**WORKSHOP**

**Accelerating Preclinical to Clinical Transition: PK/PD Modeling & Simulation in Drug Discovery & Development**

**Date/Time:** March 23, 2015, Monday, 8:30 am - 4:30 pm  
**Venue:** Marriott Cambridge, 2 Cambridge Center, Cambridge, MA 02142  
**Speakers:** Alison Betts (Pfizer), Arijit Chakravarty (Takeda), Xiao Hu (Biogen Idec), Haojing Rong (Shire)  
Pratap Singh (Pfizer), Yaning Wang (FDA)

**Key Topics:**
- How Model & Simulation was used to justify pediatric dosing of a recently approved drug, Plegridy™
- Using Model & Simulation as a tool to select the target, modality, and define target candidate profile
- Translation of CV safety endpoint from in vitro to animal model to human
- First-in-human dose projection of ADC therapeutics
- Hear from FDA on regulatory perspective and future directions of PK/PD

**Who should attend**
Drug discovery scientists in the disciplines of chemistry, pharmacology, toxicology, pharmacokinetics, translational science, clinical research, who design, synthesize, and test new drug candidates, design clinical studies, lead research and clinical teams. Registrants should possess a basic knowledge of drug discovery.

**Benefits**
- Understand stage-appropriate application of modeling and simulation (M&S) as a tool  
- Gain basic education on technical and theoretical aspects of the preclinical PK/PD modeling  
- Learn how to integrate preclinical pharmacology, biomarker response and safety end points  
- Develop confidence in interpreting M&S result for decision making  
- Hear real world case studies of applying M&S  
  - from target identification to lead optimization  
  - in dose selection for first-in-human to pivotal studies  
  - to avoid running clinical trials in difficult-to-study populations

**Fees:**  
$225 - Regular; $125 - Unemployed & Academic; $475 - Vendor Show  
**Registration:** [www.PBSS.org](http://www.PBSS.org)
## Workshop Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
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<tbody>
<tr>
<td>08:15 – 08:45</td>
<td>Breakfast and Registration</td>
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<tr>
<td>08:45 – 09:00</td>
<td>Welcome and workshop introduction — Haojing Rong, Shire</td>
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<td>09:00 – 09:30</td>
<td>Introduction to Pharmacokinetic-Pharmacodynamic modeling in drug discovery and development continuum — Arijit Chakravarty, Takeda</td>
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<td>09:30 – 10:15</td>
<td>Application of PK/PD and mechanistic modeling at early drug discovery stage (focus on target validation and lead selection) — Pratap Singh, Pfizer</td>
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<td>10:15 – 11:00</td>
<td>Case Study 1. In vitro potency-to-In Vivo response translation towards lead optimization — Pratap Singh, Pfizer</td>
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<td>11:00 – 11:15</td>
<td>Major Sponsor Presentation - 1</td>
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<tr>
<td>11:15 – 11:45</td>
<td>Break &amp; Vendor Show</td>
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<tr>
<td>11:45 – 12:30</td>
<td>PK/PD Modeling of QT prolongation: in vitro/ preclinical/clinical translation — Alison Betts, Pfizer</td>
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<td>12:30 – 13:30</td>
<td>Lunch</td>
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<tr>
<td>13:30 – 14:15</td>
<td>Case Study 2: First-in-human Dose Projections of ADC therapeutics — Arijit Chakravarty, Takeda</td>
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<td>14:15 – 15:00</td>
<td>Case Study 3: Model &amp; Simulation Applications of Plegridy™ (Pegylated Interferon Beta, Biogen Idec, FDA approval in Aug. 2014) — Shelley (Xiao) Hu, Biogen Idec</td>
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<td>15:00 – 15:15</td>
<td>Major Sponsor Presentation - 2</td>
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