Promoting Effective Drug Development Programs: Opportunities and Priorities for FDA's Office of New Drugs

Janssen Perspective

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Introduction

Combination Products

Issue:

Variable Approaches to Risk Management result in difficulty predicting what data and testing will satisfy the divisions

Possible Approach(es):

- Additional insight in understanding the Agency's views on critical task determination, residual risk and acceptable mitigation strategies
- Earlier feedback to sponsors on risk assessments and Human Factor studies
- Opportunity for informal communications

Statistical Approaches

Issue:

Inconsistencies applying Statistical Approaches

- Controlling Type I Error
- Acceptance of Adaptive Design

Possible Approach(es):

- Broader statistical experience in adaptive design
- Intensive cross-training of statisticians on Complex Innovative Designs and Bayesian Approaches to leverage relevant OND experience

Use of Modelling / Simulation / Extrapolation

Issue:

In certain disease areas (e.g., cardiovascular, thromboembolic disease, diabetes), the traditional model of development presents significant resource challenges for sponsors.

Possible Approach(es):

- Explore together innovative approaches, such as the use of modeling/simulation/extrapolation, to drive efficiencies

Conclusion