



# *Clinical Development Plan*

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## Prospective Summary of Product Characteristics (SPC or SmPC)

- ▶ Efficacy profile
  - ▶ Clinical pharmacology
  - ▶ Patient population
  - ▶ Clinical data
  - ▶ Indication claims
- ▶ Safety profile
  - ▶ Contraindications
  - ▶ Warning 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 studies
  - ▶ Animal-based efficacy studies
  - ▶ Acute toxicology results
  - ▶ Planned reproductive studies

# Commercial Rationale for Development

- ▶ Potential clinical indications
- ▶ Disease description and standard of care
- ▶ Epidemiological considerations
- ▶ Unmet clinical need(s)
- ▶ Unmet market need(s)
- ▶ Market size assumptions and projections
- ▶ Synergy with other company products
- ▶ International considerations
- ▶ Competitive situation
- ▶ Product profiles: optimal versus minimal acceptable

# Clinical Trials Plan

- Phase 1 Adult volunteers, safety studies
- Phase 2 Dose ranging and dose interval studies, randomized, controlled, blinded, efficacy studies
- Phase 3 Large scale pivotal efficacy and safety studies
- Post-marketing trials

# Clinical Trials Plan: For each phase

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

# Regulatory Considerations

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

Another reminder:  
Appoint contact person in company for regular communications with regulatory agency!

# 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