



ASCPT 2018

ANNUAL MEETING

MARCH 21 - 24, 2018 • HILTON ORLANDO • ORLANDO, FL

SYMPOSIUM

Innovation in Clinical Dose Selection and Trial Optimization Using Bayesian Approaches: Steps Toward Accelerated Patient Care

Pharmacometrics & Pharmacokinetics (PMK)
Regulatory Science (RS)

Chair: Indrajeet Singh, PhD

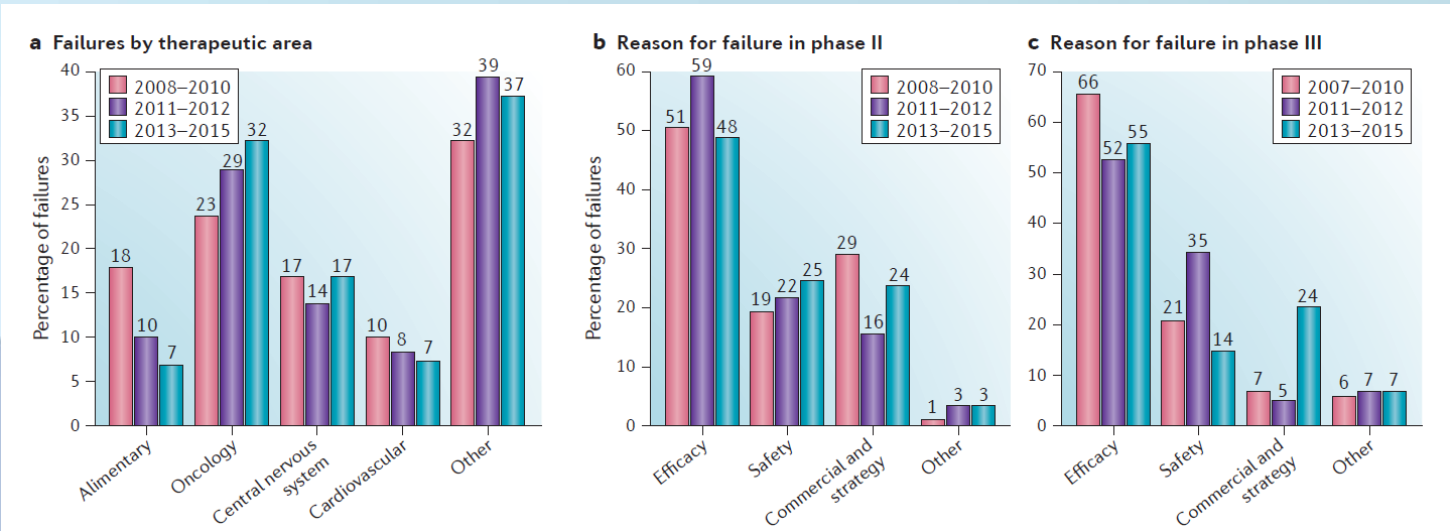
Janssen Pharmaceuticals, Spring House, PA

Chair: Ying Ou, PhD

Amgen, South San Francisco, CA

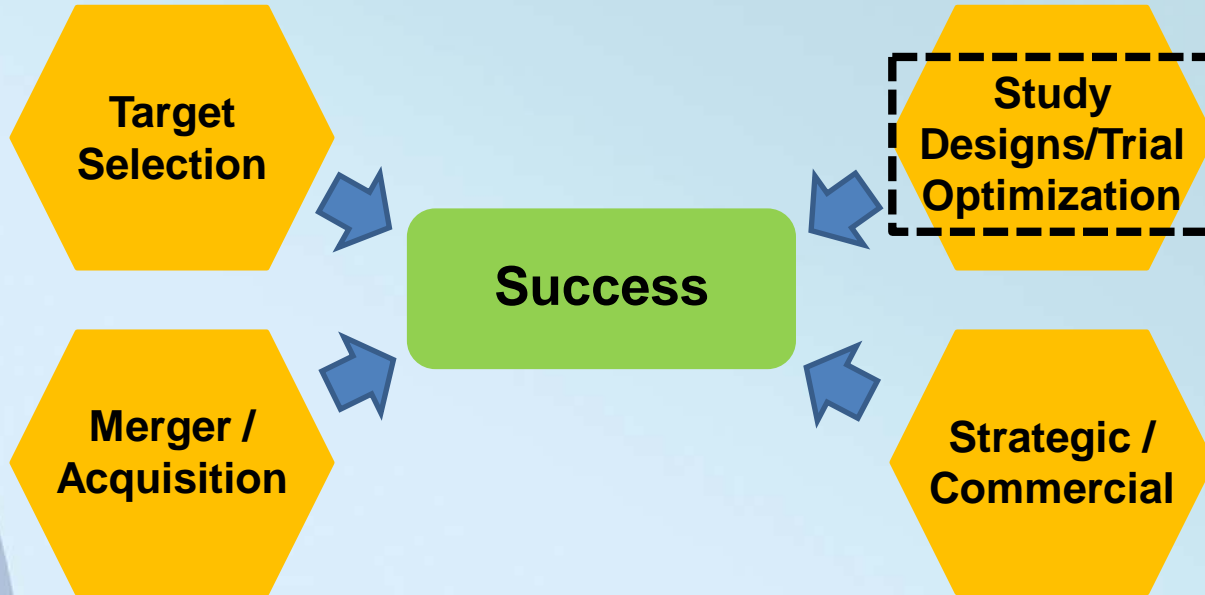
SATURDAY, MARCH 24, 2018 1:15 PM – 3:15 PM

Innovation is long due



Total Failures (%)	Ph-II (2008 → 2015)	Ph-III (2008 → 2015)
Efficacy	51 → 48	66 → 55
Safety	19 → 25	21 → 14
Efficacy + Safety	70 → 73	87 → 69

Patients are waiting



Presentations

- ***Bayesian Statistics and Its implications for Drug Development***
Stephen Ruberg, PhD
Eli Lilly, Indianapolis, IN
- ***Bayesian Adaptive Trials in Oncology Drug Development—Maximizing the Synergy Between Statisticians and Clinical Pharmacologists***
Stuart Bailey, PhD
Novartis, Cambridge, MA
- ***Challenges and Opportunities of Bayesian Adaptive Trials: Regulatory and Pharmacometrics Perspectives***
Yaning Wang, PhD
US Food and Drug Administration, Silver Spring, MD
- ***Challenges and Opportunities of Bayesian Adaptive Trials: Where Do We Go From Here?***
Carl C. Peck, MD
UCSF Center for Drug Development Science, San Luis Obispo, CA