**FUNCTIONAL REQUIREMENT DOCUMENT**

**Project:** PPS Analytics Platform for Gastroenterology

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# Project Overview

The PPS Analytics Platform for Gastroenterology aims to provide GastroGPO and Gastrologix members with advanced analytical tools to improve patient management by leveraging data-driven insights. The platform will enable efficient patient stratification, adherence to clinical pathways, and enhanced decision-making capabilities, ultimately contributing to both clinical and economic value.

# Business Objectives

* Improve Patient Outcomes: Utilize data analytics to enhance diagnostic accuracy and treatment effectiveness.
* Increase Operational Efficiency: Streamline patient management processes to reduce wait times and improve service delivery.
* Enhance Decision-Making: Provide real-time, actionable insights to clinicians for better adherence to clinical guidelines.

# Project Scope

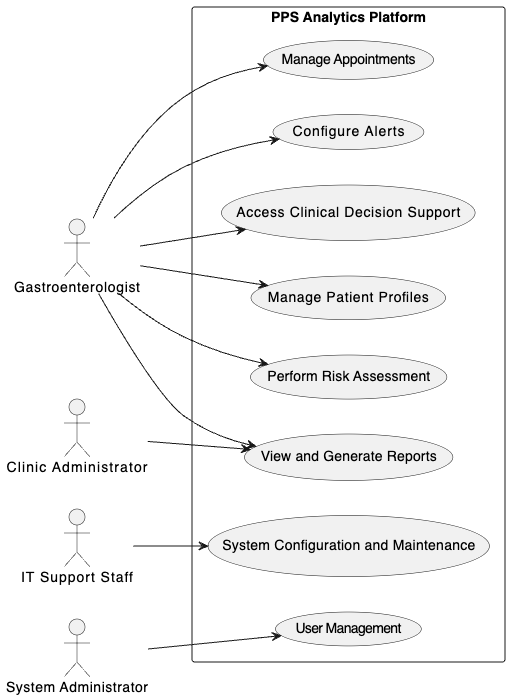
## Project In Scope

1. Data integration from EHRs
2. Patient management systems
3. Billing information
4. Development of analytics modules for risk assessment and treatment optimization
5. User interface for real-time data interaction.

## Project Out of Scope

1. Data sources outside of the agreed-upon health systems and databases
2. Legacy system replacement.

# Use Case Diagram



# Project Stakeholders

|  |  |  |
| --- | --- | --- |
| **Name** | **Department** | **Role** |
| John | Gastroenterologists | Primary users of the platform. |
| Smith | Clinic Administrators | Secondary users focusing on operational analytics. |
| Senthil | IT Lead | Responsible for the technical deployment and maintenance |
| Sawant | Project Management | Project Manager |
| Diwakar Singh | Business Analyst | To do Business Analysis |

# Business Requirements

## **Functional Requirements**

### **Data Integration and Management**

* Ability to integrate data from multiple sources with varying formats (e.g., CSV, PDF, HL7)
* Automated data cleansing and preparation for analysis.

### **Patient Stratification and Management**

* Dynamic tools for creating and adjusting patient groups based on multiple criteria.
* Visualization tools for tracking patient progress and outcomes.

### **Reporting and Analytics**

* Customizable dashboards with real-time data updates.
* Reports on adherence to clinical pathways and treatment outcomes.

### **Advanced Data Analytics**

The platform must provide advanced analytics capabilities, including predictive modeling and risk assessment algorithms, to identify patients at high risk of gastroenterological diseases.

### **Clinical Decision Support**

Implement clinical decision support systems (CDSS) that offer treatment recommendations based on the latest clinical guidelines and individual patient data.

### **User-Defined Alerts**

Enable users to configure alerts based on specific criteria such as deviations from treatment protocols or critical patient conditions.

### **Seamless Data Import/Export**

Provide functionality for easy import and export of data in various formats (e.g., CSV, PDF, HL7) to facilitate interoperability with other health systems.

### **Customizable Dashboards**

Users should be able to customize dashboards to display relevant metrics and data points critical to their specific roles and needs.

### **Appointment Scheduling and Management**

Include features for scheduling, rescheduling, and managing patient appointments directly through the platform, including integration with calendar applications.

### **Patient Communication Portal**

Facilitate direct communication channels within the platform for healthcare providers to connect with patients via secure messaging or telehealth features.

### **Audit Trails**

The system must automatically log all user actions and data changes to ensure traceability and compliance with healthcare regulations.

## **Non-Functional Requirements**

### **System Availability**

The platform should be available 24/7, with a downtime of less than 0.1% annually, excluding scheduled maintenance.

### **Scalability**

The system must be scalable to accommodate increasing amounts of data and growing numbers of users without degradation in performance.

### **Interoperability**

Must be compliant with healthcare data exchange standards such as FHIR (Fast Healthcare Interoperability Resources) and HL7 to ensure it can operate within the broader healthcare ecosystem.

### **Data Security**

Implement robust security measures including data encryption at rest and in transit, role-based access control, and regular security audits to protect sensitive patient information.

### **Performance**

Response times for loading data and executing queries should not exceed 3 seconds, ensuring that users experience minimal delay during their interactions with the platform.

### **Usability**

The user interface should be intuitive and accessible, requiring minimal training for users with basic technical skills. It should also be compliant with ADA (Americans with Disabilities Act) standards to ensure accessibility.

### **Backup and Disaster Recovery**

Regular backups of all data must be performed, and a comprehensive disaster recovery plan must be in place to ensure data can be restored quickly in the event of a system failure or other catastrophic events.

**Maintenance and Support**

Provide ongoing maintenance and technical support to address issues, perform upgrades, and ensure the system operates smoothly over time. This support should be accessible 24/7 to handle critical issues.

# Project Assumptions

* Stable integration capabilities with existing EHR systems without significant upgrades.
* It is assumed that gastroenterologists and clinic administrators have basic proficiency with digital health tools, which will minimize the training required to use the new platform.
* The success of the platform is predicated on the assumption that the data being integrated from existing sources like EHRs, and patient management systems is of high quality, accurate, and up to date.
* The healthcare facilities where the platform will be deployed are assumed to have the necessary technology infrastructure, including reliable internet access and hardware capable of running the platform efficiently.
* All data integration and handling processes are assumed to comply with existing healthcare regulations and data protection laws without requiring additional legal scrutiny.
* It is assumed that any third-party vendors or software providers involved in the project will continue to provide stable support and service throughout the platform's development and deployment phases.
* The healthcare staff at participating facilities are assumed to be receptive to adopting new technologies and will engage positively with the change management process introduced by the platform's implementation.

# Project Dependencies

* The project's timeline and success depend on the ability to integrate seamlessly with multiple existing data systems and software, which may require cooperation from various software vendors and IT departments.
* Key stakeholder availability for crucial meetings, feedback sessions, and training workshops is a critical dependency. Delays in stakeholder engagement can lead to project delays.
* The project depends on obtaining necessary regulatory approvals for data handling and processing, which might involve audits and inspections from data protection authorities.
* Successful data migration from existing systems to the new platform is a dependency that involves risks related to data loss or corruption during transfer.
* Continuous financial support and budget approval from the healthcare facilities' administration are crucial. Any cuts or delays in funding can significantly impact project timelines and scope.
* External factors such as changes in healthcare policies, market dynamics, and economic stability are dependencies that could impact project execution and outcomes.

# Project Risks

## **Data Integration Complexity**

Risk: Challenges in integrating disparate data sources could lead to delays and increased costs.

Mitigation: Implement a pilot program to identify potential integration issues early. Engage experienced data integration specialists and use middleware solutions to streamline the process.

**Regulatory Compliance Failures**

Risk: Failure to comply with healthcare regulations like HIPAA could result in legal penalties and damage to reputation.

Mitigation: Conduct regular compliance audits and engage legal experts to review project practices. Implement strict data security measures and continuous monitoring.

## **Technology Adoption Resistance**

Risk: Resistance from users due to unfamiliarity with new technology could hinder the platform's adoption and effectiveness.

Mitigation: Develop comprehensive training programs and provide continuous support. Involve end-users early in the design process to ensure the platform meets their needs and preferences.

**Budget Overruns**

Risk: Project costs may exceed initial estimates due to unforeseen technical challenges or scope changes.

Mitigation: Implement strict budget management procedures, regularly review financial performance, and maintain a contingency reserve.

## **Vendor Dependence**

Risk: Over-reliance on third-party vendors for critical software components could lead to issues if vendors fail to deliver as promised.

Mitigation: Diversify vendor options, establish clear contractual agreements with performance clauses, and maintain an active vendor management strategy.

# Project Issues

**Data Quality Issues**

Issue: Initial data collected from various sources may have inconsistencies and inaccuracies that affect platform reliability.

Resolution: Implement robust data cleaning and validation processes. Regularly update these processes as more data is integrated.

**Technical Skill Gaps**

Issue: The project team may lack certain technical skills required for advanced data analytics and platform development.

Resolution: Identify skill gaps early and consider hiring new talent or offering training to existing staff. Outsourcing can also be an option for highly specialized skills.

**Stakeholder Misalignment**

Issue: Conflicting priorities among stakeholders can lead to disagreements on the project’s direction.

Resolution: Regularly engage all stakeholders through meetings and updates to align on goals and expectations. Use conflict resolution strategies and compromise where necessary.

**Scalability Concerns**

Issue: The platform may not be able to handle the increasing load as more users and data are added, leading to performance degradation.

Resolution: Design the platform with scalability in mind from the start. Regularly perform load testing and plan for infrastructure upgrades as necessary.

**Delayed Deliverables**

Issue: Project timelines may be extended due to technical setbacks or external factors such as regulatory changes.

Resolution: Implement agile project management methodologies to adapt to changes rapidly. Keep a flexible project timeline with buffer periods for critical tasks.

# Project Acceptance Criteria

## **Data Integration and Management**

* The system must integrate data from at least three different sources (EHRs, patient management systems, lab results).
* Data integration processes must be completed within 5 minutes for daily updates consisting of up to 10,000 records.
* No more than 0.01% error rate in data integration.

#### **Patient Stratification**

* Users must be able to create and modify patient groups based on at least five different criteria (e.g., age, diagnosis, treatment history, risk factors).
* The system must update patient groups in real-time as new data becomes available.
* The stratification tool must handle up to 100,000 patient records without performance degradation.

## **Advanced Data Analytics**

* Predictive models must achieve a minimum accuracy of 90% in identifying high-risk patients as validated by retrospective data.
* Reports generated by the analytics module should load within 3 seconds.
* Users must be able to customize analytics parameters through a user-friendly interface.

#### **Clinical Decision Support**

* The system must provide at least three treatment recommendations based on current clinical guidelines.
* Decision support prompts must be triggered within 1 second of relevant data entry or update.
* Users must be able to override or ignore recommendations with documented reasons.

## **User-Defined Alerts**

* Alerts must be configurable for a variety of parameters, including lab results out of expected range and missed appointments.
* Alerts must be delivered to the designated healthcare provider's interface within 10 seconds of the triggering event.
* Users must be able to acknowledge or act on alerts directly from the notification pane.

#### **Reporting and Analytics Dashboard**

* Dashboards must refresh with updated data every 5 minutes automatically.
* Users must be able to access historical data and trends for up to 5 years.
* Export of data from dashboards to PDF or Excel should not exceed 10 seconds.

## **Security and Compliance**

* The platform must pass a third-party security audit without critical findings.
* Role-based access controls must enforce that users can only access data and functionalities specific to their roles.
* All access and changes to sensitive data must be logged and retrievable for at least 6 years.

## **System Performance and Scalability**

* The platform must support simultaneous use by up to 500 users without core functionalities slowing down by more than 10% compared to baseline.
* Scalability testing must show that adding additional data or users does not decrease system performance linearly.

# Glossary

**Analytics Module**

Definition: A component of the platform that processes data to generate insights, including predictive analytics and reporting functionalities.

**Clinical Decision Support System (CDSS)**

Definition: An integrated system within the platform that uses patient data to provide treatment recommendations based on clinical guidelines.

**Data Integration**

Definition: The process of combining data from different sources into a single, unified view to enable more effective and coherent analysis.

**Electronic Health Records (EHRs)**

Definition: Digital versions of patients’ medical histories that are maintained by the provider over time, including diagnostics, treatments, and clinical notes.

**Extract, Transform, Load (ETL)**

Definition: A process in database usage and data warehousing that involves extracting data from outside sources, transforming it to fit operational needs, and loading it into the end target (database or data warehouse).

**FHIR (Fast Healthcare Interoperability Resources)**

Definition: A standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging electronic health records.

**GastroGPO**

Definition: A group purchasing organization specifically for gastroenterology practices, aimed at leveraging purchasing power to obtain discounts from vendors based on the collective buying power of its members.

**Gastrologix**

Definition: A cooperative that works with independent gastroenterology practices to manage their operations, including financial and patient care optimization.

**HIPAA (Health Insurance Portability and Accountability Act)**

Definition: U.S. legislation that provides data privacy and security provisions for safeguarding medical information.

**Patient Management System**

Definition: Software used by healthcare providers to manage information related to patient care, including scheduling, billing, and other administrative tasks.

**Patient Stratification**

Definition: The process of segmenting patients into various groups based on predefined criteria such as risk or diagnosis to tailor care approaches effectively.

**Predictive Modeling**

Definition: A process that uses data and statistical algorithms to predict outcomes with significant accuracy within a model.

**Role-Based Access Control (RBAC)**

Definition: A method of restricting system access to authorized users based on their roles and responsibilities within the organization.

**User Interface (UI)**

Definition: The means by which the user and a computer system interact, particularly the use of input devices and software.

**User Acceptance Testing (UAT)**

Definition: The process of verifying that a solution works for the user and meets all their requirements in a real-world scenario.