### Attendees

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Alexander</td>
<td>Duke Clinical Research Institute</td>
</tr>
<tr>
<td>Patrick Archdeacon</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>David Balderson</td>
<td>Amgen, Inc.</td>
</tr>
<tr>
<td>Margaret Bash</td>
<td>Food and Drug Administration, CBER</td>
</tr>
<tr>
<td>Christopher Breder</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Barbara Buch</td>
<td>Food and Drug Administration, CBER</td>
</tr>
<tr>
<td>Ramil Cabela</td>
<td>Celgene Corporation</td>
</tr>
<tr>
<td>Robert Califf</td>
<td>Duke Translational Medicine Institute</td>
</tr>
<tr>
<td>Aloka Chakravarty</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Henry Che</td>
<td>Astellas Pharma Global Development</td>
</tr>
<tr>
<td>Christy Chuang-Stein</td>
<td>Pfizer, Inc.</td>
</tr>
<tr>
<td>Sabrina Comic-Savic</td>
<td>The Medicines Company</td>
</tr>
<tr>
<td>Brenda Crowe</td>
<td>Eli Lilly and Company</td>
</tr>
<tr>
<td>Milbhor D'Silva</td>
<td>Astellas Pharma Global Development</td>
</tr>
<tr>
<td>Diana Daly</td>
<td>Human Genome Sciences</td>
</tr>
<tr>
<td>Dave DeMets</td>
<td>University of Wisconsin</td>
</tr>
<tr>
<td>Rita Deng</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Jethro Ekuta</td>
<td>Janssen Research &amp; Development, LLC</td>
</tr>
<tr>
<td>Patricia French</td>
<td>Medical Writer</td>
</tr>
<tr>
<td>Cheryl Grandinetti</td>
<td>Food and Drug Administration, CDER</td>
</tr>
<tr>
<td>Achim Guettner</td>
<td>Novartis Pharma AG</td>
</tr>
<tr>
<td>Ruth Hager</td>
<td>Vertex Pharmaceuticals</td>
</tr>
<tr>
<td>David Hall</td>
<td>Boehringer Ingelheim</td>
</tr>
<tr>
<td>Diane Harrison</td>
<td>Janssen Research &amp; Development, LLC</td>
</tr>
<tr>
<td>Grant Huang</td>
<td>US Department of Veterans Affairs</td>
</tr>
<tr>
<td>Cheri Janning</td>
<td>Clinical Trials Transformation Initiative</td>
</tr>
</tbody>
</table>
Qi Jiang
MaryAnn Karolchyk
Elias Kouchakji
Judith Kramer
Mike Lauer
Ron Leong
Joanne Less
Elliott Levy
Eric Lewis
Debbie Lucas
Leanne Madre
Diane Maloney
Ann Meeker-O'Connell
Anthony Murgo
Janet Norden
Ann O'Brien
Bob O'Neill
Dan Odenheimer
Jackie O'Shaughnessy
Bray Patrick-Lake
Richard Platt
Kamal Shah
Stephanie Shapley
Steve Snapinn
Kathleen Swanson
Bob Temple
Jose Vega
Stuart Warren
Janice Wherry
Leslie Williams
Janet Wittes
Christopher Wohlberg
Amy Xia

Amgen, Inc.
Novartis Pharmaceuticals
Amgen, Inc.
Duke Translational Medicine Institute
National Heart, Lung and Blood Institute, NIH
AstraZeneca
Food and Drug Administration, OGCP
Bristol-Myers Squibb
GlaxoSmithKline
Clinical Trials Transformation Initiative
Clinical Trials Transformation Initiative
Food and Drug Administration, CBER
Food and Drug Administration, CDER
Food and Drug Administration, CDER
Food and Drug Administration, CDER
GlaxoSmithKline
Food and Drug Administration, CDER
Human Genome Sciences
Food and Drug Administration, CDER
Patient Advocate
Harvard Pilgrim Health Care Institute
Celgene Corporation
Food and Drug Administration, CDER
Amgen, Inc.
US Department of Veterans Affairs
Food and Drug Administration, CDER
Amgen, Inc.
US Department of Veterans Affairs
Bristol-Myers Squibb
The Medicines Company
Statistics Collaborative, Inc.
Pfizer, Inc.
Amgen, Inc.