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

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<tbody>
<tr>
<td>Efficacy</td>
<td>51 ➔ 48</td>
<td>66 ➔ 55</td>
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<tr>
<td>Safety</td>
<td>19 ➔ 25</td>
<td>21 ➔ 14</td>
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<tr>
<td>Efficacy + Safety</td>
<td>70 ➔ 73</td>
<td>87 ➔ 69</td>
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*Harrison et al. 2016, Nature Reviews*
Patients are waiting

- Target Selection
- Merger / Acquisition
- Study Designs/Trial Optimization
- Strategic / Commercial

Success
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