



Financial Example  
Save time and cost using rasH2

- 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



Description	Traditional 2-year mouse study	6 month rasH2 study
Mice	\$2 (500 mice)	\$131 (250 mice)
Housing	\$479	
Compound Administration	\$1,297	\$171
Post in-life procedures and evaluation	\$129	\$64
Study Administrative Costs	\$2	\$2
Total	\$1,909	\$434

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

