Financial Example
Save time and cost using rasH2
Topics

- Customer Snapshot
- Customer Spend on Carcinogenicity Testing
- Action
- Result
Customer Snapshot

- Company X is a global pharmaceutical company with 50,000+ employees and annual revenues in excess $20 billion. Company discovers, develops, manufactures and markets human therapeutic compounds. The products of Company X are sold primarily to drug wholesalers and retailers, hospitals, clinics, government agencies and health care providers such as health maintenance organizations and other institutions.

- Company’s Division of Drug Safety Assessment was tasked with reducing cost of safety testing for small molecule compounds in late stages of development.

- Key Defined Levers:
  - Supply Chain Cost Drivers
  - Process Improvements
  - Price Savings
Customer Spend on Carcinogenicity Testing

• To meet FDA requirements for 2 species for carcinogenicity testing Company X was performing the standard 2 year rat study and a traditional 2 year mouse study.

• Traditional mouse studies consisted of:
  – 5 treatment groups of 50 per sex per group (N=500)
    • 4 compound dosages
    • 1 vehicle group
  – All animals housed one per cage
  – Animals received compound via oral gavage 5x per week for 104 weeks
  – At end of in-life portion animals were sacrificed, tissues collected and examined for tumors.

• Average cost of one traditional 2 year mouse study was $1.9 million
Action: Use of rasH2 in carcinogenicity testing

- FDA accepts data from 6 month studies with transgenic mice, such as the rasH2, instead of 2 year studies with traditional mice.
- Transgenic mouse studies consisted of:
  - 5 treatment groups of 25 per sex per group (N=250)
    - 4 compound dosages
    - 1 vehicle group
  - All animals housed one per cage
  - Animals received compound via oral gavage 5x per week for 26 weeks
  - At end of in-life portion animals were sacrificed, tissues collected and examined for tumors.
- Average cost of one 6 month transgenic mouse study was $0.4 million
## Results: Significant Cost Savings

<table>
<thead>
<tr>
<th>Description</th>
<th>Traditional 2-year mouse study</th>
<th>6 month rasH2 study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mice</td>
<td>$2 (500 mice)</td>
<td>$131 (250 mice)</td>
</tr>
<tr>
<td>Housing</td>
<td>$479</td>
<td></td>
</tr>
<tr>
<td>Compound Administration</td>
<td>$1,297</td>
<td>$171</td>
</tr>
<tr>
<td>Post in-life procedures and evaluation</td>
<td>$129</td>
<td>$64</td>
</tr>
<tr>
<td>Study Administrative Costs</td>
<td>$2</td>
<td>$2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$1,909</strong></td>
<td><strong>$434</strong></td>
</tr>
</tbody>
</table>

Dollar values in 1,000’s/cost to manufacture compound not included