Product Requirements Document

Project Name: ClinFlow Clinical Trial Manager
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1.0 Introduction
This document defines the software requirements for ClinFlow, a system designed to streamline the management of clinical trials. The system will handle patient recruitment, data collection, and regulatory reporting, ensuring data accuracy and compliance.

2.0 Business Goals
The primary goal is to accelerate the clinical trial lifecycle by 25% and ensure all trial data is auditable and ready for submission to regulatory bodies.

3.0 Target Users
* **Clinical Researcher:** Manages trial protocols and data.
* **Study Coordinator:** Recruits and enrolls patients, manages appointments.
* **Data Manager:** Ensures data accuracy and integrity, generates reports.

4.0 Functional Requirements
* **REQ-020: Patient Recruitment:** The system shall allow study coordinators to screen and enroll participants.
* **REQ-021: Data Collection:** The system shall provide electronic case report forms (eCRFs) for data entry, capturing data from multiple sources.
* **REQ-022: Data Integrity:** The system shall perform automated checks to identify and flag data inconsistencies.
* **REQ-023: Informed Consent:** The system shall store and secure all electronic informed consent documents.

5.0 Non-Functional Requirements
* **NFR-004: Scalability:** The system shall support a minimum of 1,000 active users and 10 concurrent trials.
* **NFR-005: Security:** All trial data, including patient information, shall be protected with multi-layered security.

6.0 Regulatory and Compliance
The software must comply with the following standards.

Requirement ID	Description	Applicable Standard(s)
REQ-020	Patient screening and enrollment.	ICH-GCP (Good Clinical Practice)
REQ-022	Data integrity and validation.	FDA 21 CFR Part 11, Subpart B
REQ-023	Electronic informed consent.	FDA 21 CFR Part 11, Subpart C
NFR-005	Data security.	HIPAA, ISO 27001

7.0 Assumptions
* All trial sites will have access to a reliable network.
* Users will be trained on the system's use.

8.0 Out of Scope
* Integration with third-party lab management systems in the initial release.

9.0 Glossary
* **eCRF:** Electronic Case Report Form
* **ICH-GCP:** International Council for Harmonisation - Good Clinical Practice