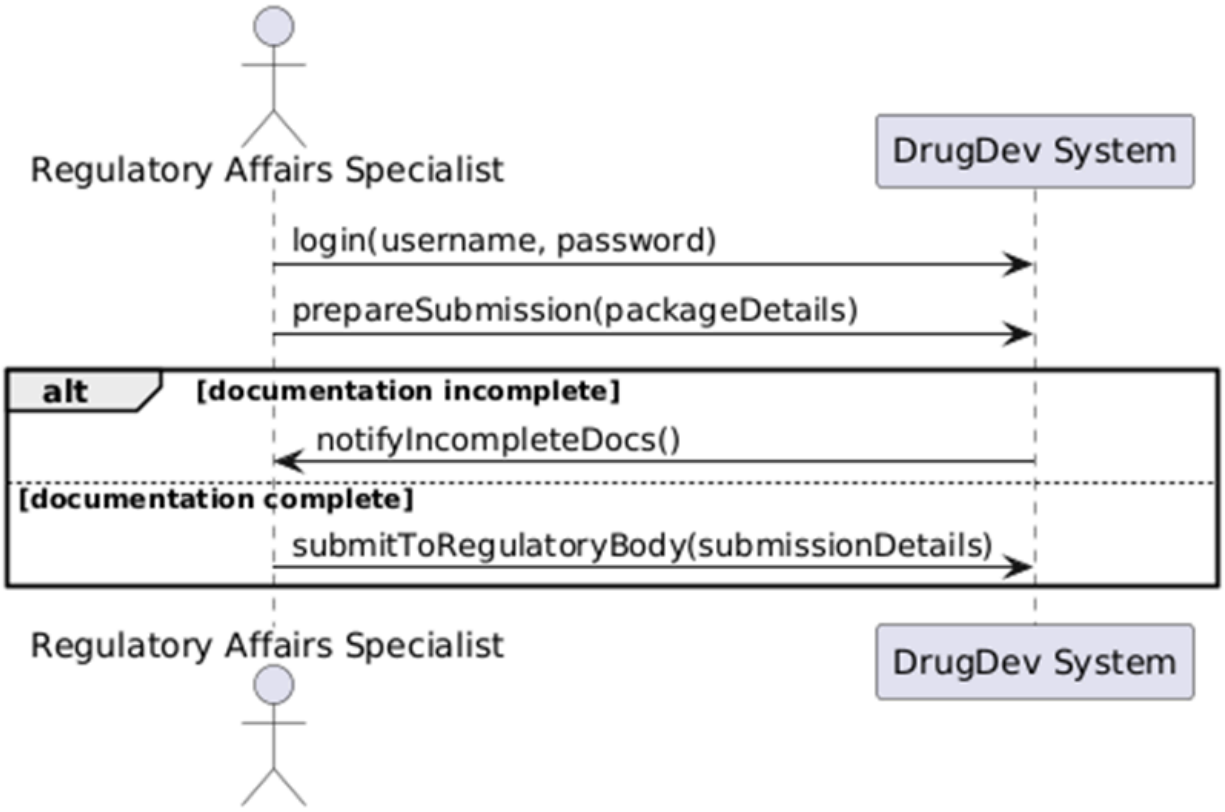
6. Quality Assurance



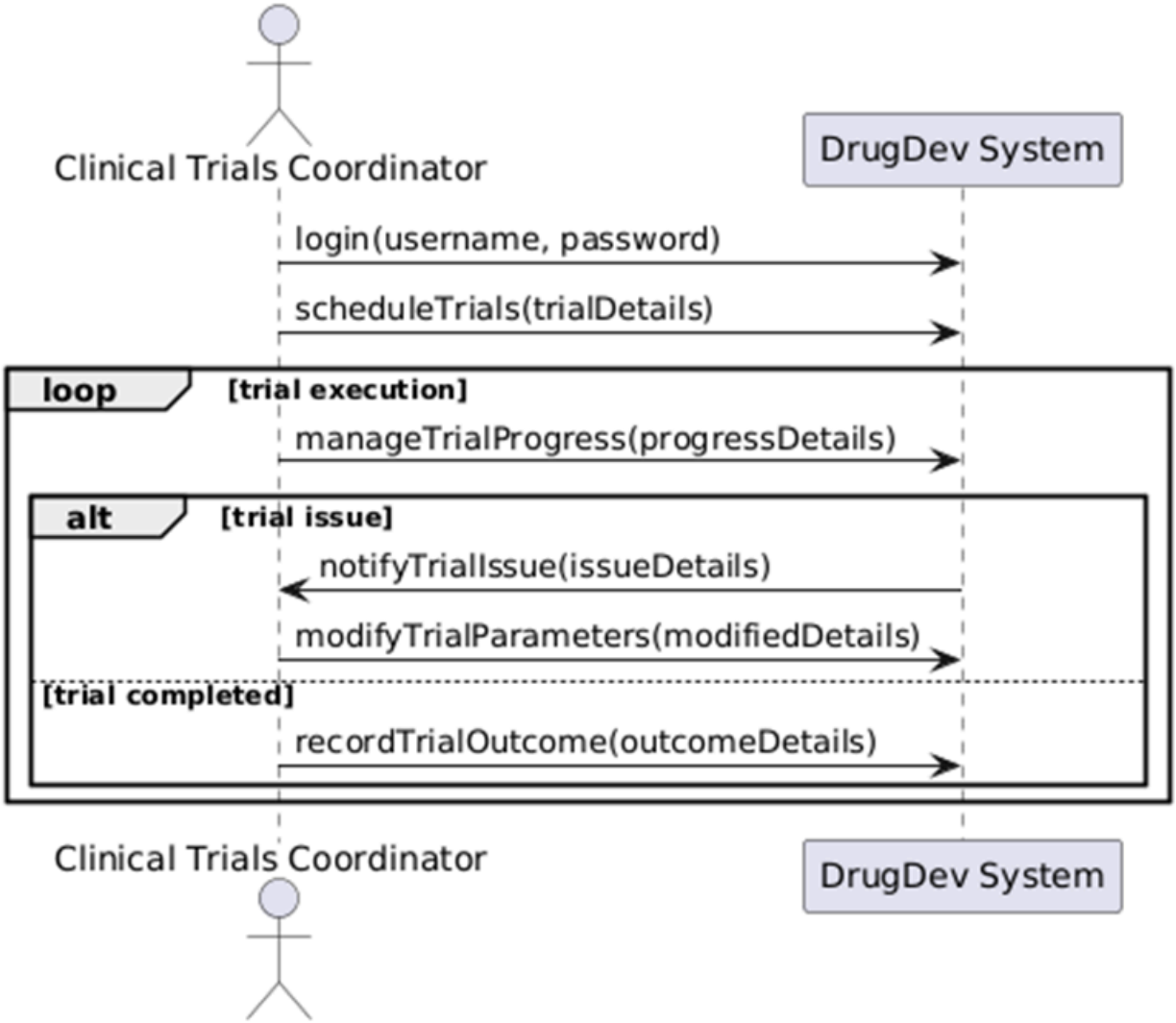
7. Regulatory Preparation



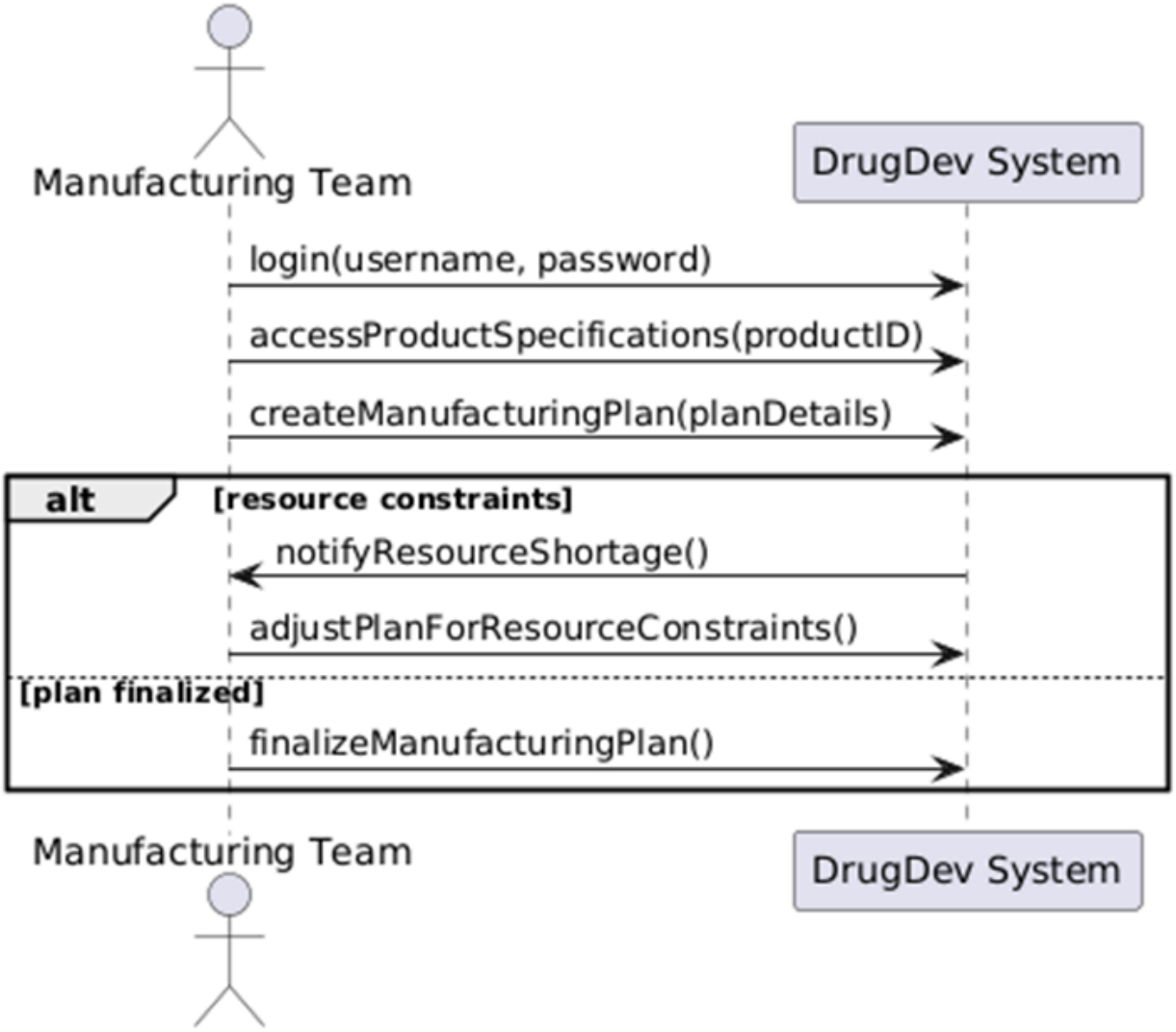
8. Regulatory Submission



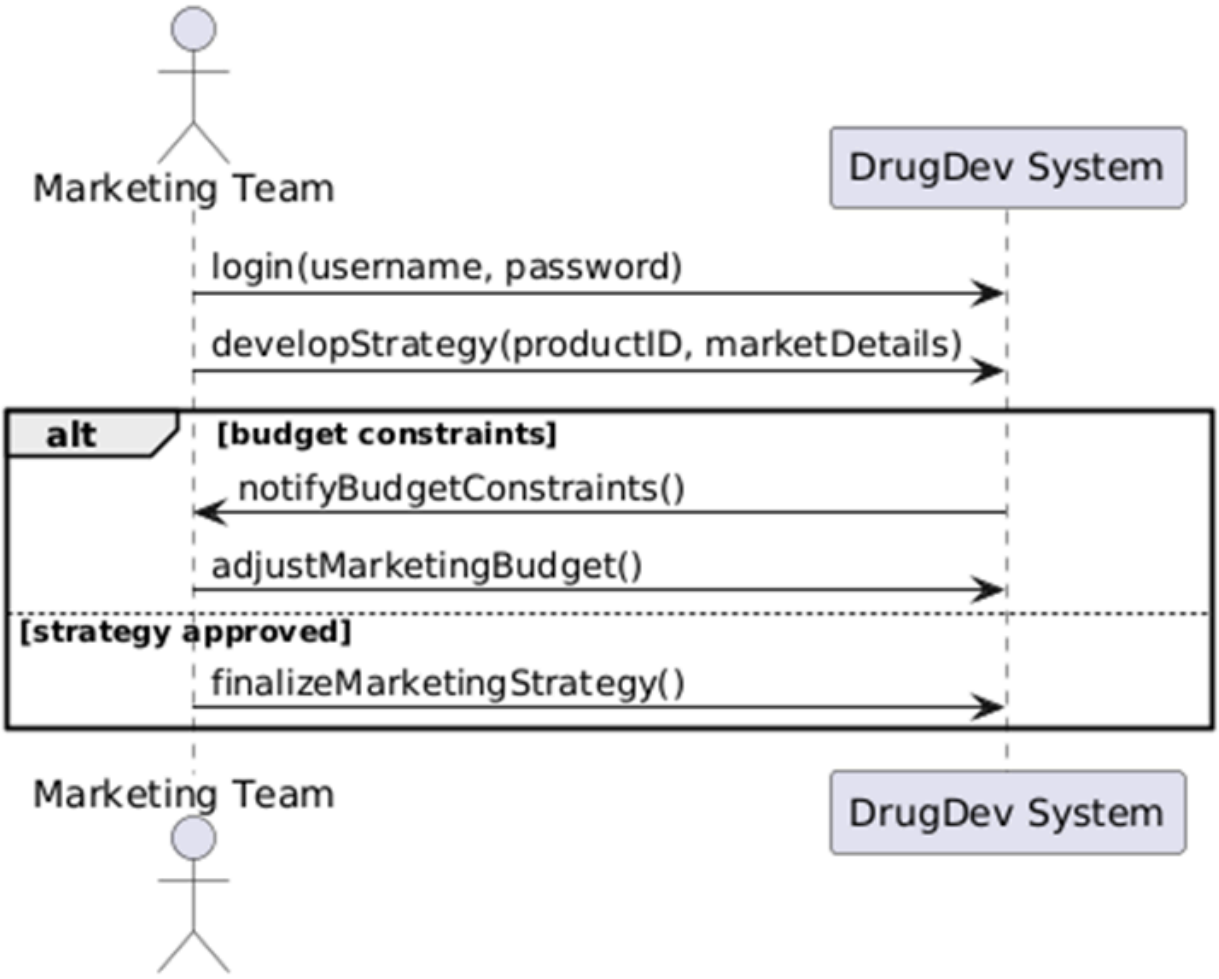
9. Clinical Trials Management



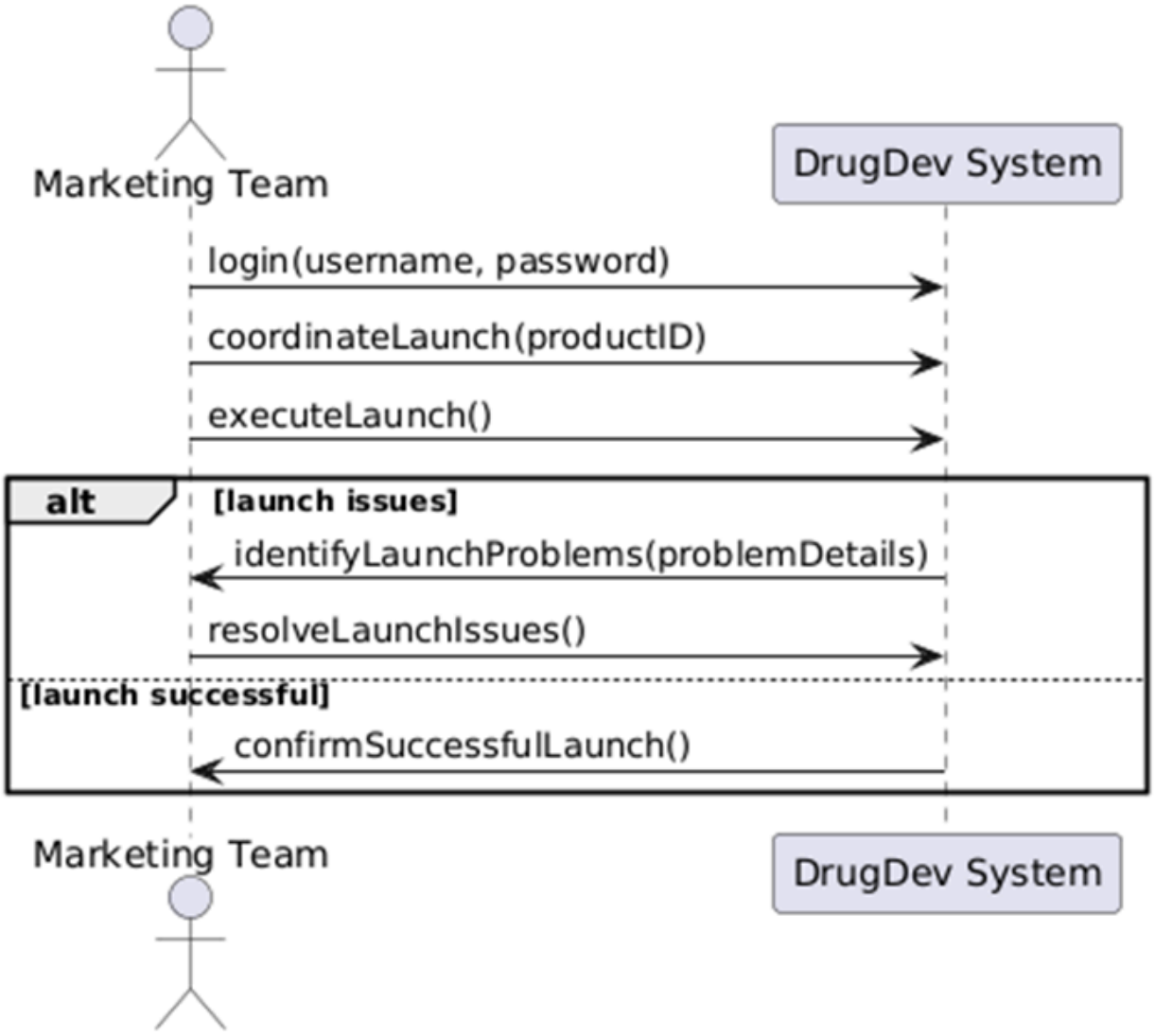
10. Manufacturing Plan



11. Marketing Strategy

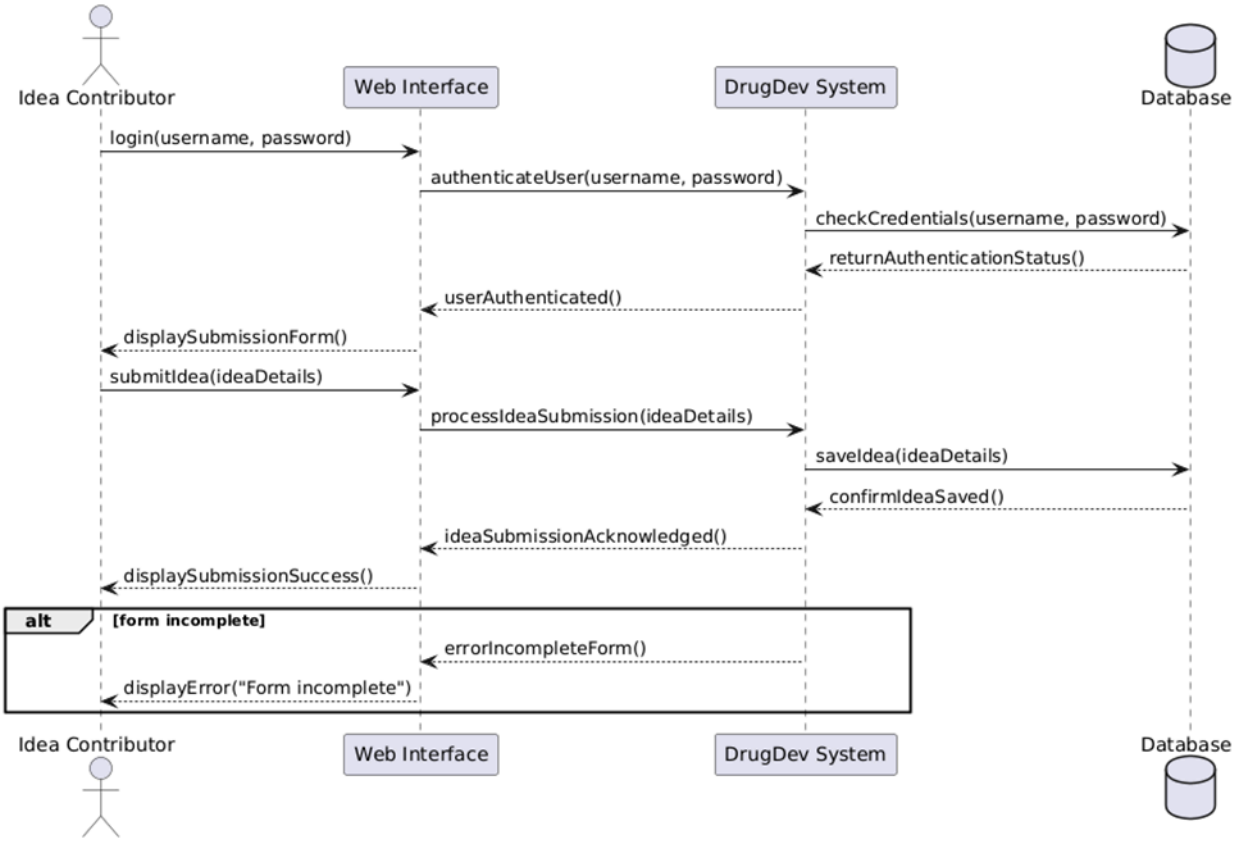


12. Product Launch

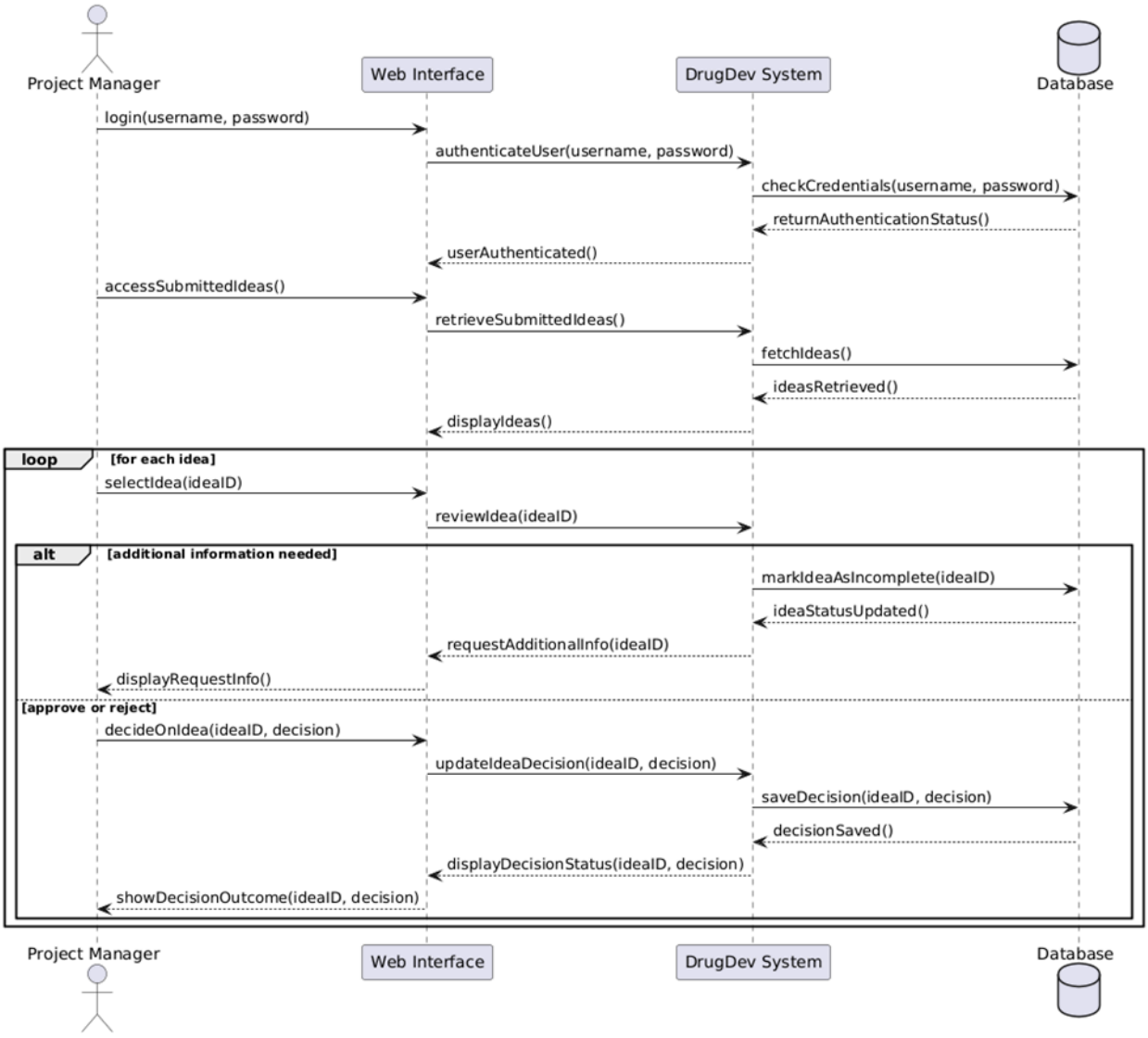


6. Sequence Diagram

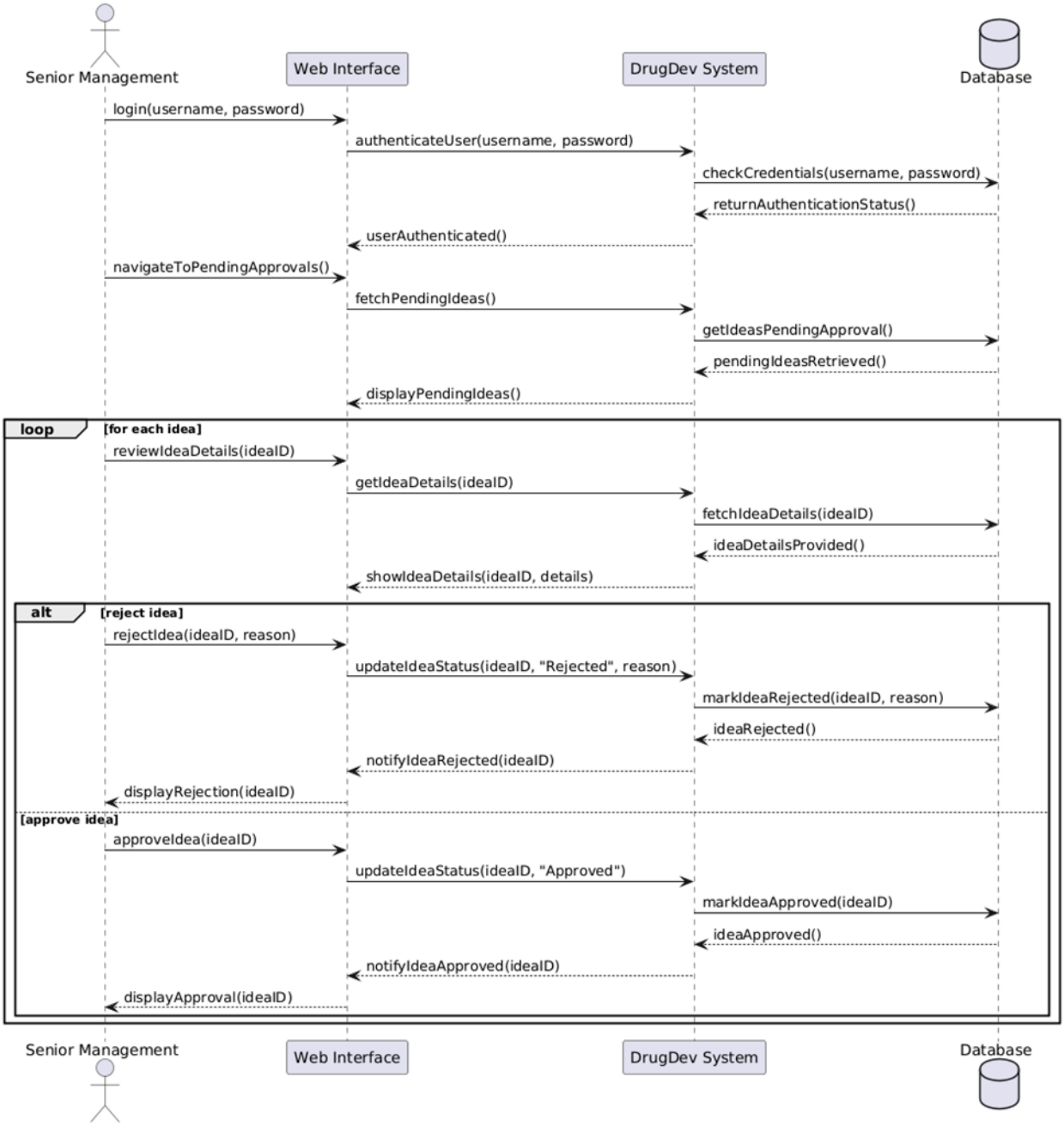
1. Idea Submission



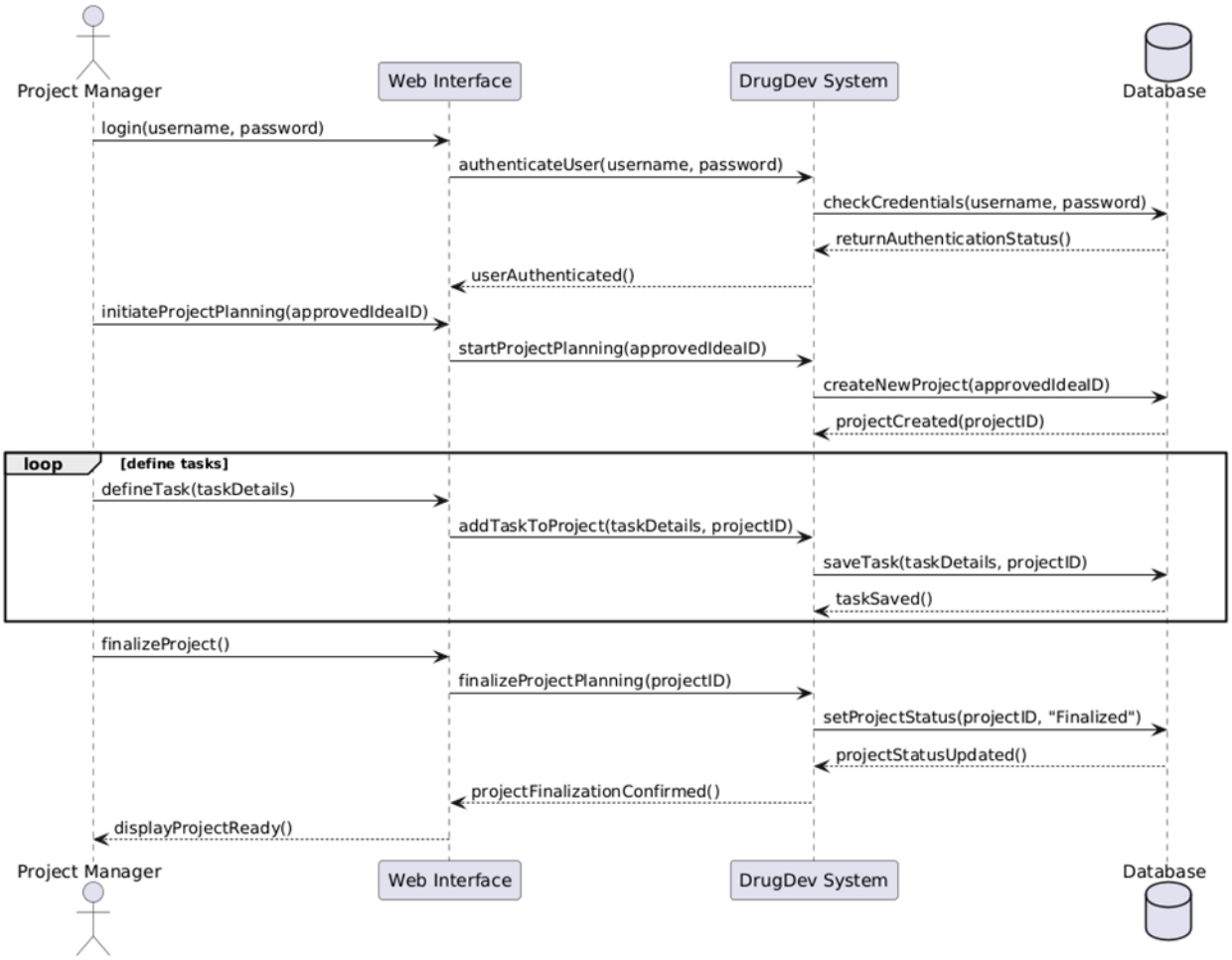
2. Idea Review



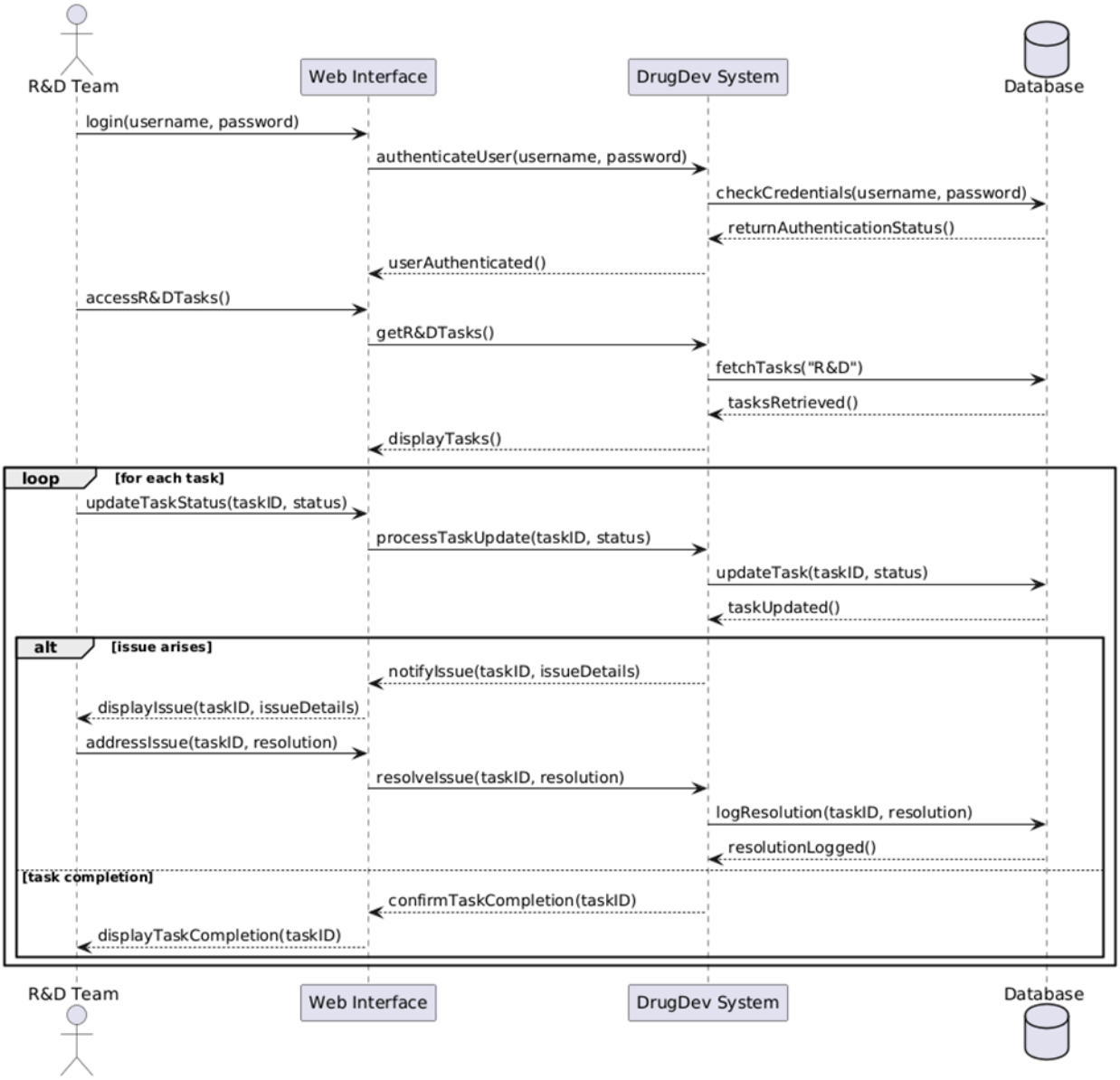
3. Idea Approval



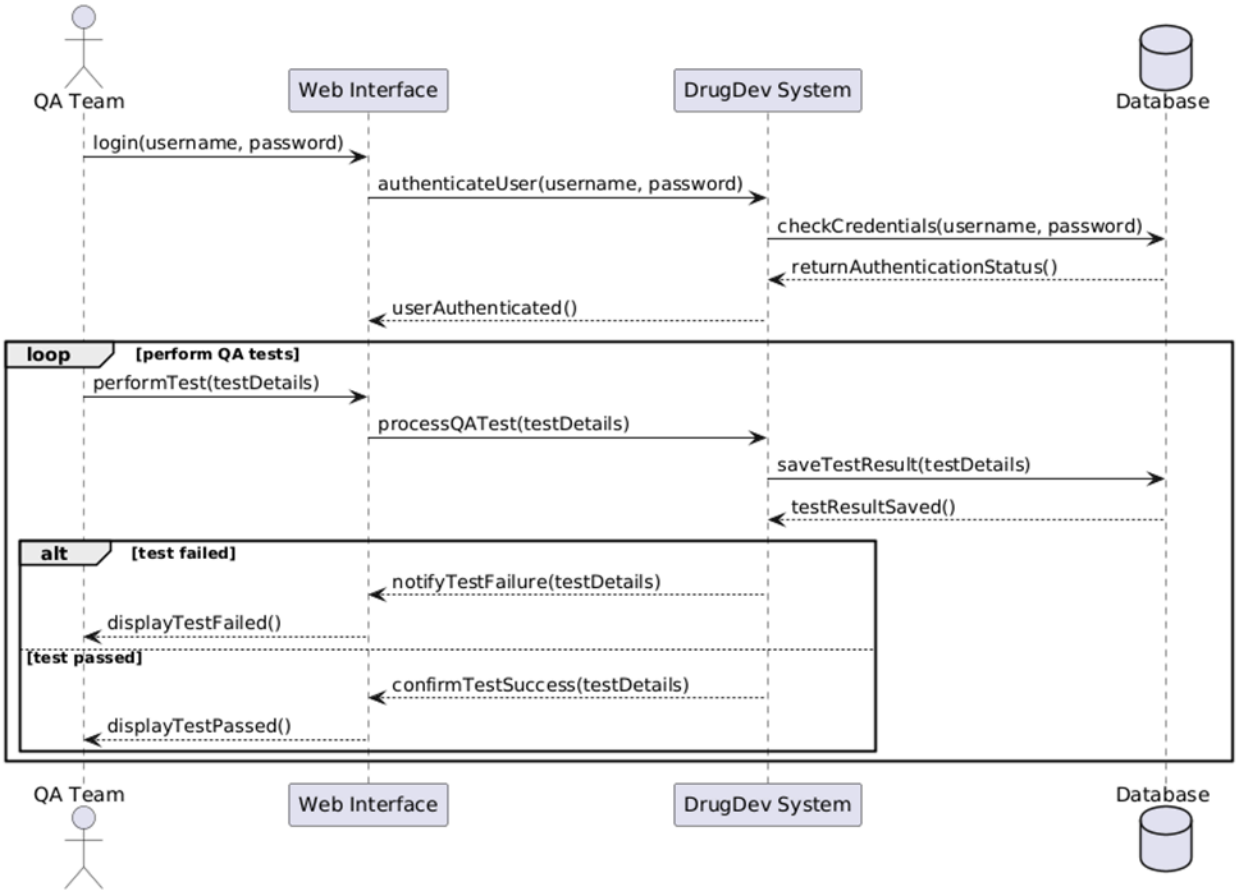
4. Project Planning



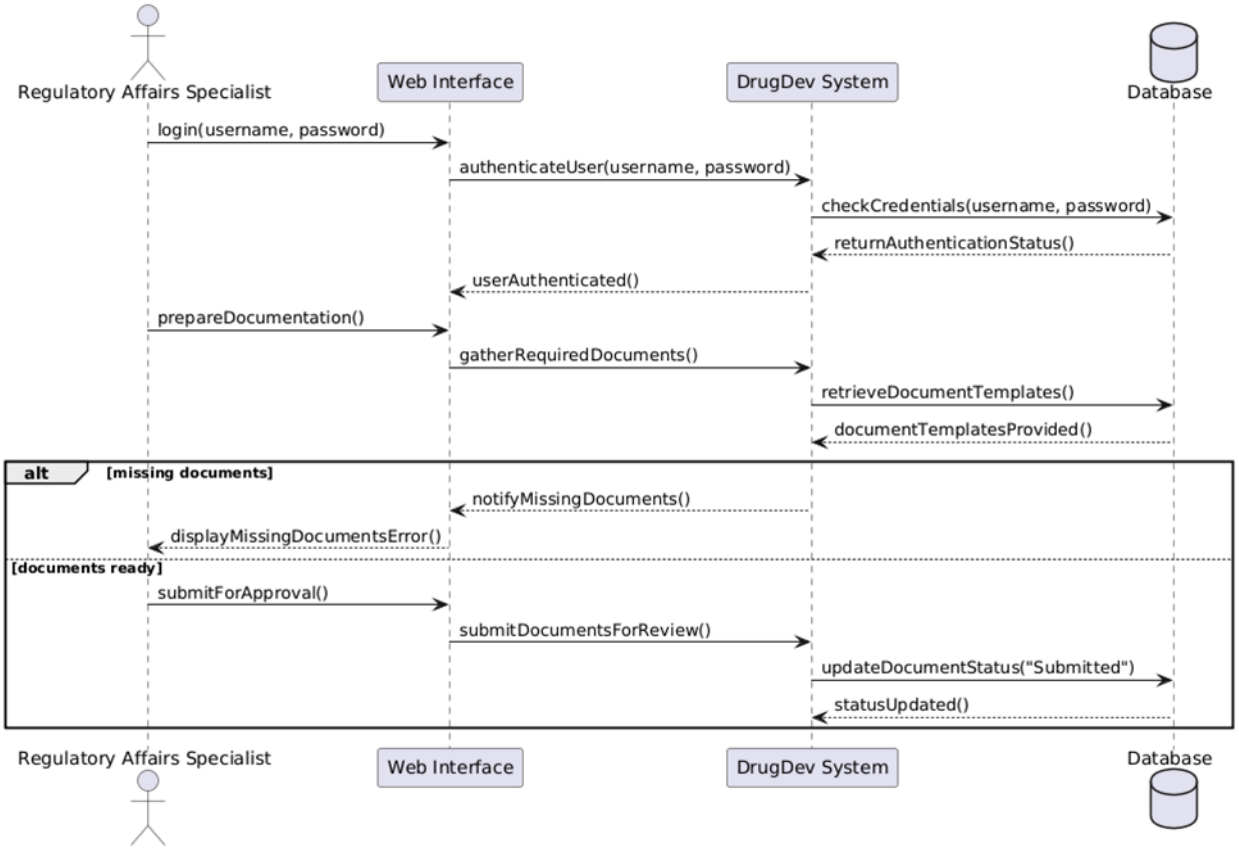
5. R&D Execution



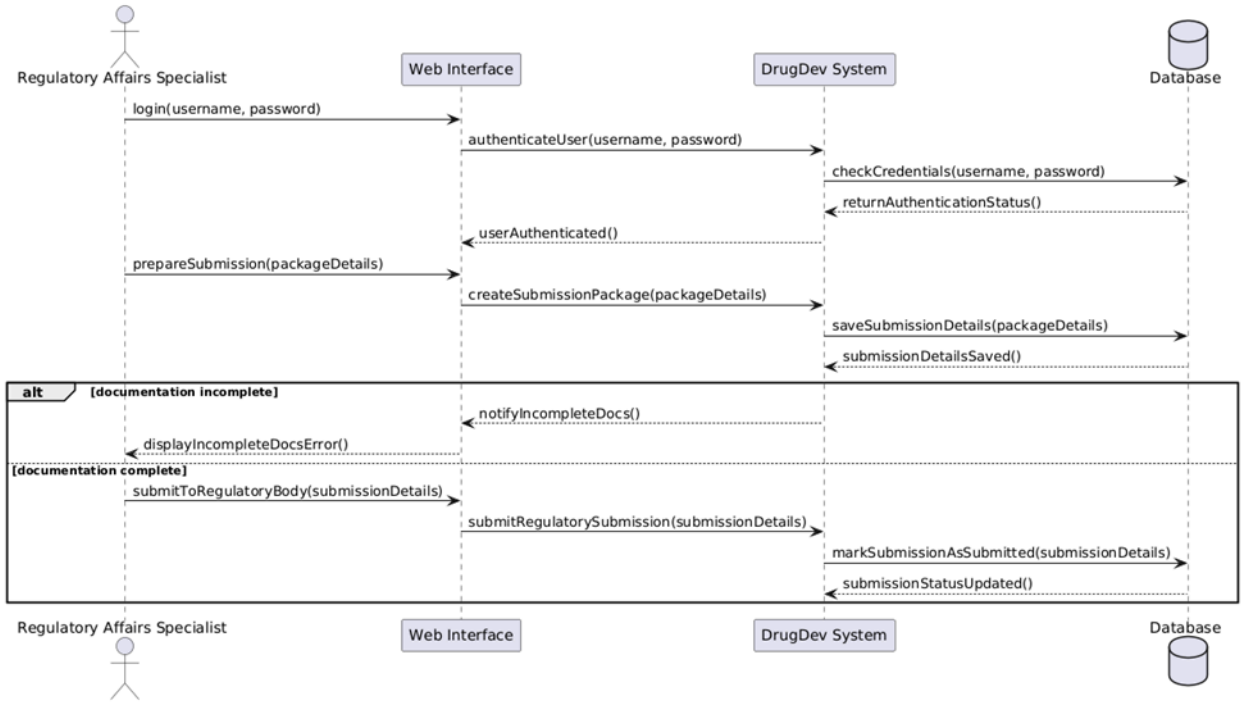
6. Quality Assurance



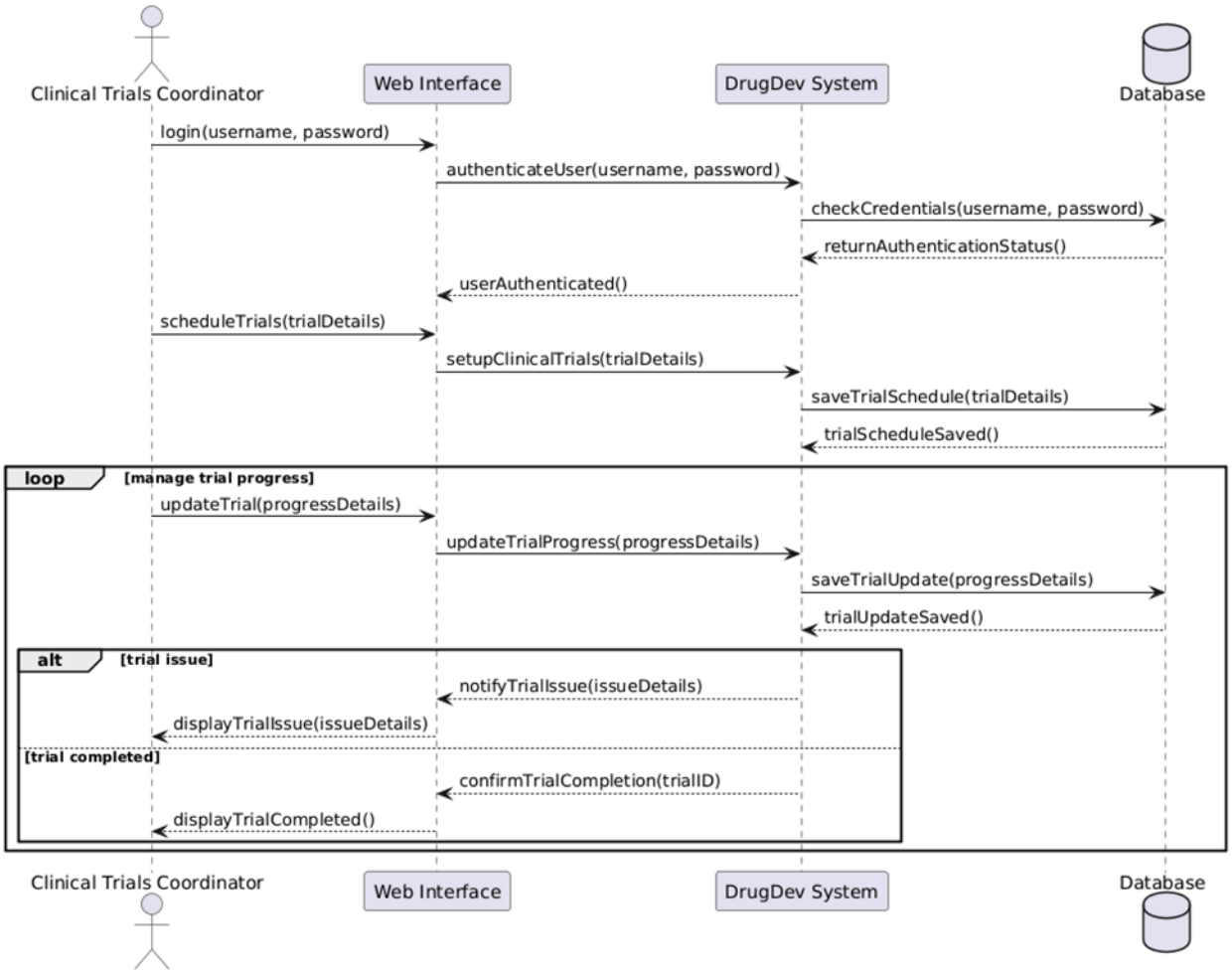
7. Regulatory Preparation



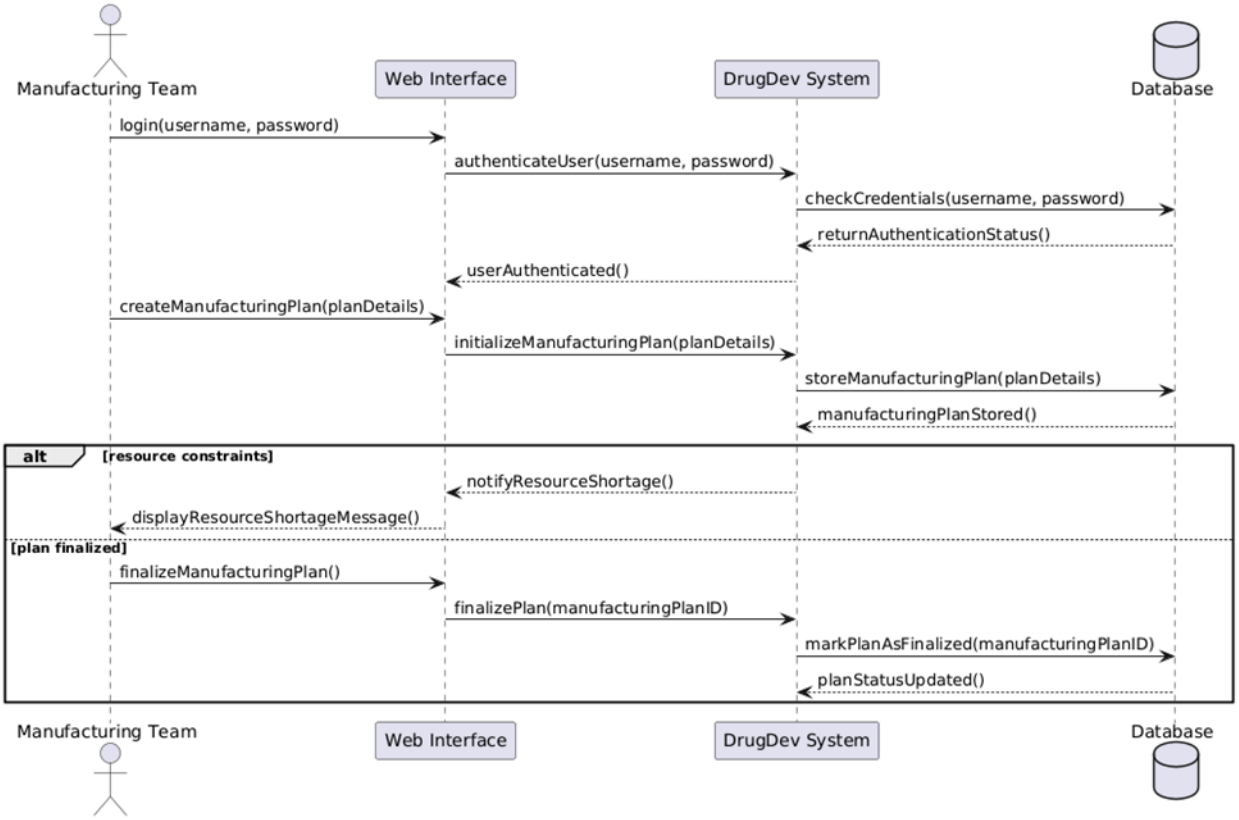
8. Regulatory Submission



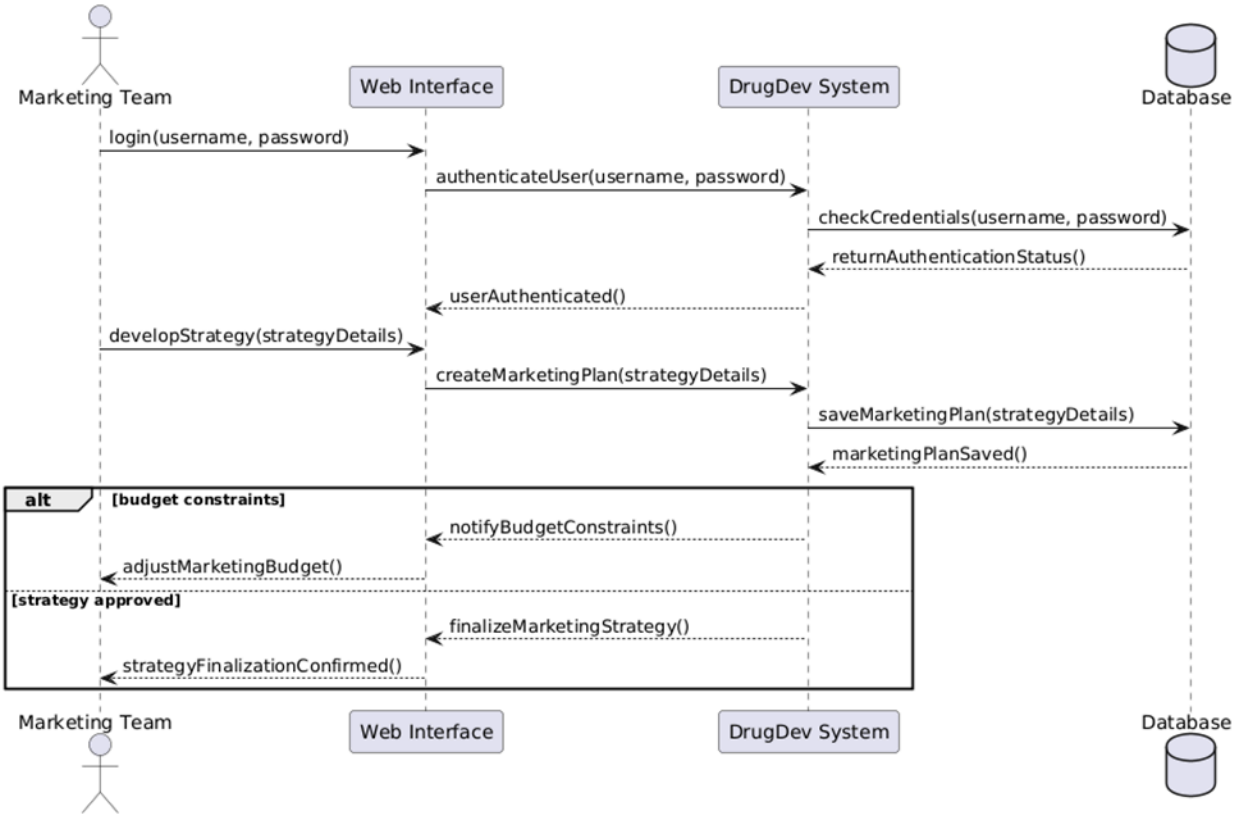
9. Clinical Trials Management



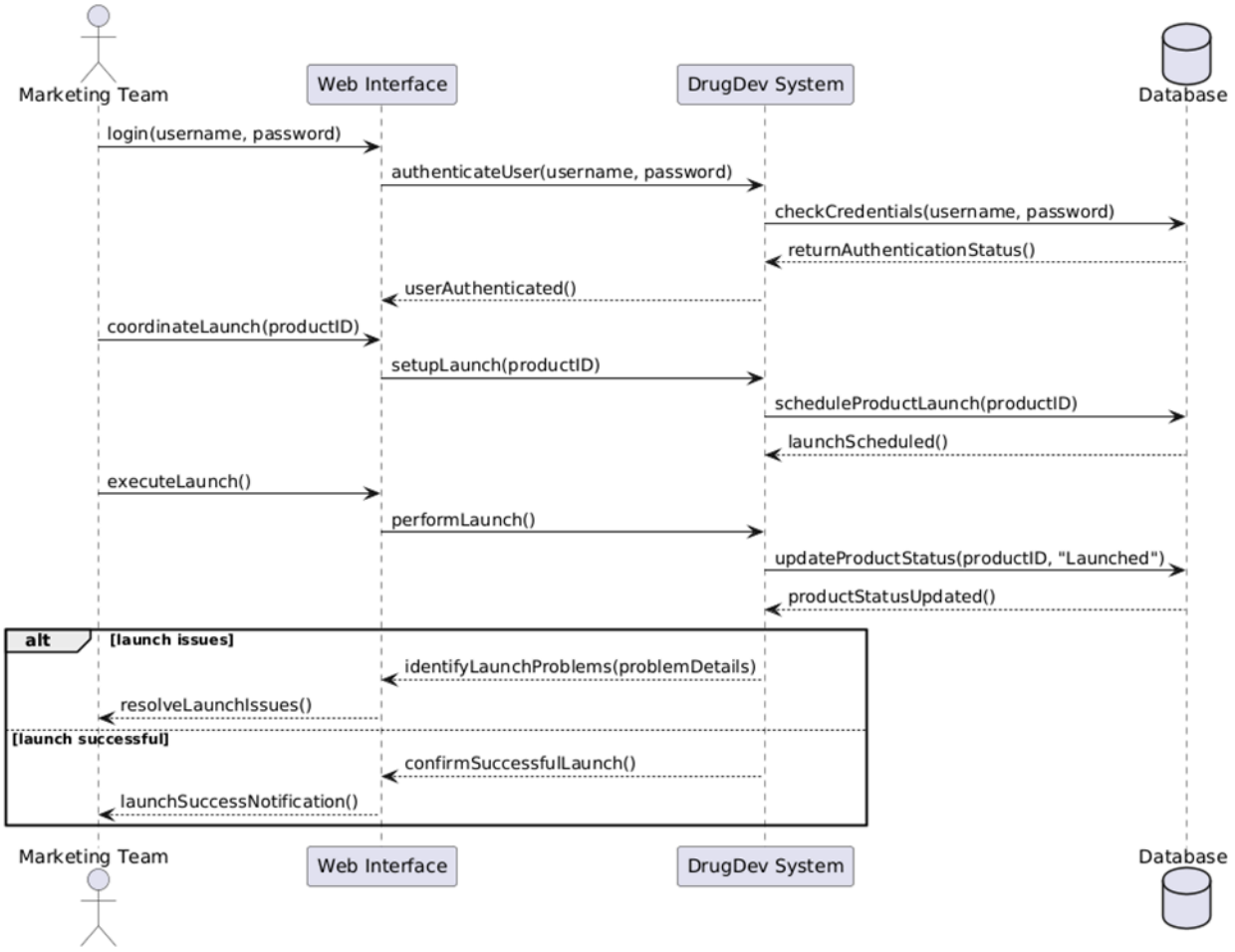
10. Manufacturing Plan



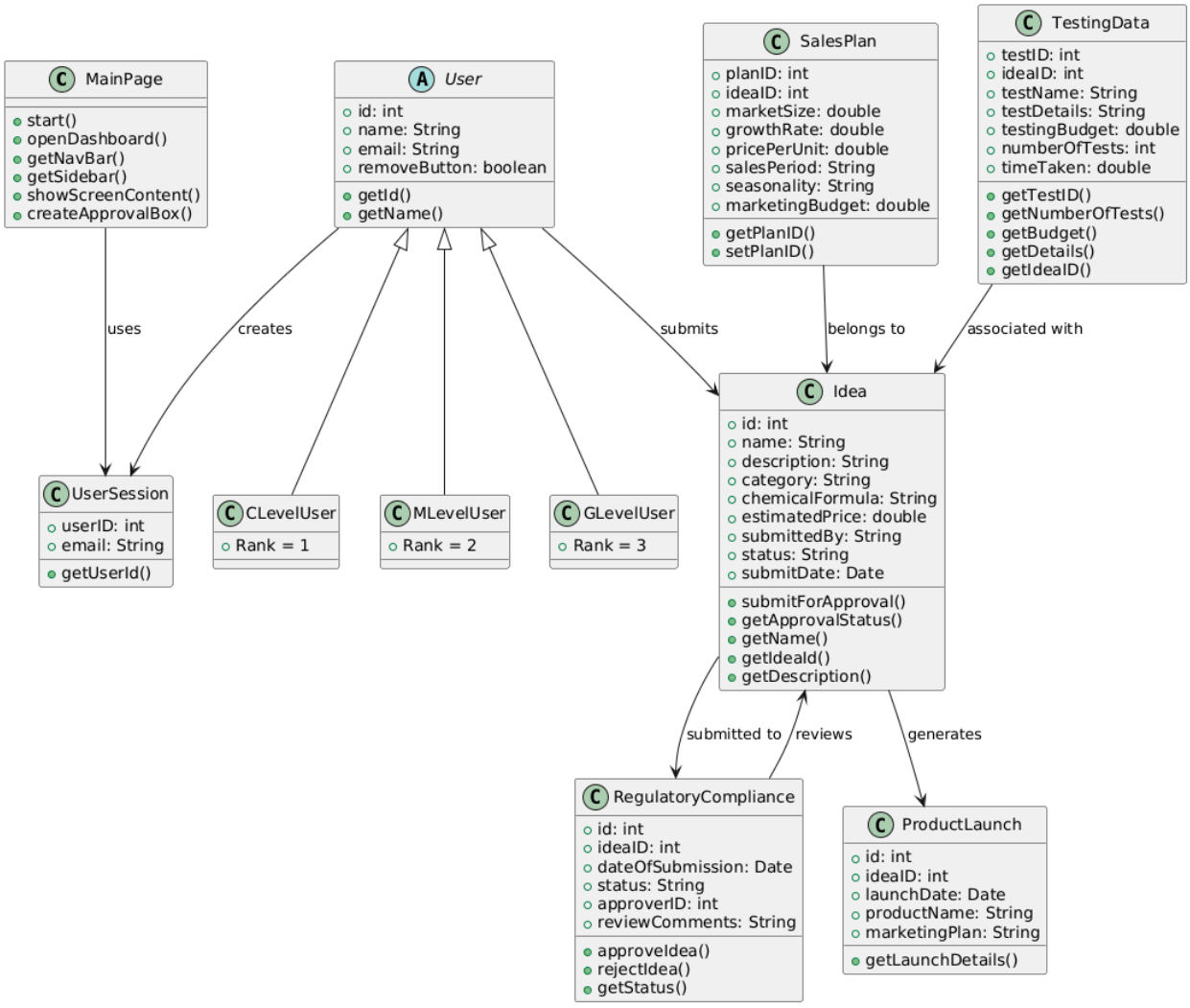
11. Marketing Strategy



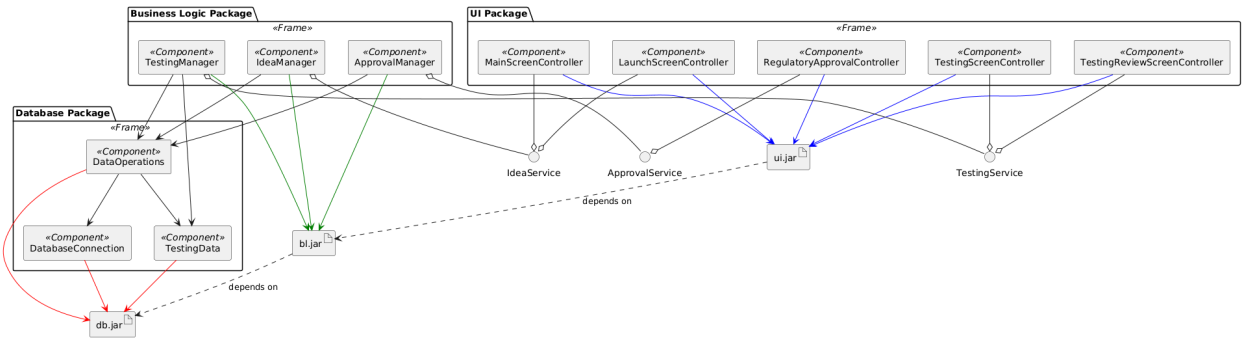
12. Product Launch



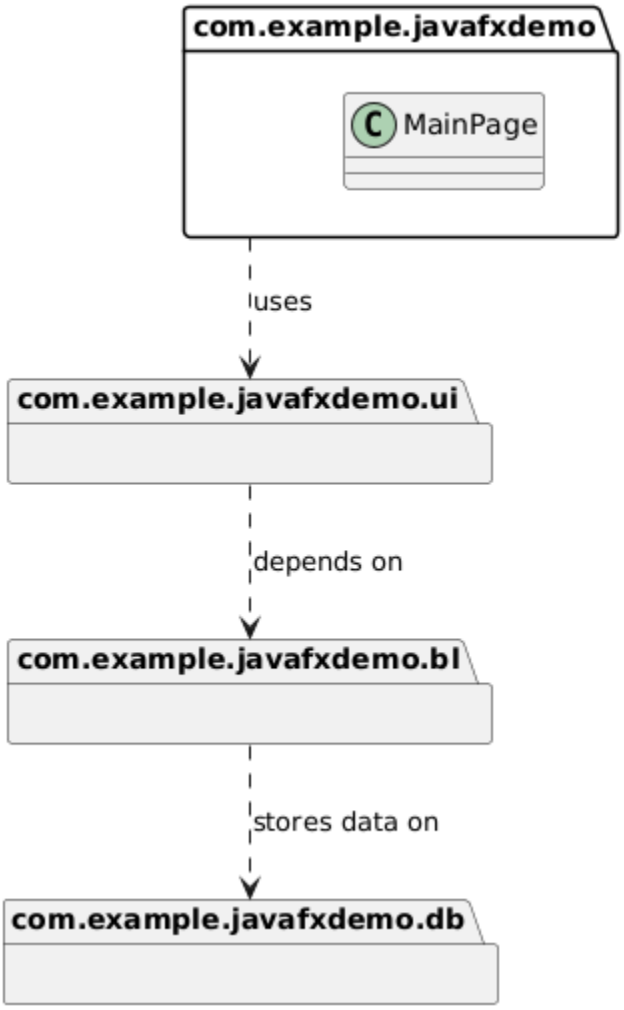
7. Class Diagram



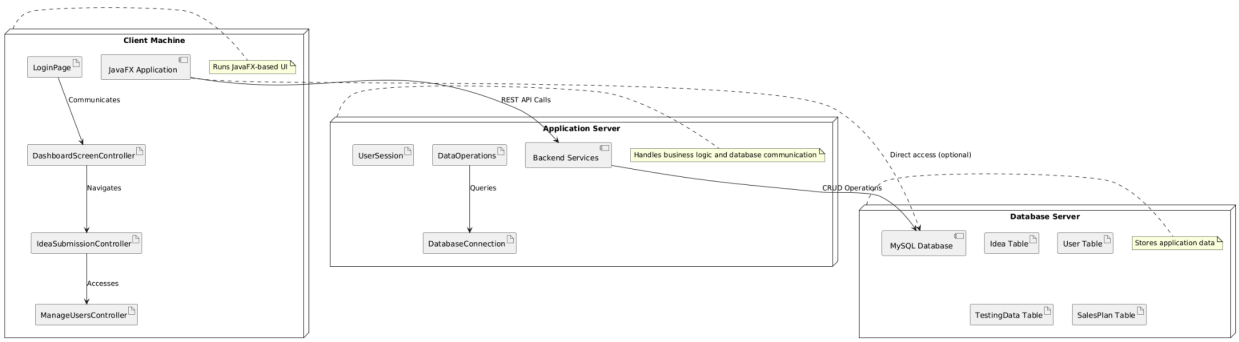
8. Component Diagram



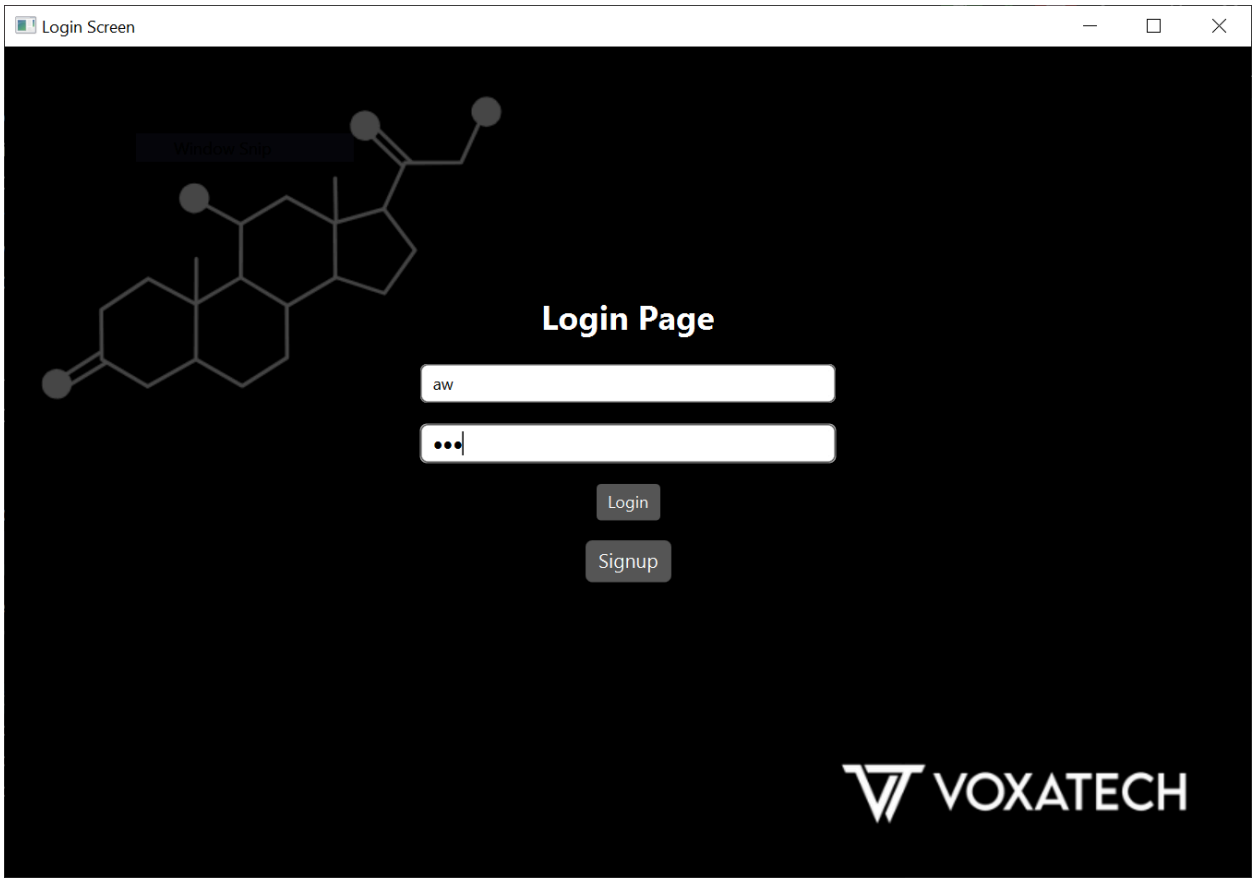
9. Package Diagram

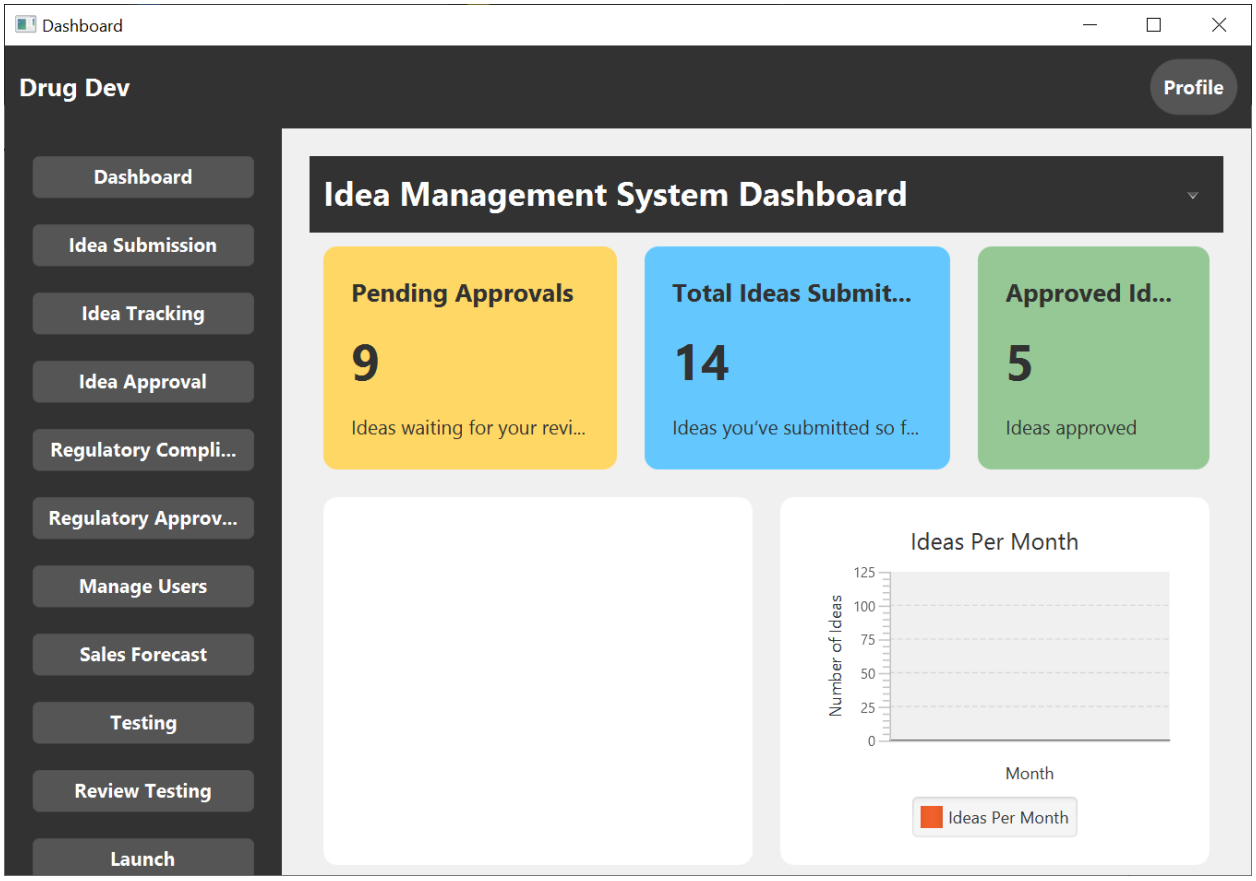


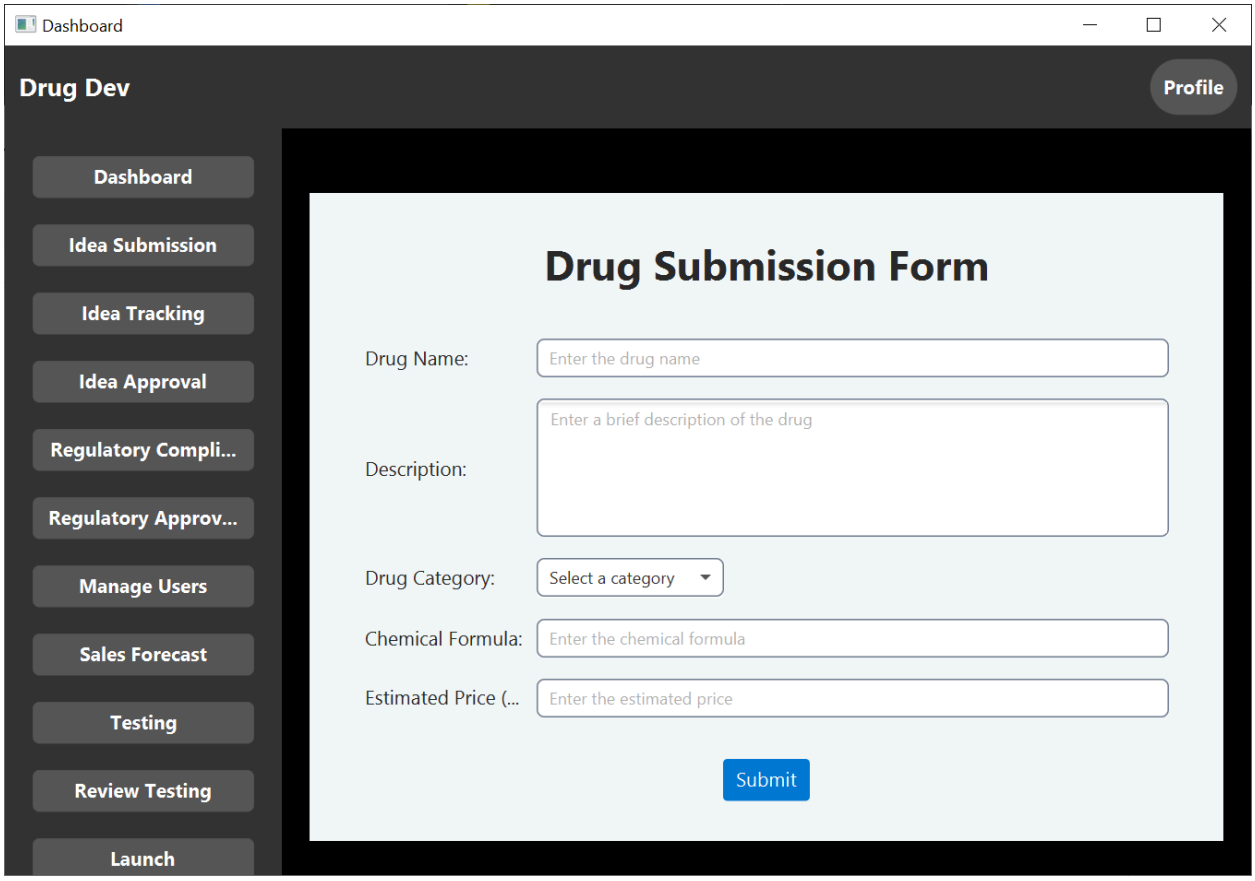
10. Deployment Diagram

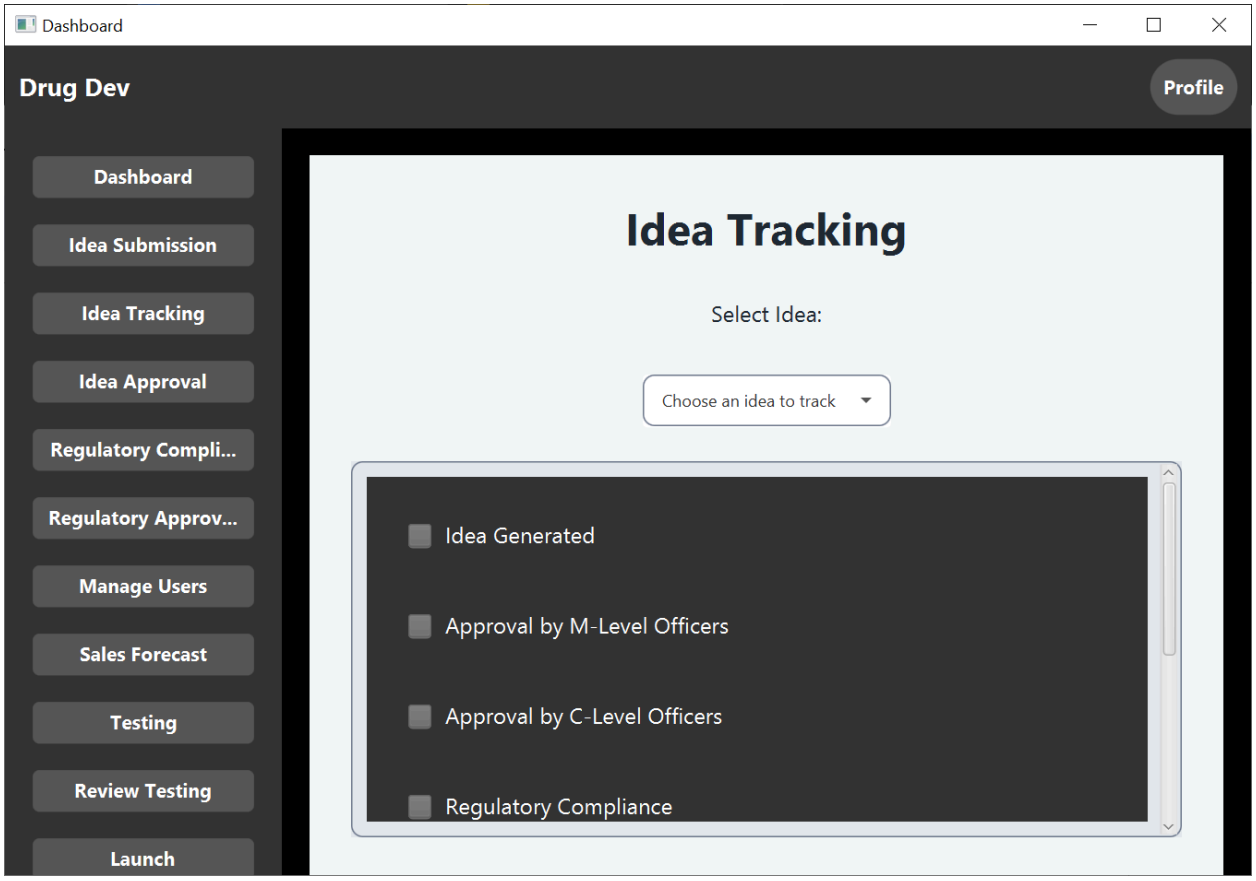


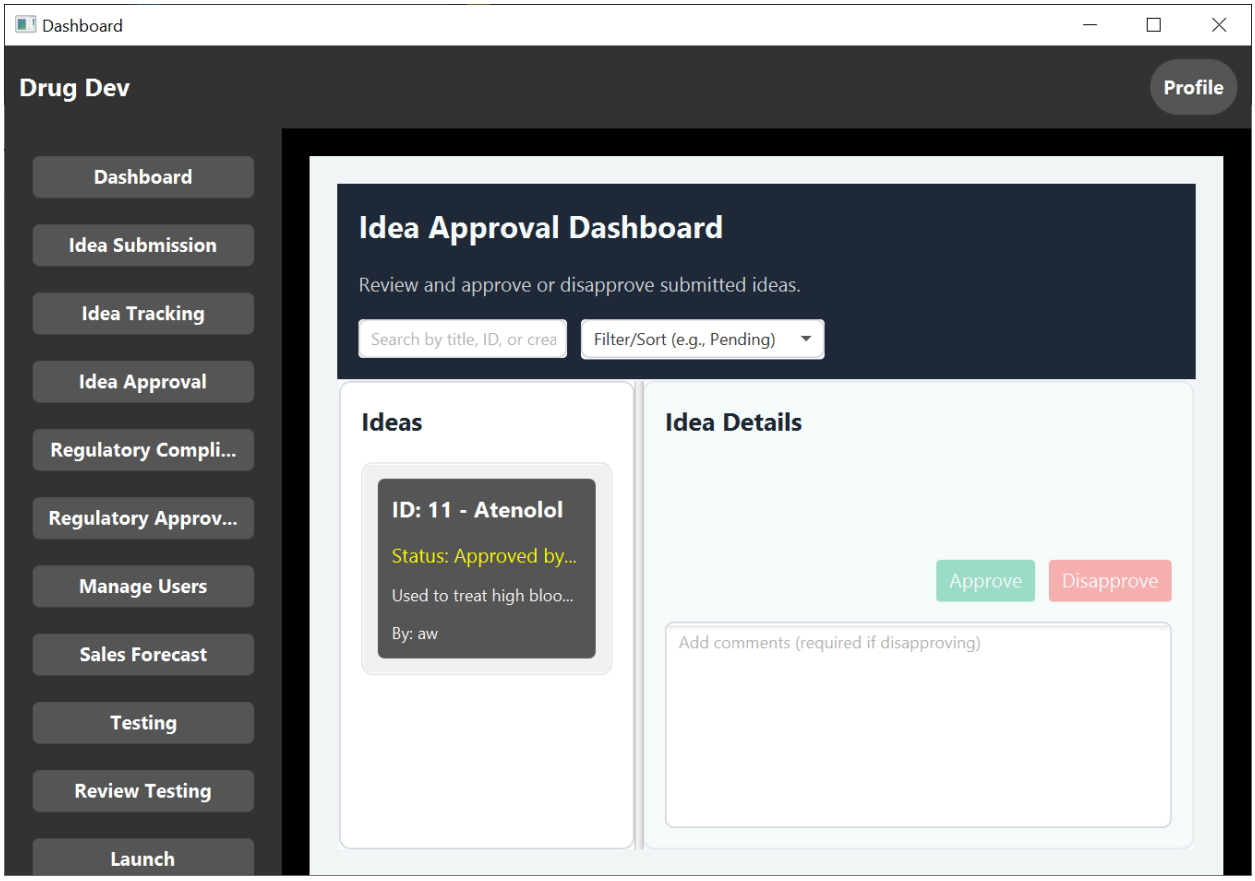
11. UI Interface

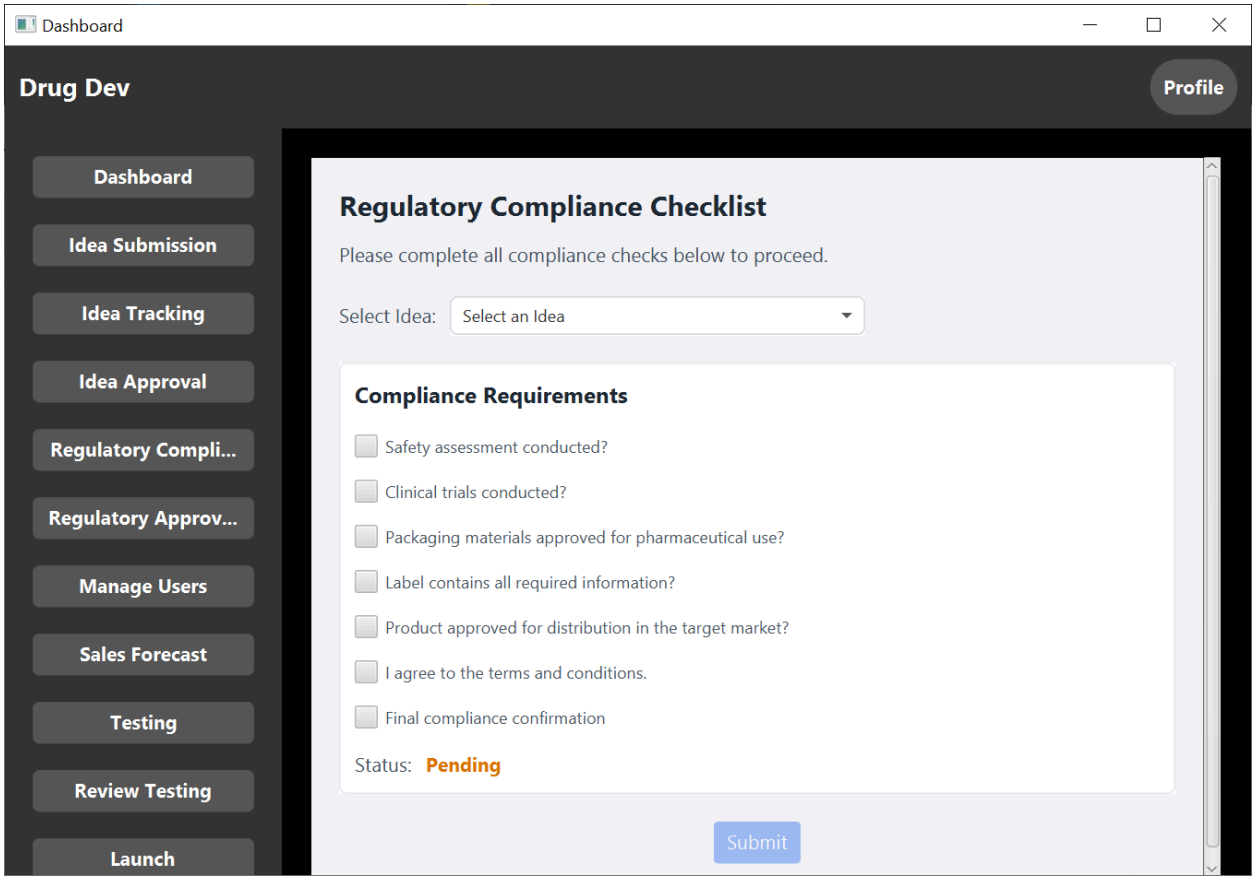


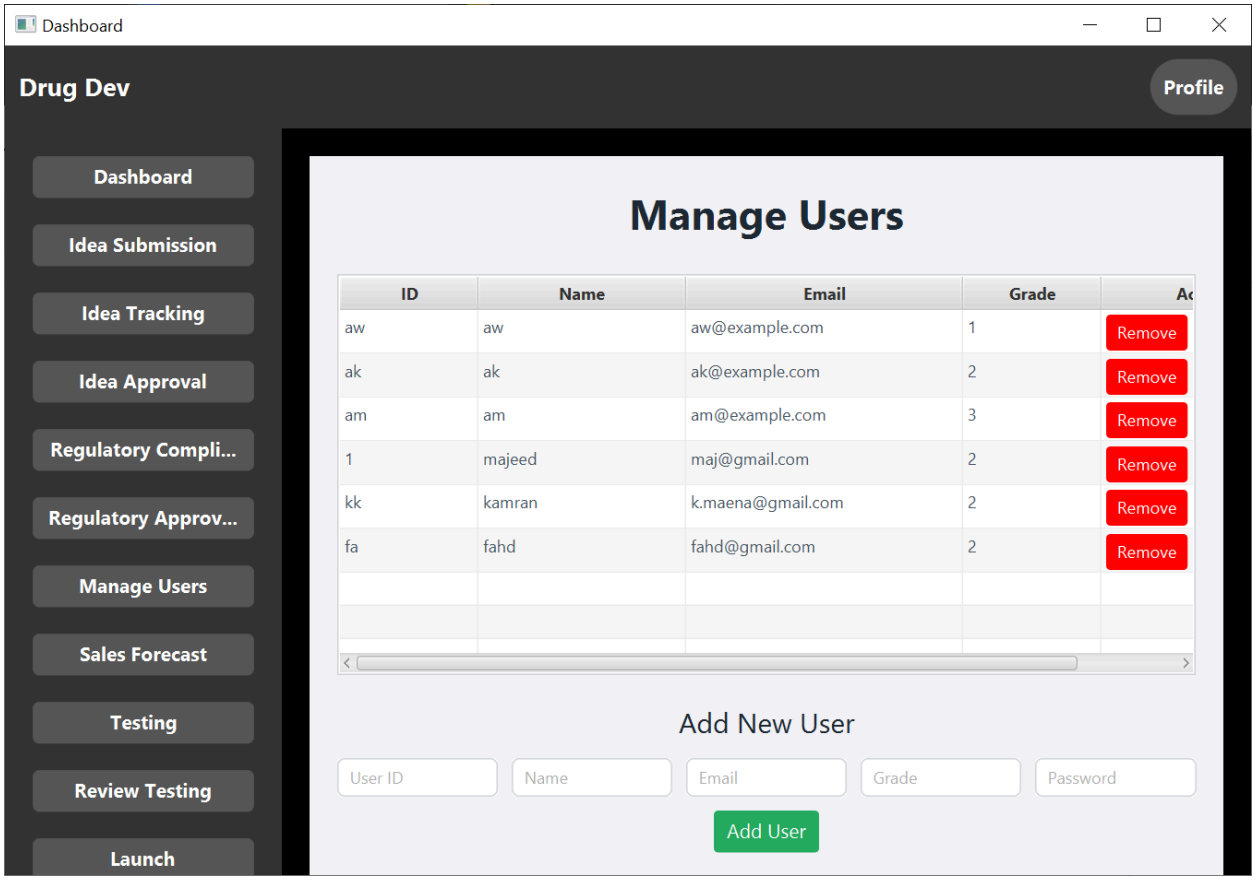

Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Idea Management System Dashboard
Pending Approvals
9
Ideas waiting for your revi...
Total Ideas Submit...
14
Ideas you've submitted so f...
Approved Id...
5
Ideas approved
Ideas Per Month
125
100
75
50
25
0
Number of Ideas
Month
Ideas Per Month

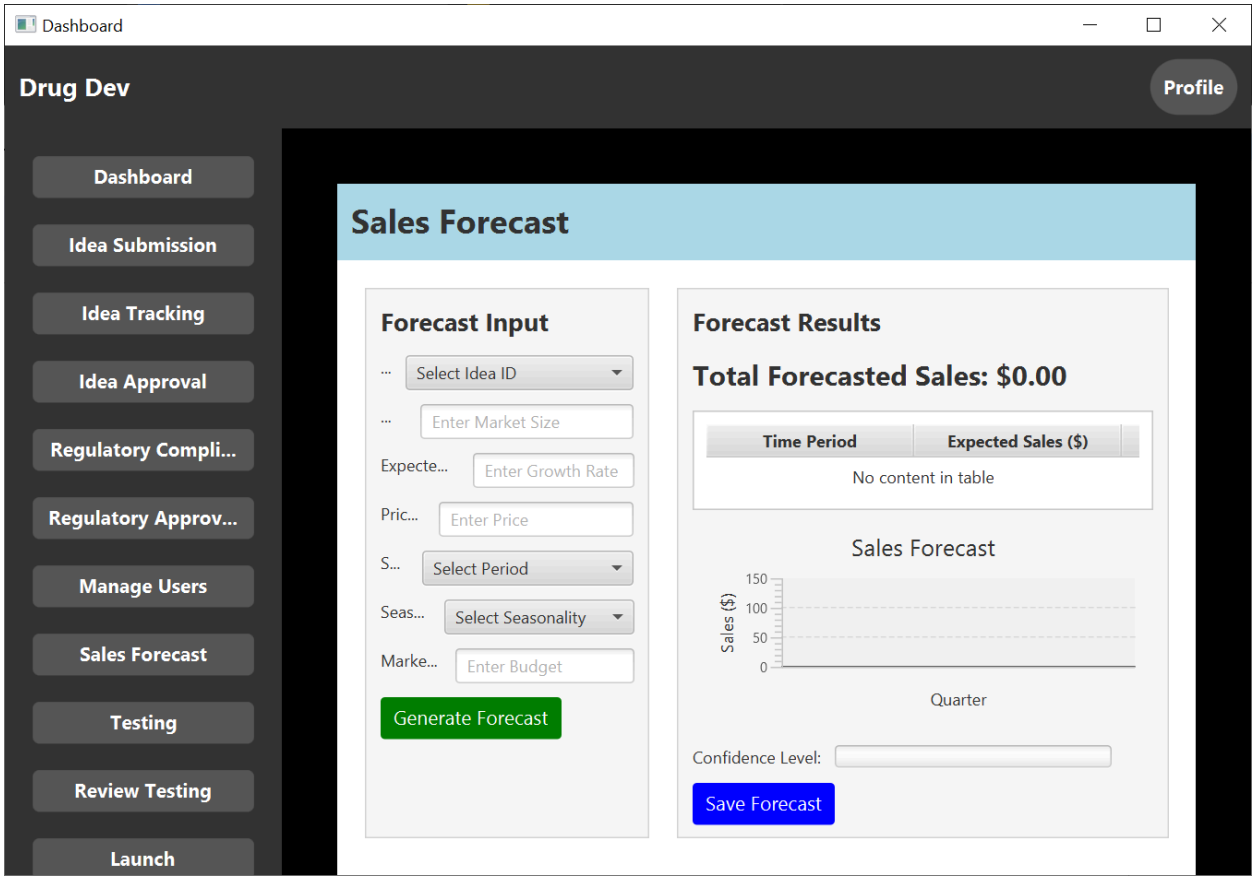

Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Drug Submission Form
Drug Name:
Enter the drug name
Description:
Enter a brief description of the drug
Drug Category:
Select a category
Chemical Formula:
Enter the chemical formula
Estimated Price (...
Enter the estimated price
Submit

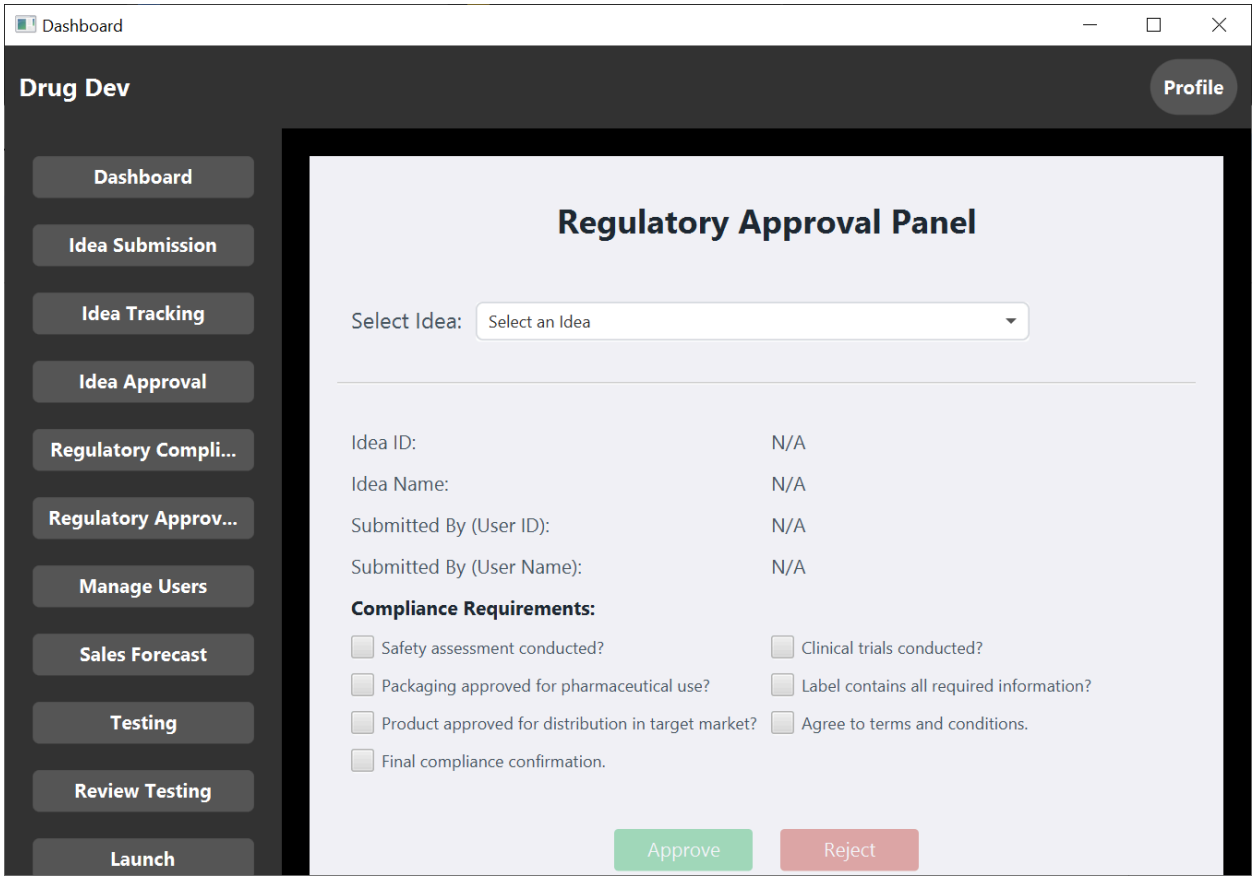

Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Idea Tracking
Select Idea:
Choose an idea to track
Idea Generated
Approval by M-Level Officers
Approval by C-Level Officers
Regulatory Compliance

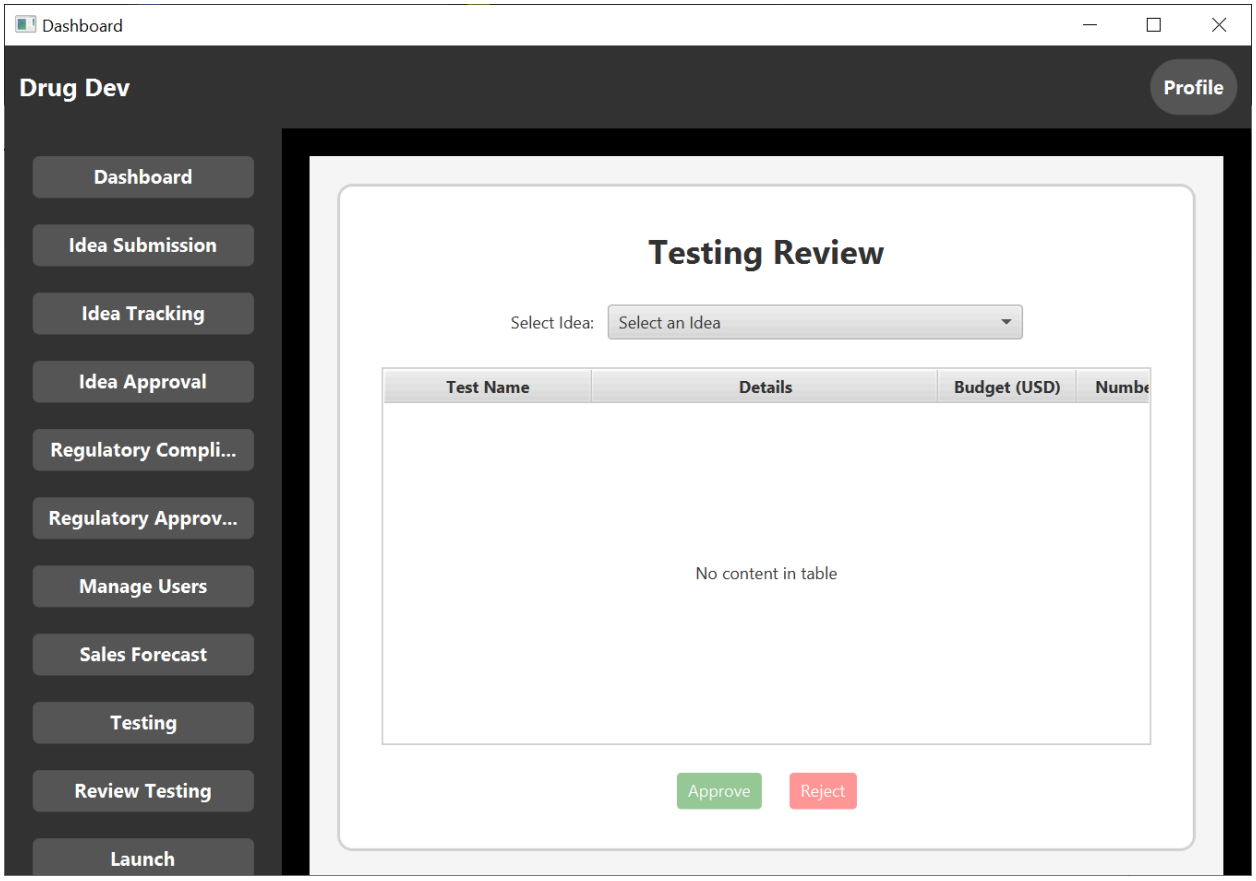

Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Idea Approval Dashboard
Review and approve or disapprove submitted ideas.
Search by title, ID, or crea
Filter/Sort (e.g., Pending)
Ideas
ID: 11 - Atenolol
Status: Approved by...
Used to treat high bloo...
By: aw
Idea Details
Approve
Disapprove
Add comments (required if disapproving)

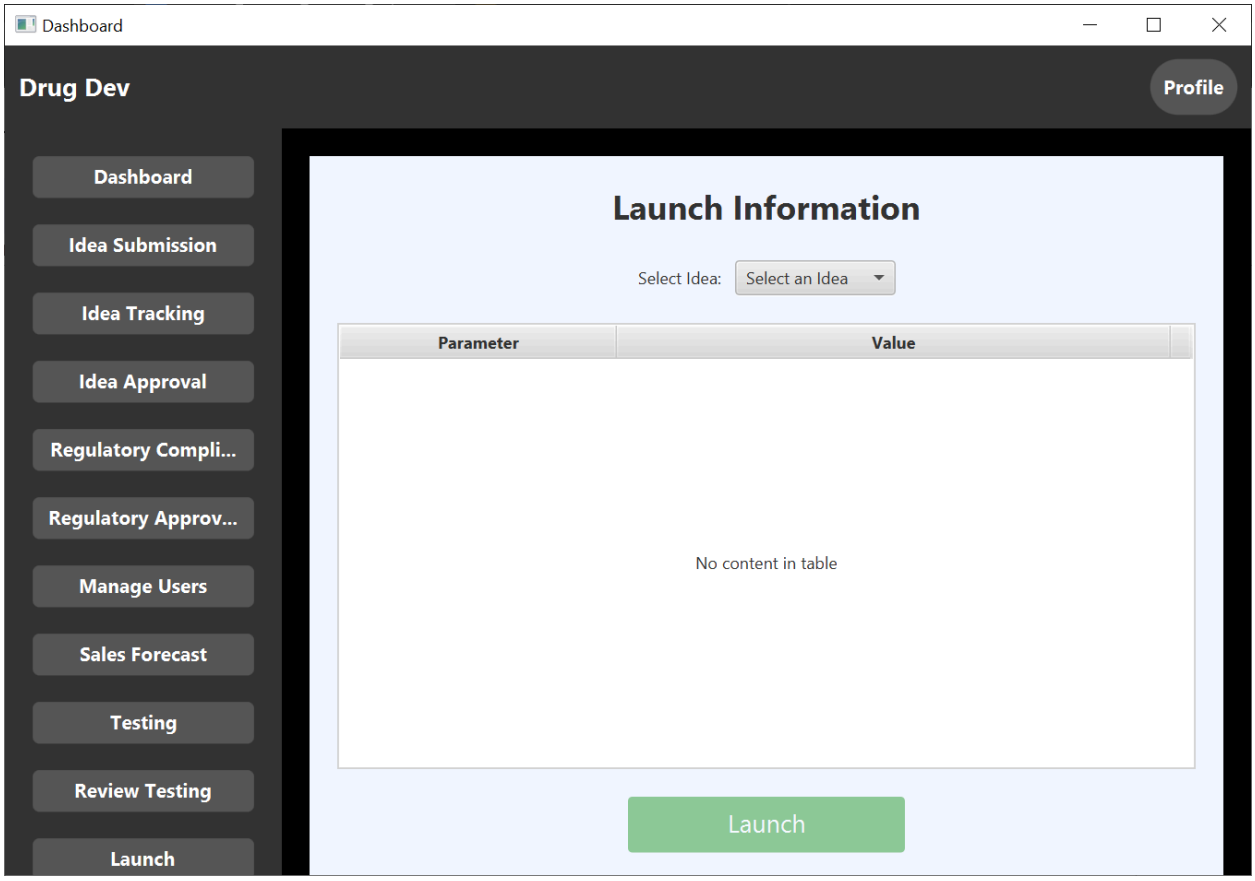

Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Regulatory Compliance Checklist
Please complete all compliance checks below to proceed.
Select Idea:
Select an Idea
Compliance Requirements
Safety assessment conducted?
Clinical trials conducted?
Packaging materials approved for pharmaceutical use?
Label contains all required information?
Product approved for distribution in the target market?
I agree to the terms and conditions.
Final compliance confirmation
Status: Pending
Submit

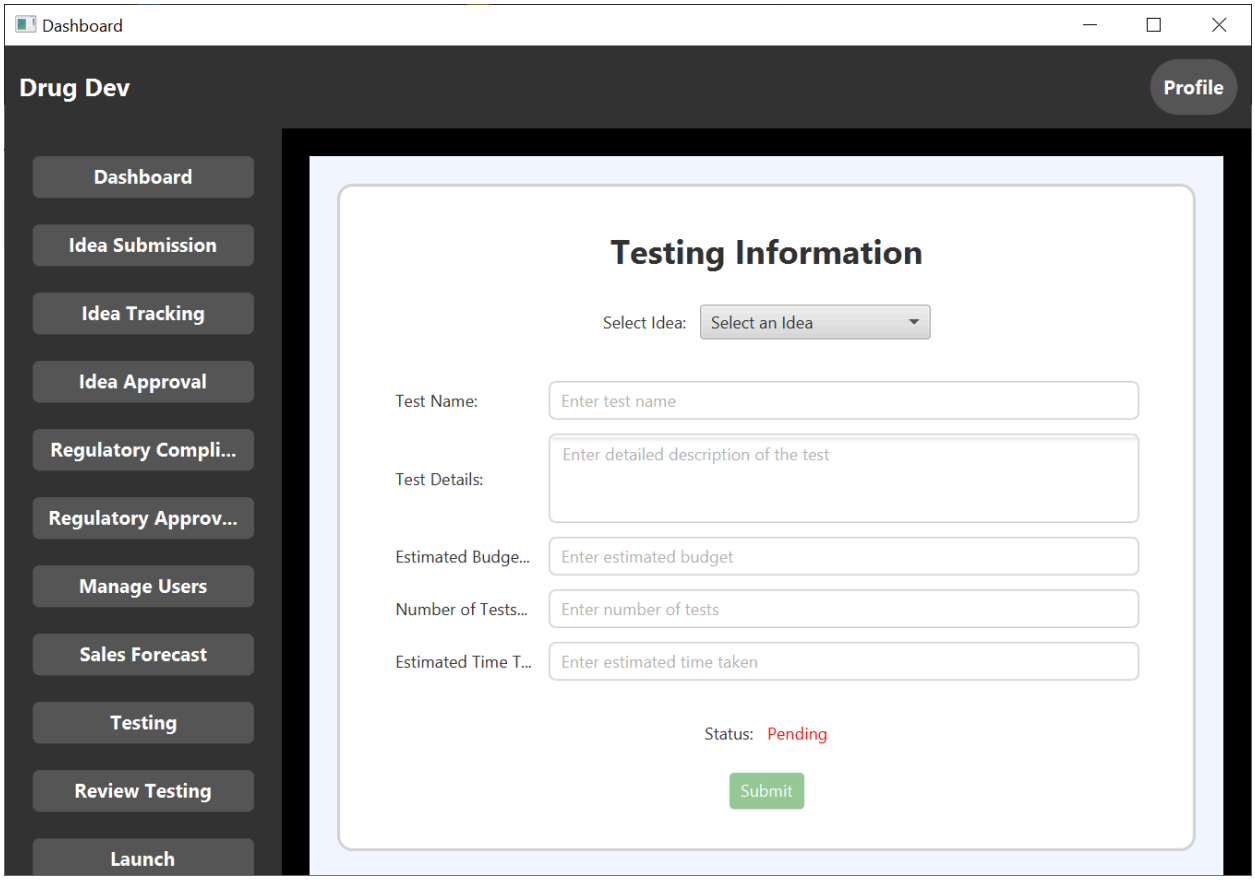

Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Manage Users
ID
Name
Email
Grade
aw
aw
aw@example.com
1
Remove
ak
ak
ak@example.com
2
Remove
am
am
am@example.com
3
Remove
1
majeed
maj@gmail.com
2
Remove
kk
kamran
k.maena@gmail.com
2
Remove
fa
fahd
fahd@gmail.com
2
Remove
Add New User
User ID
Name
Email
Grade
Password
Add User


Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Sales Forecast
Forecast Input
Select Idea ID
Enter Market Size
Expecte...
Enter Growth Rate
Pric...
Enter Price
S...
Select Period
Seas...
Select Seasonality
Marke...
Enter Budget
Generate Forecast
Forecast Results
Total Forecasted Sales: $0.00
Time Period
Expected Sales ($)
No content in table
Sales Forecast
150
100
50
0
Sales ($)
Quarter
Confidence Level:
Save Forecast


Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Regulatory Approval Panel
Select Idea:
Select an Idea
Idea ID:
N/A
Idea Name:
N/A
Submitted By (User ID):
N/A
Submitted By (User Name):
N/A
Compliance Requirements:
Safety assessment conducted?
Clinical trials conducted?
Packaging approved for pharmaceutical use?
Label contains all required information?
Product approved for distribution in target market?
Agree to terms and conditions.
Final compliance confirmation.
Approve
Reject


Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Testing Review
Select Idea:
Select an Idea
Test Name
Details
Budget (USD)
Numbe
No content in table
Approve
Reject


Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Launch Information
Select Idea:
Select an Idea
Parameter
Value
No content in table
Launch


Dashboard
Drug Dev
Profile
Dashboard
Idea Submission
Idea Tracking
Idea Approval
Regulatory Compli...
Regulatory Approv...
Manage Users
Sales Forecast
Testing
Review Testing
Launch
Testing Information
Select Idea:
Select an Idea
Test Name:
Enter test name
Test Details:
Enter detailed description of the test
Estimated Budge...
Enter estimated budget
Number of Tests...
Enter number of tests
Estimated Time T...
Enter estimated time taken
Status: Pending
Submit