

The Clinical Development Plan Guide

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BioStrategics Consulting Ltd



The Clinical Development Plan Guide

There are two essential documents that any company developing a new pharmaceutical or biotechnology derived product requires to ensure it achieves its strategic goals. The first is the prospective patient package insert (PPI) that defines the goals of the product, and is therefore a description of the destination of the strategy. The second is the Clinical Development Plan (CDP), which can be viewed as the map of how to get there. The CDP should not to be confused with the FDA's IND section entitled "General Investigational Plan" which is a short summary of the trials planned for the upcoming year, the CDP is an internal corporate management document.

While more tactically oriented than the prospective PPI, the CDP is nevertheless every bit as strategic in that it serves key goal-setting, performance assessment, communications, and decision-making functions. The CDP also requires a multidisciplinary and aspirational approach, while also providing the conceptual framework for the entire clinical trials program relating to the compound in question.

The CDP lays out a logical sequence of the scientific rationale, the commercial rationale, and the clinical trial plan that should be conducted to generate the information necessary to support the label claims. It is noteworthy to say that creating such a document, while entailing considerable time, thought and effort on the part of all members of the development team, is extremely valuable and predictive of the success of any program. Only if the perspectives of all relevant disciplines are integrated into the development plan can the project truly reflect corporate goals.

Key Components of the Clinical Development Plan (see below)

- Prospective Patient Package Insert
- Scientific Rationale for Development
- Commercial Rationale for Development
- Clinical Trials Plan
- Regulatory Considerations
- Strategic Planning

While it is axiomatic that every program will experience unanticipated results and meet unexpected hurdles during its lifetime, an inclusive planning process creates an organization consensus about the project's ultimate goals and criteria for success.



The CDP is a bridge between the purely strategic asset management planning process on the one hand, and, on the other, the highly tactical scientific and operational realms of the clinical trial process. Its creation is generally spearheaded by the clinical research department, which then becomes accountable for its execution. Clinical research professionals are responsible for ensuring that every protocol contributes to the body of

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knowledge specified by the prospective PPI and the CDP, and that the resulting data are expressed and communicated in a way that allows corporate decision makers to act upon them accordingly.

A DETAILED GUIDE TO THE CLINICAL DEVELOPMENT PLAN

Prospective Patient Package Insert

- Efficacy profile
 - Clinical pharmacology
 - Patient population
 - Clinical data
 - Indication claims
- Safety profile
 - Contraindications
 - Warnings and precautions
 - Adverse reactions
 - Drug abuse and dependence
 - Overdosage
- Dosage and administration
- How supplied

Scientific Rationale for Development

- Chemical and physical composition
 - Chemical class and structure
 - Chemical properties
 - Formulation characteristics
 - Manufacturing process, scalability and cost of goods projection
- Nonclinical pharmacology
 - In vitro pharmacology
 - In vivo pharmacology
 - Absorption, distribution, metabolism, and excretion
 - Pharmacokinetic studies behavior
 - Pharmacokinetic/pharmacodynamic correlations
 - Drug-drug interactions
- Nonclinical studies
 - Animal-based efficacy studies
 - Acute toxicology results
 - Planned chronic toxicology program
 - Planned carcinogenicity studies
 - Planned reproductive studies

Commercial Rationale for Development

- Potential clinical indications
- Disease description and standard of care
- Epidemiologic considerations
- Unmet clinical need(s)
- Unmet market need(s)
- Market size assumptions and projections

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- Synergy with other company products (marketed or under development)
- International considerations
- Competitive situation (existing and potential)
- Product profiles: optimal versus minimal acceptable

Clinical Trials Plan

- Phase 1 Human volunteer, safety studies
- Phase 2 Dose ranging studies, randomized, controlled, blinded, efficacy studies
- Phase 3 Large scale pivotal efficacy and safety studies
- Post-marketing trials

- For each phase
 - Proposed population
 - Scientific hypotheses and protocol objectives
 - Trial design considerations
 - Sample sizes
 - Projected resource needs
 - People requirements
 - Costs
 - Clinical supplies
 - Third party vendors
 - Timelines
 - International considerations

Regulatory Considerations

- Pre-IND meeting planning
- IND documentation
- Regulatory communications and meetings
- Regulatory trends and intelligence
- International regulatory planning

Strategic Planning

- Milestones and critical information availability
- Key decision points
- Go/no-go criteria
- Risk assessment and contingency plans
- Partnering, licensing and other business development issues