ChecklistGuro

Pharmaceutical Development Project Checklist Template

Show only Checklist

Display Style
Default

Target Identification & Validation

Activities related to identifying and validating the disease target.

Initial Disease Area Selection Rationale

Write something...

Disease Prevalence Data Source

- [ ] WHO Data
- [ ] CDC Data
- [ ] Internal Market Research
- [ ] Published Literature

Estimated Patient Population (Millions)

Enter a number...

Unmet Medical Need Assessment Summary

Write something...

Supporting Data Files (Market Research, Epidemiology)

Upload File

Target Validation Approach

- [ ] Genetic Studies
- [ ] Cellular Assays
- [ ] Animal Models
- [ ] Combination

Date of Target Validation Milestone Completion

Enter date...

Drug Discovery

Focuses on identifying potential drug candidates.

Initial Target Hypothesis

Write something...

Target Validation Method

- [ ] Genetic Studies
- [ ] Cellular Assays
- [ ] Animal Models
- [ ] Literature Review

Number of Initial Hit Compounds

Enter a number...

Initial Screening Data Files

Upload File

Screening Technologies Used

- [ ] High-Throughput Screening (HTS)
- [ ] Fragment-Based Screening
- [ ] Virtual Screening
- [ ] Affinity Chromatography

Date of Initial Hit Identification

Enter date...

Preclinical Development

Includes in vitro and in vivo studies to assess drug safety and efficacy.

Rationale for Preclinical Study Design

Write something...

In Vitro Assay Raw Data

Upload File

Maximum Tolerated Dose (MTD)

Enter a number...

Start Date of In Vivo Toxicology Study

Enter date...

Animal Species Used in Toxicology Studies

- [ ] Rat
- [ ] Mouse
- [ ] Dog
- [ ] Other

Toxicology Endpoints Evaluated

- [ ] Clinical Chemistry
- [ ] Hematology
- [ ] Histopathology
- [ ] Body Weight
- [ ] Food Consumption

Summary of Key Findings from Preclinical Studies

Write something...

Formulation Development

Activities surrounding drug formulation and dosage form design.

Target Dosage (mg)

Enter a number...

Dosage Form

- [ ] Tablet
- [ ] Capsule
- [ ] Oral Solution
- [ ] Injection
- [ ] Other

Excipient Selection Rationale

Write something...

Preliminary Formulation Data (e.g., solubility, stability)

Upload File

Particle Size (µm)

Enter a number...

Polymorphic Form

- [ ] Form I
- [ ] Form II
- [ ] Other

Formulation Optimization Completion Date

Enter date...

Clinical Trial Planning (Phase 1)

Planning and preparation for the first phase of clinical trials (safety).

Clinical Trial Protocol Summary

Write something...

Protocol Approval Date

Enter date...

Planned Number of Participants

Enter a number...

Primary Endpoint Measurement

- [ ] Pharmacokinetics (PK)
- [ ] Pharmacodynamics (PD)
- [ ] Safety & Tolerability

Key Inclusion Criteria

- [ ] Age >= 18
- [ ] Confirmed Diagnosis
- [ ] Stable Medication Regimen
- [ ] Adequate Organ Function

First Patient Enrollment Planned Date

Enter date...

Investigator's Brochure (IB) Review & Updates

Write something...

Clinical Trial Execution (Phase 1)

Execution and monitoring of Phase 1 clinical trials.

Patient Enrollment Start Date

Enter date...

First Patient Dosing Date

Enter date...

Number of Patients Enrolled

Enter a number...

Adverse Event Reporting Summary (Phase 1)

Write something...

Investigational Product Batch Number

- [ ] Batch 1
- [ ] Batch 2
- [ ] Batch 3

Dosing Time (Example Patient)

Enter time...

Patient Consent Form (Sample)

Upload File

Clinical Trial Planning (Phase 2)

Planning for Phase 2 trials (efficacy and dose-ranging).

Detailed Protocol Description

Write something...

Planned Patient Enrollment Number

Enter a number...

Planned Study Start Date

Enter date...

Estimated Study End Date

Enter date...

Primary Endpoint Measurement Method

- [ ] Objective Measurement
- [ ] Patient Reported Outcome
- [ ] Clinical Assessment

Investigational Site Selection Criteria

- [ ] Patient Population Availability
- [ ] Investigator Experience
- [ ] Equipment Capabilities
- [ ] Regulatory Compliance

Statistical Analysis Plan Review Status

- [ ] Not Started
- [ ] In Progress
- [ ] Completed

Statistical Analysis Plan Document

Upload File

Clinical Trial Execution (Phase 2)

Execution and monitoring of Phase 2 clinical trials.

Patient Enrollment Start Date

Enter date...

Patient Enrollment End Date

Enter date...

Number of Patients Enrolled

Enter a number...

Summary of Adverse Events Reported

Write something...

Data Monitoring Committee (DMC) Review Status

- [ ] Pending
- [ ] Completed
- [ ] Deferred

Data Quality Checks Completed?

- [ ] Data Entry Verification
- [ ] Source Data Verification
- [ ] Query Resolution

Time of Critical Event (e.g., Serious Adverse Event)

Enter time...

Clinical Study Report Draft

Upload File

Clinical Trial Planning (Phase 3)

Planning for Phase 3 trials (confirmatory efficacy).

Phase 3 Trial Protocol Summary

Write something...

Planned Number of Participants

Enter a number...

Primary Endpoint Measurement Method

- [ ] Subjective Assessment
- [ ] Objective Measurement
- [ ] Biomarker Analysis

Planned First Patient Enrollment Date

Enter date...

Estimated Trial Completion Date

Enter date...

Key Inclusion Criteria

- [ ] Age Range
- [ ] Disease Stage
- [ ] Prior Treatment History
- [ ] Specific Biomarker Status

Statistical Analysis Plan (SAP)

Upload File

Clinical Trial Execution (Phase 3)

Execution and monitoring of Phase 3 clinical trials.

Trial Start Date

Enter date...

Number of Participants Enrolled

Enter a number...

Summary of Protocol Deviations (if any)

Write something...

Data Monitoring Committee (DMC) Review Status

- [ ] Pending
- [ ] Completed - No Concerns
- [ ] Completed - Concerns Identified
- [ ] Completed - Recommendation Made

Date of Last Safety Review

Enter date...

Key Findings from Interim Analysis (if applicable)

Write something...

Interim Analysis Report (if applicable)

Upload File

Investigational Product Accountability Status

- [ ] Complete and Accurate
- [ ] Minor Discrepancies
- [ ] Significant Discrepancies

Regulatory Submission (NDA/MAA)

Preparation and submission of the New Drug Application (NDA) or Marketing Authorization Application (MAA).

Summary of Clinical Data

Write something...

Clinical Study Reports (CSRs)

Upload File

Patient Enrollment Numbers

Enter a number...

Submission Date

Enter date...

Regulatory Agency

- [ ] FDA
- [ ] EMA
- [ ] Other

Description of Manufacturing Process

Write something...

CMC Data

Upload File

Manufacturing Process Development & Validation

Development and validation of the manufacturing process for commercial production.

Process Flow Description

Write something...

Critical Process Parameter (CPP) - Temperature (Celsius)

Enter a number...

CPP - pH

Enter a number...

Equipment Validation Status

- [ ] Not Started
- [ ] In Progress
- [ ] Completed
- [ ] Failed

Process Validation Protocol Document

Upload File

Process Validation Start Date

Enter date...

Process Validation Completion Date

Enter date...

Critical Quality Attributes (CQA) Addressed

- [ ] Purity
- [ ] Potency
- [ ] Dissolution
- [ ] Moisture Content
- [ ] Particle Size

Post-Approval Activities & Phase 4 Trials

Activities following drug approval, including Phase 4 clinical trials and ongoing safety monitoring.

Phase 4 Trial Start Date

Enter date...

Summary of Post-Approval Safety Data

Write something...

Number of Adverse Events Reported

Enter a number...

Protocol Deviations Identified?

- [ ] Yes
- [ ] No

Supporting Documentation (e.g., Safety Reports)

Upload File

Summary of Risk Management Plan Updates

Write something...

Next Periodic Safety Update Report Due Date

Enter date...

Intellectual Property Management

Management of patents, trademarks, and other intellectual property related to the drug.

Patent Application Number(s)

Write something...

Filing Date (Patent Application 1)

Enter date...

Filing Date (Patent Application 2)

Enter date...

Trademark Registration Number(s)

Write something...

Patent Status (Application 1)

- [ ] Filed
- [ ] Published
- [ ] Pending
- [ ] Granted
- [ ] Abandoned
- [ ] Expired

Number of Patent Claims

Enter a number...

Summary of IP Strategy

Write something...

Copies of Patent Documents

Upload File

Project Management & Reporting

Overall project management activities and reporting to stakeholders.

Project Budget (Total)

Enter a number...

Actual Spend to Date

Enter a number...

Project Start Date

Enter date...

Projected Completion Date

Enter date...

Project Status

- [ ] Not Started
- [ ] In Progress
- [ ] On Hold
- [ ] Completed
- [ ] Cancelled

Key Risks & Mitigation Strategies

Write something...

Project Dashboard Report

Upload File

Reporting Frequency

- [ ] Weekly
- [ ] Bi-Weekly
- [ ] Monthly