Clinical Development Plan
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