

Resources for Clinical Trials

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The Path to Today

- BS, Biology, MS Biology/Pharmacology
- MBA, RIT
- 6 ½ yrs Pharmacology Pre-clinical Research (Revlon Healthcare)
- 10 yrs Clinical Research including Director, Clinical Operations (Fisons)
- Adjunct Professor, RIT Clinical Research Management (Graduate Program)
- 16 yrs Founder/Owner CRO Research Dynamics (Drugs, Devices, Biologics, Gene Therapy)
- Total of 33 yrs in medical product development (25 yrs clinical trial experience)

The Path to New Medical Products

Strategy

- Prepare a **plan** to develop the new medical product that includes projected development **cost** (time, resources, and people)

AND

- Determine the potential of the medical product to obtain **approval** in a marketable state and sell sufficiently to recover development costs plus profit

Moving from concept to market

- Costs at each stage
- Funding
- Market analysis
- Probability of approval
- Manufacturing
- Patents and IP and Orphan drugs
- Package insert or product manual
- Safety concerns
- Formularies, Reimbursement
- Marketing
- Sales

Resources Required

- FUNDING!
- Scientists/Engineers
- Testing Facilities
- Manufacturing experts and source
- Clinicians and other medical practitioners
- Clinical Trial experts
- Statisticians
- Data collection functions
- Attorneys
- Regulatory experts
- Economists
- Health administrators
- Marketing and sales experts

Clinical Development Plan (CDP)

(for products requiring clinical trials.)

Plan that produces efficacy / safety data to meet FDA approval requirements

- Requirements from FDA meetings or guidance documents at start and each stage
- General design of each trial and expected result to move forward
- Major Efficacy data parameters and results required
- Major Safety data parameters and results required
- GO/No GO decisions
- Updated with each trial result
- Human resources required
- Financial resources required
- Timelines and deadlines for:
 - Each phase
 - Manufacturing of clinical supplies
 - Each disciplines' deliverables
 - IND/NDA/BLA filings, 510k or IDE/PMA

Clinical Development Plan (CDP) (for products NOT requiring clinical trials.)

- Requirements from FDA meetings or guidance documents at start and each stage
- Outline data required for 510k (that does not require trials)
 - Predicate device
 - Performance characteristics
- GO/No GO decisions
- Update plan
- Human resources required
- Financial resources required
- Timelines and deadlines for:
 - Each stage of development
 - Manufacturing
 - Each disciplines' deliverables
 - 510k filing
 - Launch/marketing

Challenges moving from concept to market

- Highly regulated process
- Knowledge of FDA process and requirements
- Complex
- Expensive
- Risky
- Safety issues

Critical difference from other products

- Regulatory control
- Risk management (product safety and liability)

Clinical Trial Requirements

- CDP outlines trial requirements to obtain efficacy and safety data
- Clinical trial experts that know the process and the FDA requirements (e.g., Experienced Project Managers, Monitors, Physicians, etc)
- Knowledge and experience in FDA requirements
- GCP knowledge and experience
- Well designed protocol that will deliver results of efficacy and safety data.
- Qualified experienced Investigator sites
- Established and validated data collection methods, preferably EDC
- Statisticians with FDA reporting experience
- Regulatory experts.
- High quality data

For faster Clinical Trials..

- Develop a workable CDP with funding (prevents repeating trials and need for additional funding)
- Meet with FDA to learn their requirements for your product (prevents unnecessary work and costs)
- Work with companies/consultants who are experienced in FDA clinical trials (Prevents delays, rework and GCP non-compliance)
- Use Electronic Data Capture (EDC) for faster data collection and analysis (faster trial completion and more trial data control)

Your Future Path in Clinical Trials ?

- So, where are you in your development?
- What barriers or hurdles do you have?
- Have you discussed your CDP with FDA?
- Do you have the experts needed for a efficient and FDA-compliant development?

Any Questions?

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