Preparation for FDA Advisory Committee Meetings

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Agenda

- “Standard” FDA Meetings
  - Part of Everyday Life for Regulatory Affairs
- Advisory Committee Meetings
  - For Many, A “Once in a Lifetime Opportunity”!
    (For Some, More Than Once)
Standard FDA Meetings

- Confidential Discussion
- Audience → FDA
- Pre-IND, End-of-Phase 2, pre-NDA / BLA
- Driven by Sponsor-Generated Questions
- Variety of Topics at Various Stages of Product Development
- Guidance on FDA / Sponsor Meetings
Advisory Committee Meeting

- Very Different Forum – Public Discussion
- Audience → Advisory Committee Members (Independent Experts Selected by FDA)
- Driven by FDA-Generated Questions
- Clinical / Statistical Discussions of Safety & Efficacy
Advisory Committee Meeting

- Balanced Presentation of Issues
  - Sponsor Presents Position; Q&A
  - FDA Presents Position; Q&A
- Open Public Hearing (e.g., Patient Groups)
- Committee Deliberations
- Committee Votes on Questions Posed by FDA
Advisory Committee Meeting
First Steps (1)

- Identify the Appropriate **Team Composition**
  - Team Leader (e.g., Regulatory Affairs)
  - Potential Presenters
  - Data Experts (e.g., Clinicians, Statisticians)
  - Outside Experts / Consultants (e.g., KOL)
  - Other Support (e.g., Medical Writers, Administrative Assistants, IT)

- Establish Clear **Roles and Responsibilities**
Advisory Committee Meeting
First Steps (2)

- Need for **Intensive** Preparation – Not Like Any Other Meeting!
  - Block Out Calendars (Months to Prepare!)
  - Arrange Off-site Preparation Meetings (e.g., Several Multiple-day Meetings)
  - No Interruptions (e.g., No Cell Phones, e-mail, or PDAs)

- **CRITICAL** – Determine Your Company’s Discipline!
  - Internal Preparation or Off-site With Consultants
Advisory Committee Meeting
Know Your Data!

- Understand the FDA’s Point of View, Concerns, and Issues
  - “Why an Advisory Committee?”
    - NCE, New Drug Class, Public Health Issues, Use of Surrogate Endpoints
  - Review Product File’s Regulatory History (e.g., Letters, Telephone Records)
- Take a Fresh Look at All the Data
Advisory Committee Meeting
Know Your Data!!

- Are There Perceived or Potential... 
  - Safety Issues?
  - Efficacy Issues?
  - Statistical Issues?

- Know Your Position on Every Issue
Advisory Committee Meeting
Know the Audience – Do Research!

- Varying Disciplines
  - Practicing / Academic Physicians, Nurses
  - Statisticians
  - Consumer and Industry Representatives

- Varying Levels of Specific Disease Understanding
  - Obtain Biographies of Committee Members
  - Obtain Transcripts of Previous Meetings and Voting Records
  - Obtain Literature and Publications

- Varying Levels Of Product Understanding
  - Investigator in Product’s Clinical Study vs No Knowledge of Product
Advisory Committee Meeting
Information Package

- **Target the Audience**
  - Find Balance Between “Lecturing” and “Educating”

- **Scientific Discussion of Data Supported by Peer-Reviewed Literature, as Appropriate**

- **Discuss FDA’s Position / Issues and Provide Scientifically-Based Explanations**

- **Clear, Concise, Unambiguous**

- **Releasable to Public**
  - Don’t Include Proprietary Information
Advisory Committee Meeting Presentation

- Target the Audience
- Use Information Package as Basis for Preparing Presentation
- Address FDA’s Position / Issues and Present Scientifically-Based Responses
- Be Clear; Keep to the Point
  - The Panel Has Reviewed the Information Package in Advance
Advisory Committee Meeting
Q&A Preparation

- Most Difficult Part of the Meeting and Requires **Most Preparation**
- Anticipate Every Question (>50 Questions)
  - Review FDA’s Information Package
  - Generate Questions From Issues Identified by FDA and by the Team
- Write a Response to **Every** Question
Advisory Committee Meeting
Q&A Preparation

- Develop Backup Slides, as Necessary, to Support Responses (Hundreds of Slides)
- Use Data Experts as Backup Slide Callers
- Presenters and Data Experts Memorize the Responses and Related Backup Slide Call Numbers
Advisory Committee Meeting
Practice, Practice, Practice!!

- Again, Practice at Offsite Location (No Interruptions) – Recommend at Least 4 Sessions of 3 to 4 Days Each
- Conduct Several Mock Advisory Sessions
- Videotape Practice Sessions and Review Performance
Advisory Committee Meeting
Practice, Practice, Practice Some More!

- Utilize Slide Presentation Technology With Multiple Laptops, Preview and Main Screens
- Effectively Manage Stress and Differences of Opinion
- Manage Public Relations, Internal Relations and Senior Management Expectations
Advisory Committee Meeting
The Day Before

**Dos**
- Dry-Run of Presentation
- “Light” Q&A Practice
- Keep It Fresh
- Early to Bed!

**Don’ts**
- Drastically Change Presentation
- Change Responses to Questions
Advisory Committee Meeting
Conclusions

- Planning and Practice Are Key
- One of the Highest Visibility and Important Events for a Company

However

- Also a Chance for a Company to Shine!