Industry Perspective on Regulatory Science

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Industry Needs of Regulators

• Timely and predictable reviews of new drug applications
• Unbiased third party assessment of benefit/risk
• Collaboration with academia and industry to solve problems
• Harmonization of global regulatory expectations
• Science based, judgment based decision making
Goals of Regulatory Science and FDA

√ • Modernize Toxicology to Enhance Product Safety

√ • Stimulate Innovation in Clinical Evaluations and Personalized Medicine to Improve Product Development and Patient Outcomes

√ • Support New Approaches to Improve Product Manufacturing and Quality

√ • Ensure FDA Readiness to Evaluate Innovative Emerging Technologies
Goals of Regulatory Science and FDA

- Harness Diverse Data through Information Sciences to Improve Health Outcomes
- Implement a New Prevention-Focused Food Safety System to Protect Public Health
- Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Safety
- Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Product
Drug Discovery Challenge
Why do Clinical Candidates Fail?

- Lack of Efficacy: 30%
- Pharmacokinetics: 39%
- Animal Toxicity: 11%
- Commercial Reasons: 5%
- Adverse Effects in Man: 10%
- Miscellaneous: 5%
Industry’s Challenge

• Increase in expense
• Decrease in approvals
• Increase in patent expiries
• Loss of experienced talent
• Non-science based distraction
Modernize Toxicology

• Better prediction of human clinical outcomes
• Better selection of animal models to ensure human safety
• Improved correlation of whole animal studies to human disease outcomes
• Select better development candidates sooner
• Improve *in silico* modeling

Will we ever be able to predict all adverse clinical events through preclinical models?
Stimulate Innovation in Clinic and Personalized Medicine

• Better clinical trial design
• Better understanding of genotypic/phenotypic responses
• Better understanding of clinical trial data including placebo response
• Develop better understanding of drug effects in special populations
Support New Approaches to Improve Manufacturing and Quality

• Needs a global solution
• When margins and supply get smaller, product loss becomes bigger problem and predictability is key
• Reduce contamination and improve reliability
Ensure FDA Readiness to Evaluate New Technologies

• Innovative new technologies must be understood in terms of potential and risk
• Judgment based evaluation of potential of new technologies
• Reliability of new innovation
Harness Diverse Data

• Size of New Drug Applications increasing
• Amount of data increasing
• Patient outcome data more readily available linking disease, intervention and outcome in comprehensive ways
Implementation of New Food Safety System

- Better understanding of food chains and disease outcomes.
Medical Countermeasures

- National shared responsibility for human health
- Better prediction and strategy for interventions
- Cooperation in establishing supply chains
- Better methods of diagnosis and treatment
Strengthen Social and Behavioral Science

- Partnering in describing risk/benefit of intervention
- Cooperate in reducing public misperceptions
- Educate nonscientists on science-related issues affecting human health
Barriers

• Difficult to cooperate on design and execution of new drug plan
• FDA is one regulatory face in our global submission
• Variability may be greater than our precision in using predictive markers for a few more years
• Not all decisions are science based
• Collaboration and cooperation need better definition
• Existing academia, industry, and regulator consortia are not well coordinated
• Economics are evolving

……but Opportunities are Endless!