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