Interacting with FDA

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Products
Overview

• Structures
  – Organizational
  – Team Dynamics
  – Statutory and Regulatory

• Processes
  – Pre-IND Submission Activities
  – IND Submission and Review
  – Post-Submission Activities and Responsibilities
Structures

• Organizational
• Team Dynamics
• Statutory and Regulatory
Note: This is a simplified organizational chart for presentation purposes and does not reflect all Offices/Division within CDER
Structures: Organizational (3)

CDER

Office of New Drugs

- Medical TL* ("Cross Discipline TL")
- Medical Officer
- Pharmacology Reviewer and TL
- Regulatory Health Project Manager

Office of Pharmaceutical Science

- CMC* Reviewer and TL

Office of Translational Sciences

- Statistics Reviewer and TL
- Clinical Pharmacology Reviewer and TL

**others**

Review Team

*CMC = Chemistry, Manufacturing and Controls
*TL = Team Leader
Structures

- Organizational
- Team Dynamics
- Statutory and Regulatory
Structures: Team Dynamics (1)

- Regulatory Health Project Manager = BSN, MSN, PharmD, RPh, MS, MPH, BS
- Medical Team Leader ("Cross Discipline TL") = MD, PhD, MPH
- Medical Officer = MD, PhD, MPH
- Statistics Reviewer = PhD, MS
- Clinical Pharmacology Reviewer = PhD, PharmD
- Pharmacology Reviewer = PhD
- Chemistry, Manufacturing and Controls Reviewer = PhD, MS
Structures: Team Dynamics (2)

*RPM = Regulatory Health Project Manager
Structures: Team Dynamics (3)

- Clinical
- Statistics
- **others**
- Clinical Pharmacology
- Animal Pharmacology/Toxicology
- Chemistry, Manufacturing and Controls

Review Issues
Structures: Team Dynamics (4)

Communications w/ Sponsors: E.g., Information Request

Scientific/Regulatory Recommendations to Signatory Authority
Structures

- Organizational
- Team Dynamics
- Statutory and Regulatory
Structures: Statutory/Regulatory (1)

- An Act of Congress
  - Food, Drug, and Cosmetic Act / Public Health Service Act
    - Code of Federal Regulations (21 CFR)
      - Guidances
      - Policy and Procedures (MaPPs)

Search:
- “legislation” @ www.FDA.gov
- “CFR” @ www.FDA.gov
- “Guidances” @ www.FDA.gov
- “Manual of Policies and Procedures” @ www.FDA.gov
Structures: Statutory/Regulatory (2)

Investigational New Drug Application (IND)
- 21 CFR Part 312

New Drug Application (NDA)
- 21 CFR Part 314

Biologics Licensing Application (BLA)
- 21 CFR 600’s
Process: What you can expect

• Pre-IND Submission Activities
• IND Submission and Review
• Post-Submission Activities and Responsibilities
Process: Pre-IND Submission Activities

• Pre-IND Meeting
  – Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants
    • Search: “Formal Meetings” @ www.FDA.gov
  – Tracked Timeframe: Type B
    • Meeting date: ~60 days from date of request
    • Formal meeting request required
    • Background package: due to FDA 4 weeks prior to meeting date
  – Pre-IND file created
Process: Pre-IND Submission Activities

• Other Formal Meetings to Plan For:
  – Certain End-of-Phase 1 Meetings (Type B)
  – End-of-Phase 2 Meetings (Type B)
  – Pre-NDA/Pre-BLA Meetings (Type B)
  – Others (Type C)

• Other Correspondence
Process: What you can expect

• Pre-IND Submission Activities
• IND Submission and Review
• Post-Submission Activities and Responsibilities
Process: IND Submission/Review (1)

• IND Content and Format (21 CFR 312.23)
• Notify FDA
• Submit one original and two copies to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of ____________
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
HFM-99, Room 200N
1401 Rockville Pike
Rockville, MD 20852-1448
Process: IND Submission/Review (2)

- 30-day review “clock”
  - RPM will generally communicate the “30-day review date”
- Reviewers are assigned upon receipt
  - Document Room processing time
- Studies can not start until 30-days following FDA receipt of a new IND
Process: IND Submission/Review (3)

- Frequency and timing of communications between sponsor and FDA
- Clinical holds
  - Defined by 21 CFR 312.42
  - Teleconferences: be available to discuss potential hold issues
  - “Complete Response to Clinical Hold”
Process: What you can expect

• Pre-IND Submission Activities
• IND Submission and Review
• Post-Submission Activities and Responsibilities
Process: Post-Submission

• Safety reporting
  – 21 CFR 312.32
• Annual reports
  – 21 CFR 312.33
• IND withdrawal
  – 21 CFR 312.38
• Other Responsibilities
  – 21 CFR 312.50 through 312.70