



Challenges with Conducting Tobacco Industry-Sponsored Research – A CRO Perspective

FDA Workshop on Third Party Governance of Industry-Sponsored Tobacco Product Research

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Benefits of CRO involvement

- **Successful third-party model in place**
 - Leverage best practices and industry standards from Pharma experience
 - Areas of essential expertise include GxP and regulatory submissions
 - Results in cleaner data (for the FDA) more quickly and at a lower cost (for the sponsor)
 - Primary objective is a high-quality deliverable
- **Independent oversight may improve public perception**
 - Involvement in study design, statistical analysis, and data interpretation may reduce the potential for bias
- **Capacity to handle the studies required for new product applications**

Key Challenges

***How do we meet
FDA's requirements
and expectations?***

- Current draft guidance documents provide high-level direction but details are yet to be determined
- Exposure and most health risk evaluations are relatively straight-forward, consumer-type studies and post-marketing surveillance may be more challenging
- Evaluations of adolescents and other vulnerable populations
- Statistically what will be the burden of proof?
- Balancing the benefit to individuals to that of the population as a whole

Key Challenges

Site selection challenges and facility needs

- Both early phase and late phase program components will be required
- Few states have clear language within their tobacco regulations that provide clinical research exemptions for indoor combustible product use
- Special facilities, processes, and procedures are required to safely perform this work
- Staffing considerations and investigator qualifications

Ethical considerations

- How do we fully understand new products without encouraging/increasing their use?
- Evaluating perceptions of adolescents and other vulnerable populations who are not tobacco consumers
- Studies require participant payment and may require that study products be provided free of charge

Key Challenges

“As a healthcare professional, how do you justify working on tobacco products?”

- Contending with the stigma attached to tobacco products and tobacco-related research
- There is significant need for education regarding how tobacco research and healthcare align
- IRB/EC review
- Identifying facilities, vendors, and subject matter experts that will participate in tobacco research

Even the Pharma model has its drawbacks

- Significant pharmaceutical experience does not guarantee success in this market space
- May be gaps in the current expertise available
- Not all CROs can provide comprehensive oversight
- Bias and preconception may be minimized but can never be eliminated

Concluding Thoughts

- We must not forget that the objective of MRTP approval is to provide safer products for consumers who wish to take part in a legal activity
- The Pharma-CRO model would provide an excellent starting point to provide independent third-party oversight of tobacco-related research

Questions

