

# Pharmaceutical Investment

## Commercial Opportunity Assessment Framework

Ashfia Rahman  
Micah Schipior  
Xianglei Yin  
Lei Zhang

# Outline

- The Big Picture
- Introduction
- Problem Description
- Problem Formulation
- Solution Methodology
- Conclusion

# The Big Picture

- In the United States, the gains from medical innovation are estimated to be over \$500 billion per year.
- However, finding new cures is an extremely expensive exercise. The cost of developing a new drug varies widely by therapeutical areas, from a low of \$800 million to nearly \$2 billion per drug.
- These costs are mostly undertaken by the private sector.

# Introduction

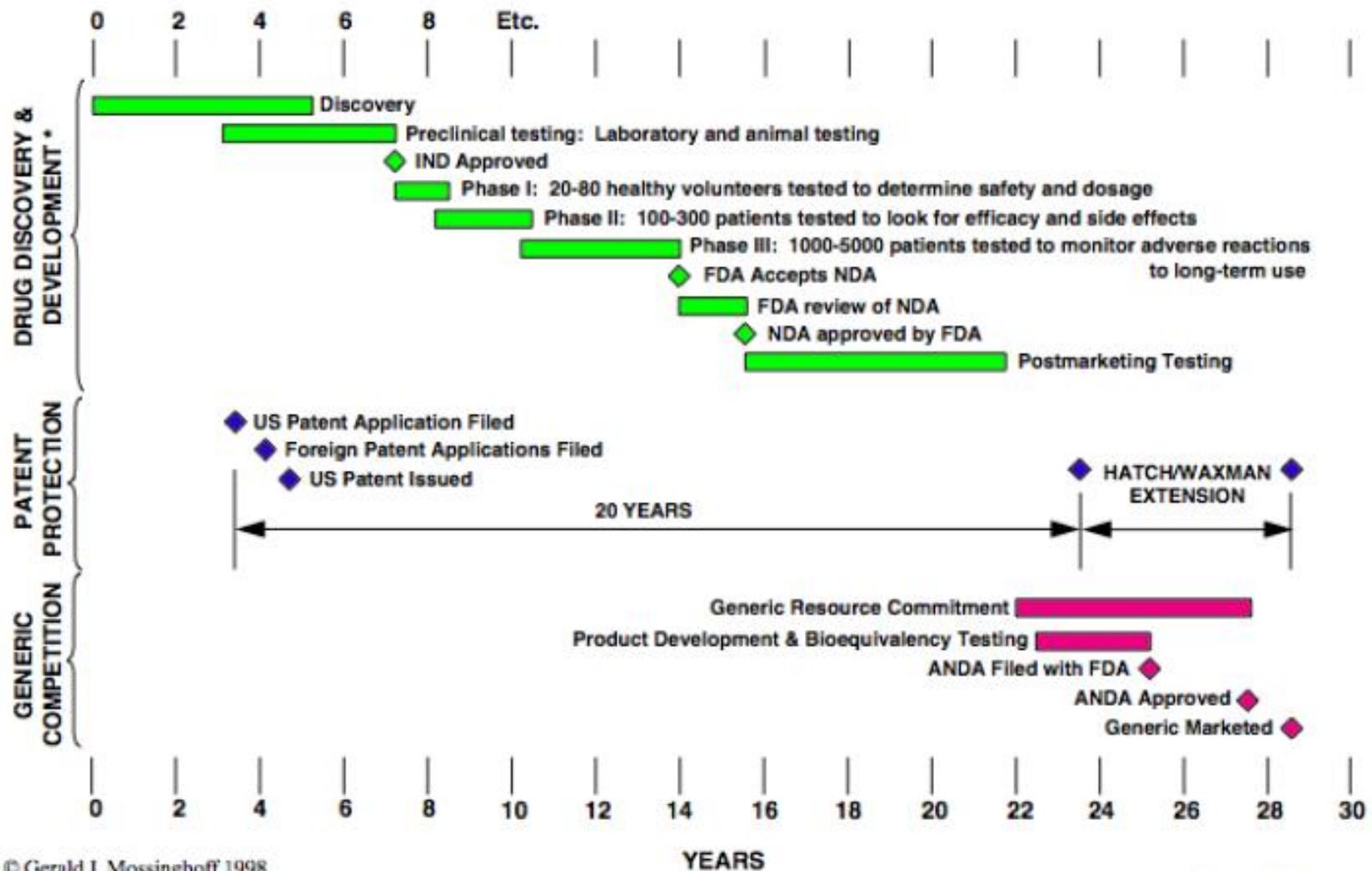
- Pharmaceutical companies are faced with investment choices for drugs with different financing costs and probabilities of success
- Each drug is required to go through 3 phases of approval. In the final stage, these drugs must pass FDA requirements.
- Additional investment for each phase increases the likelihood of success.

# Phase Description

- Phase I – testing the drug on a very small group of volunteers to evaluate whether the drug is safe
- Phase II – testing the drug on small sample of patients who suffer from an illness to assess whether the drug has intended effects
- Phase III – testing the drug on a wide range of patients to determine different kinds of effects
- FDA Approval – after reviewing the report, the FDA may grant the pharmaceutical company approval to market the drug

# FDA Process

## NEW MEDICINES TIMELINE



# Problem Description

- *How to optimally allocate resources in order to maximize returns from investing in a new drug development program?*
- **Decision Variables**
  - Initial investment choice
  - License out or keep developing at each phase
  - Additional investment to increase phase success rate
- **Objective Function**
  - Maximize risk adjusted return from the investment

# Problem Formulation

- A pharmaceutical company must first choose whether to invest \$100 million in developing a drug in the Oncology area
- Each phase has a historical probability of success
- If a phase is successful, a company chooses whether to keep developing at a cost, or license out
- A company must decide whether to make additional investments in order to maximize overall return

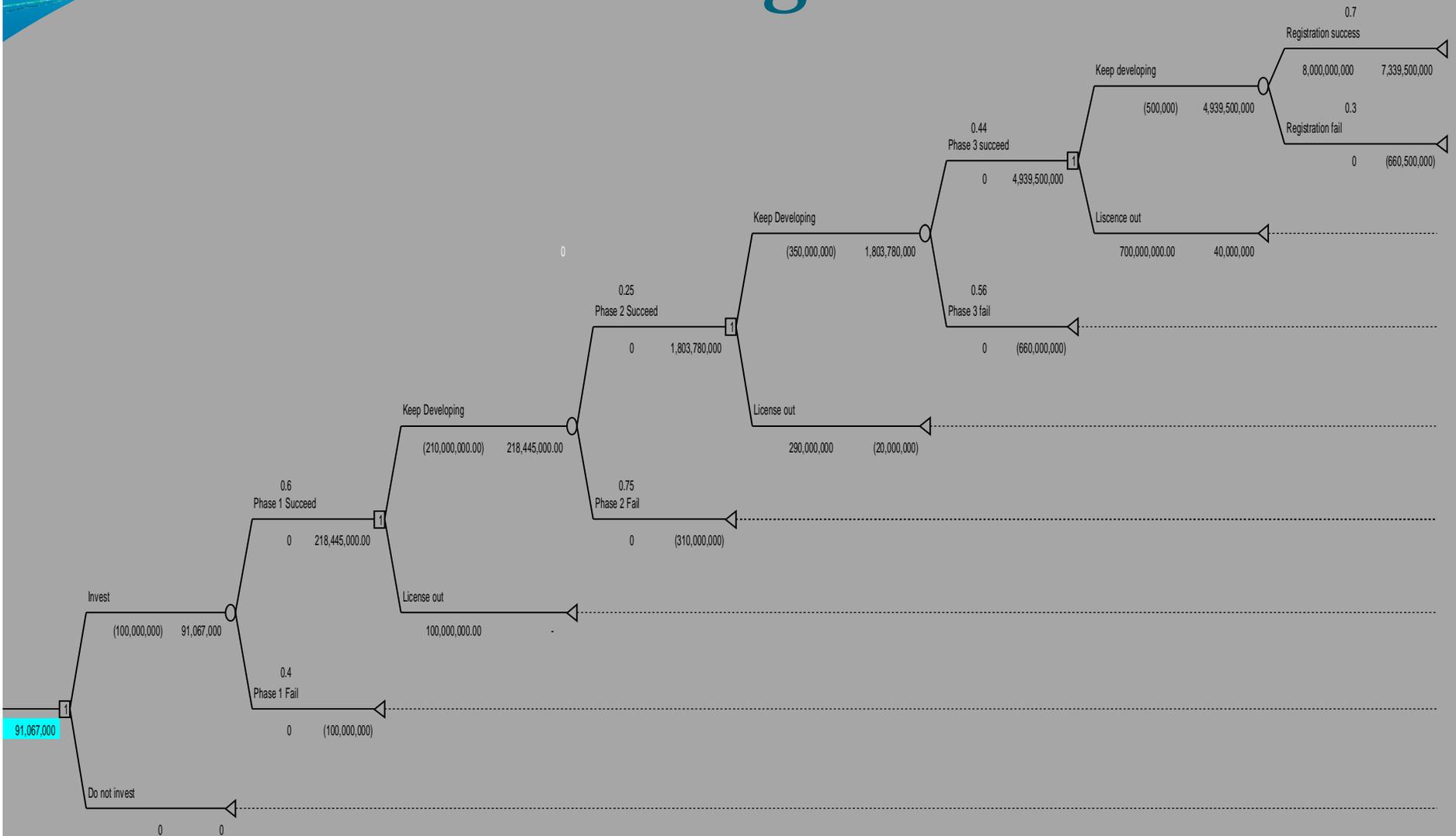
# Solution Methodology

- Precision tree is used to find optimal investment choice at each decision node for a given drug
- Crystal ball is used to determine if it is optimal to invest additional funds to increase the likelihood of success for Phase I, Phase II or Phase III.
- A forecast is used to calculate the Sharpe Ratio which allows us to compare it to different investment returns

# Probability of Success at Each Phase Based on Industry Averages of Oncology Drug Development

Company	Phase 1	Phase 2	Phase 3	FDA Registration	Total Success %
AstraZeneca	60%	25%	43%	71%	4.58%
BMS	57%	30%	44%	72%	5.42%
Eli Lilly	52%	30%	45%	74%	5.19%
Roche	55%	33%	47%	72%	6.19%
GSK	56%	35%	45%	73%	6.41%
JNJ	82%	36%	48%	70%	9.92%
Novartis	51%	25%	47%	69%	4.13%
Pfizer	85%	35%	50%	68%	10.12%
Shering-Plough	51%	25%	45%	70%	4.05%
Merck	62%	23%	43%	73%	4.48%
Genzyme	69%	34%	42%	70%	6.90%
Sandoz	51%	21%	41%	68%	3.01%
Abbott	71%	19%	46%	69%	4.28%
Biodel	58%	25%	42%	67%	4.10%
King Pharma	58%	18%	41%	65%	2.78%
Renogen	55%	17%	40%	66%	2.47%
Biogen	51%	17%	39%	67%	2.26%
Watson Pharma	54%	16%	42%	68%	2.49%
Charles River	57%	12%	44%	69%	2.08%
<b>Average Level</b>	<b>60%</b>	<b>25%</b>	<b>44%</b>	<b>70%</b>	<b>4.57%</b>

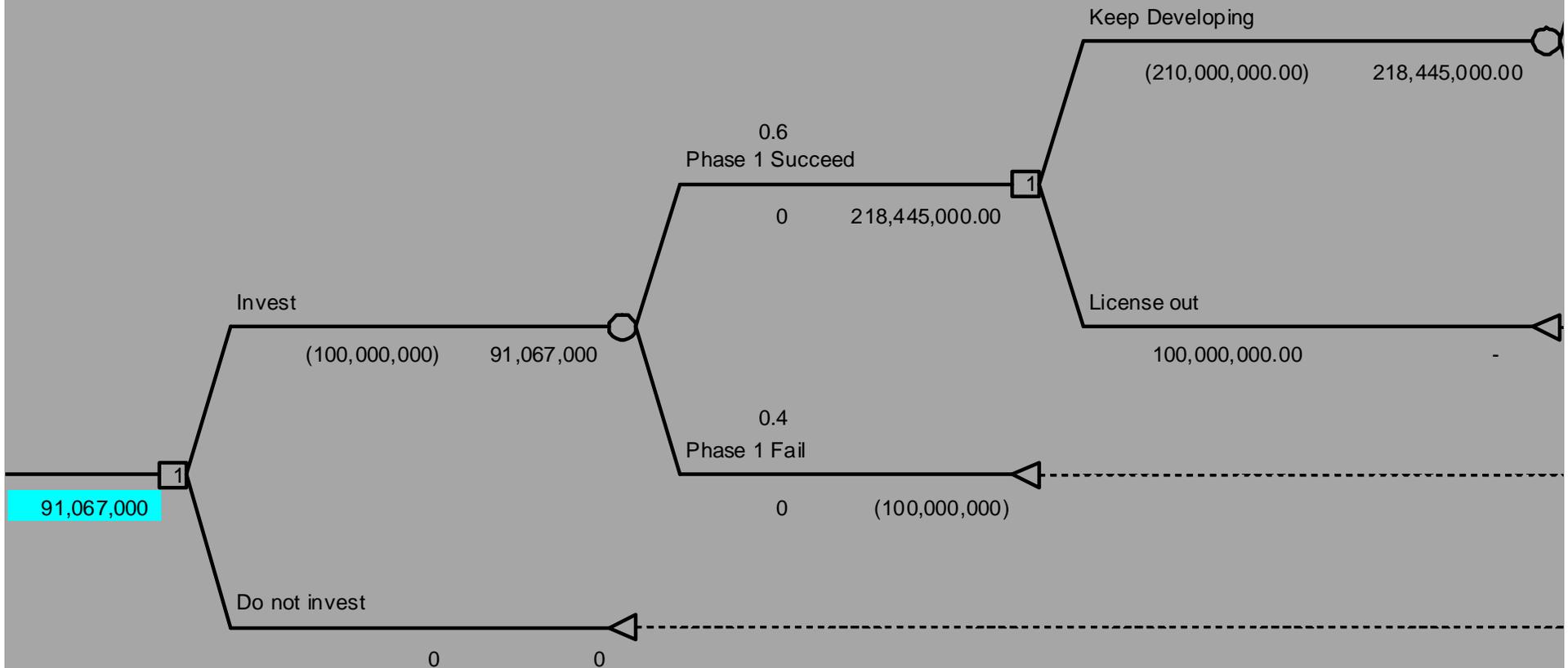
# Precision Tree-Original Investment



All values are in millions

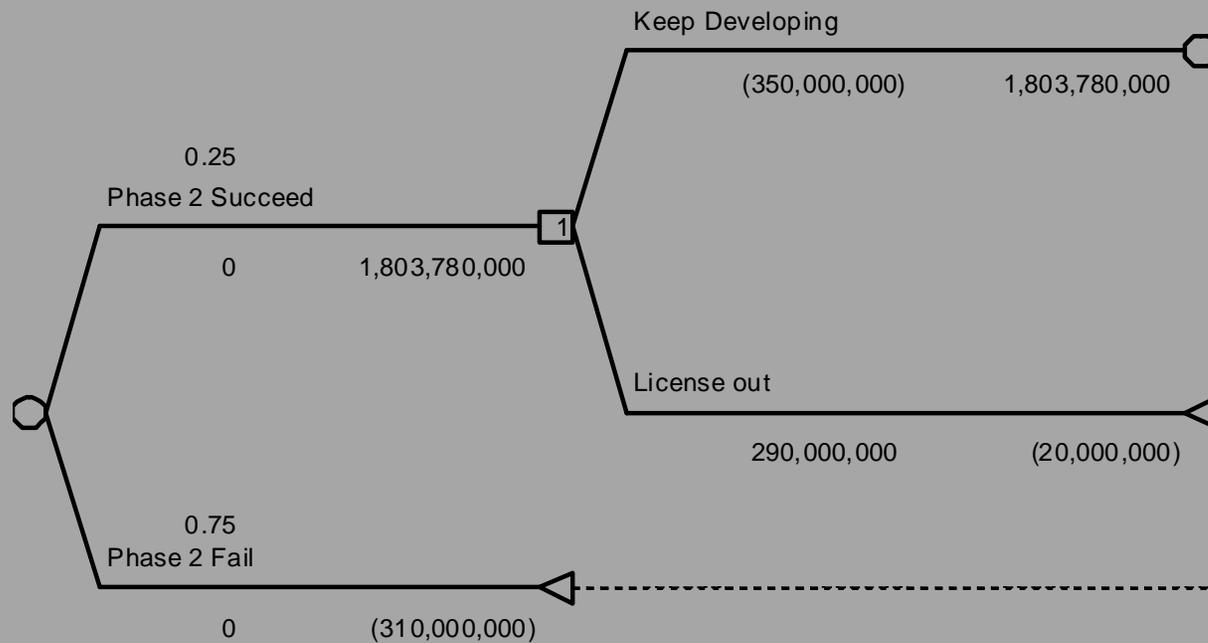
# Phase I

*If we make the initial investment, depending on the success of Phase I, a company must choose whether to keep developing the drug or license it out for a fee.*



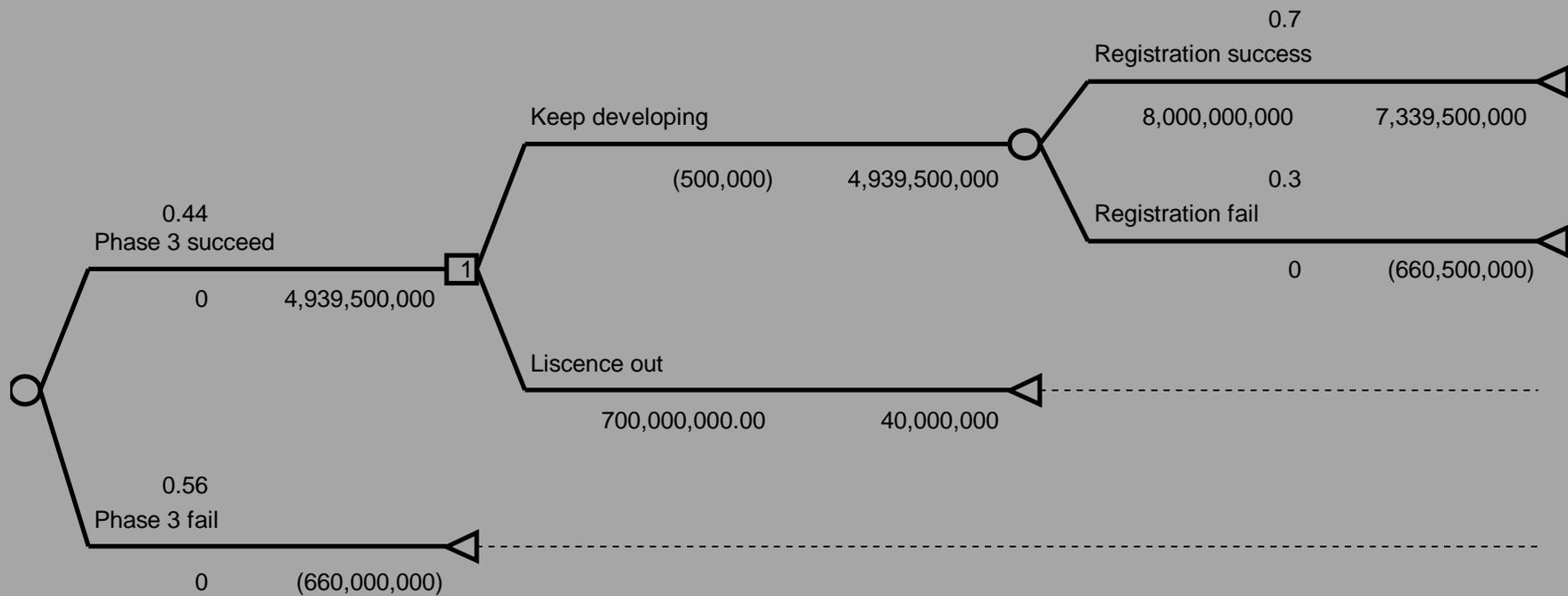
# Phase 2

*If Phase 2 is successful, a company chooses whether to continue developing, or license out the drug*



# Phase 3

*If Phase 3 is successful, a company chooses whether to continue developing, or license out the drug. If it chooses to keep developing, it will then go through FDA approval as the final stage*



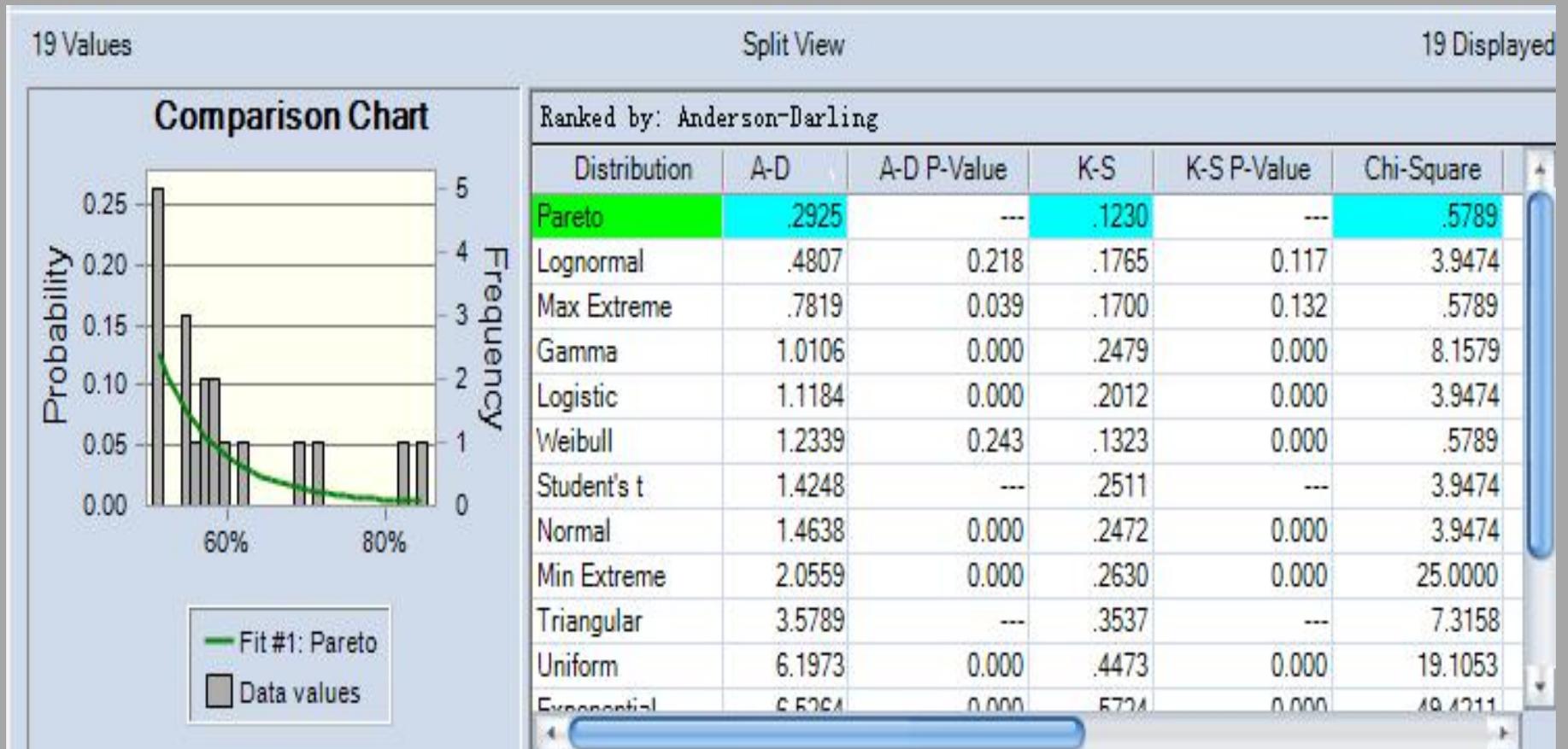
# Simulation Method

*Crystal Ball is used to find the distribution for the following data*

Company	Phase 1	Phase 2	Phase 3	FDA Registration	Total Success %
AstraZeneca	60%	25%	43%	71%	4.58%
BMS	57%	30%	44%	72%	5.42%
Eli Lilly	52%	30%	45%	74%	5.19%
Roche	55%	33%	47%	72%	6.19%
GSK	56%	35%	45%	73%	6.41%
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Novartis	51%	25%	47%	69%	4.13%
Pfizer	85%	35%	50%	68%	10.12%
Shering-Plough	51%	25%	45%	70%	4.05%
Merck	62%	23%	43%	73%	4.48%
Genzyme	69%	34%	42%	70%	6.90%
Sandoz	51%	21%	41%	68%	3.01%
Abbott	71%	19%	46%	69%	4.28%
Biodel	58%	25%	42%	67%	4.10%
King Pharma	58%	18%	41%	65%	2.78%
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Watson Pharma	54%	16%	42%	68%	2.49%
Charles River	57%	12%	44%	69%	2.08%
<b>Average Level</b>	<b>60%</b>	<b>25%</b>	<b>44%</b>	<b>70%</b>	<b>4.57%</b>

# Simulation Results

*Phase 1 distribution fit test for historical success rate*



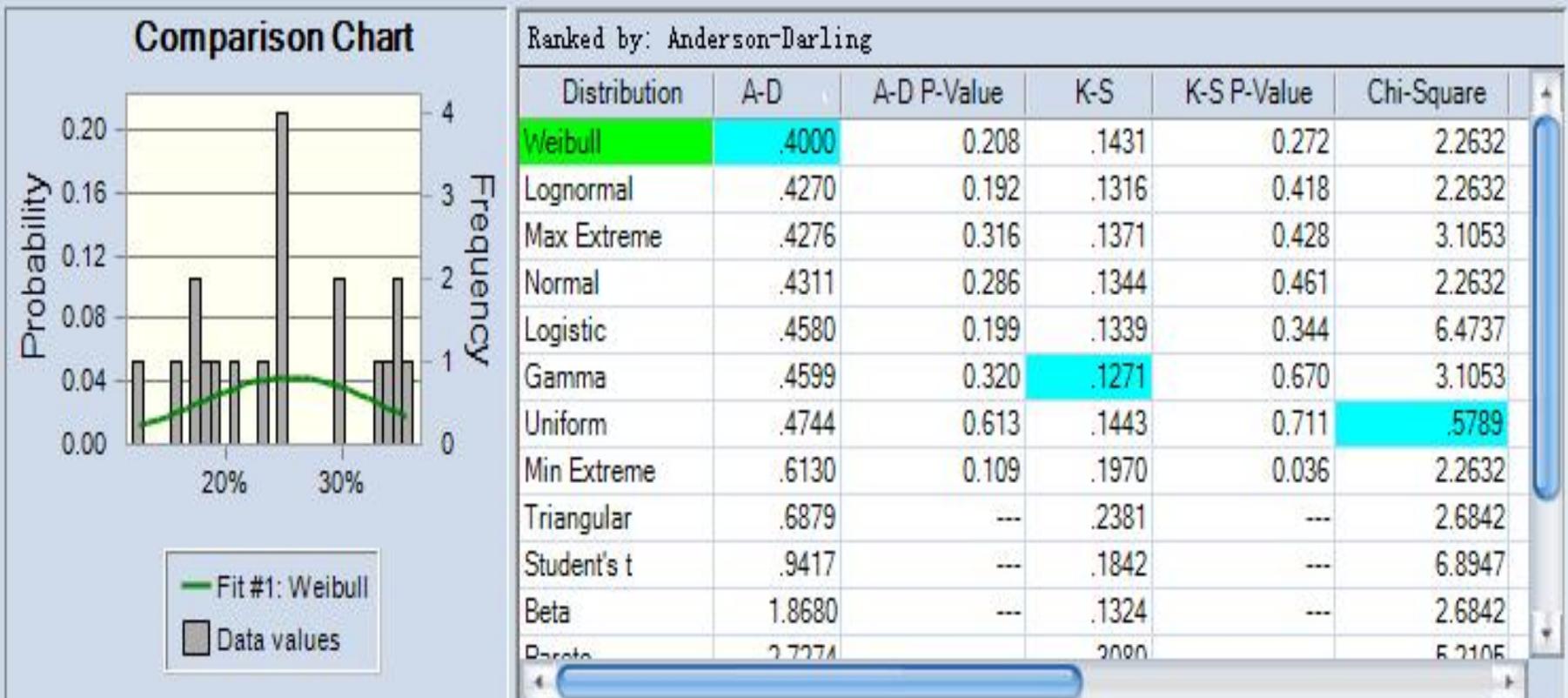
# Simulation Results

## *Phase 2 distribution fit test for historical success rate*

19 Values

Split View

19 Displayed



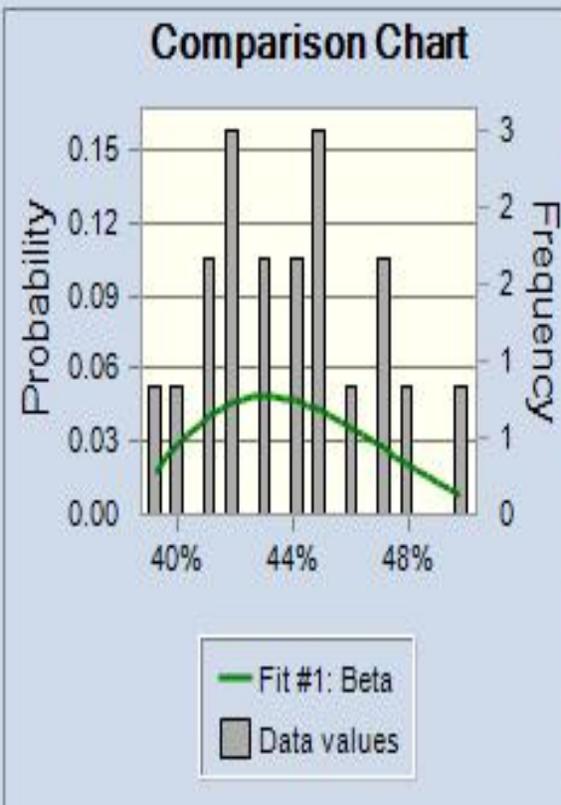
# Simulation Results

## *Phase 3 distribution fit test for historical success rate*

19 Values

Split View

19 Displayed



Ranked by: Anderson-Darling

Distribution	A-D	A-D P-Value	K-S	K-S P-Value	Chi-Square
Beta	.1437	---	.0844	---	.1579
BetaPERT	.1503	---	.0898	---	.1579
Lognormal	.1518	0.916	.0990	0.824	.1579
Weibull	.1591	0.570	.1071	0.622	.1579
Gamma	.1642	0.990	.1019	0.967	.1579
Normal	.1845	0.892	.1128	0.742	.1579
Max Extreme	.2005	0.873	.1128	0.743	.1579
Logistic	.2080	0.816	.1170	0.589	.1579
Triangular	.2677	---	.1207	---	.5789
Min Extreme	.4590	0.269	.1479	0.304	1.4211
Student's t	.5929	---	.1732	---	2.6842
Uniform	0.105	0.200	1.055	0.242	2.1052

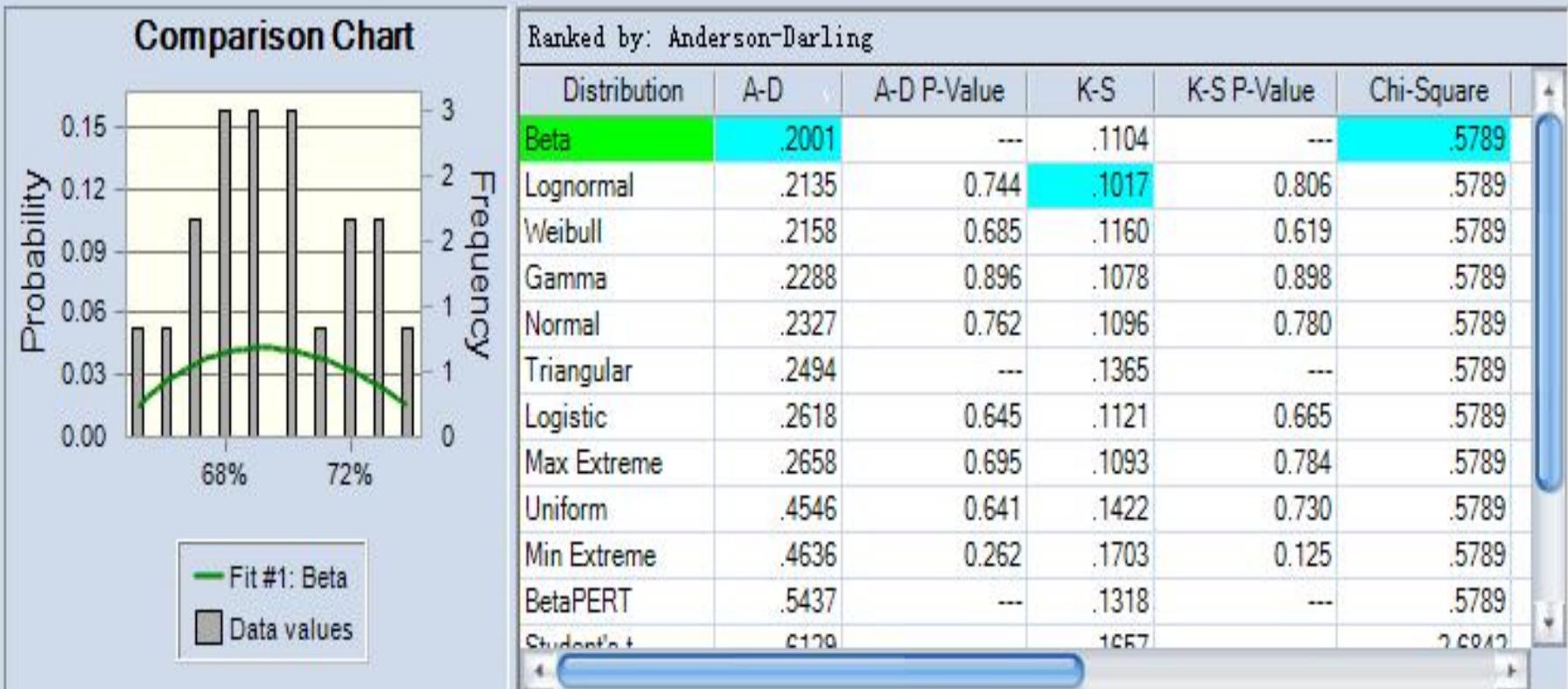
# Simulation Results

*Registration phase distribution fit test for historical success rate*

19 Values

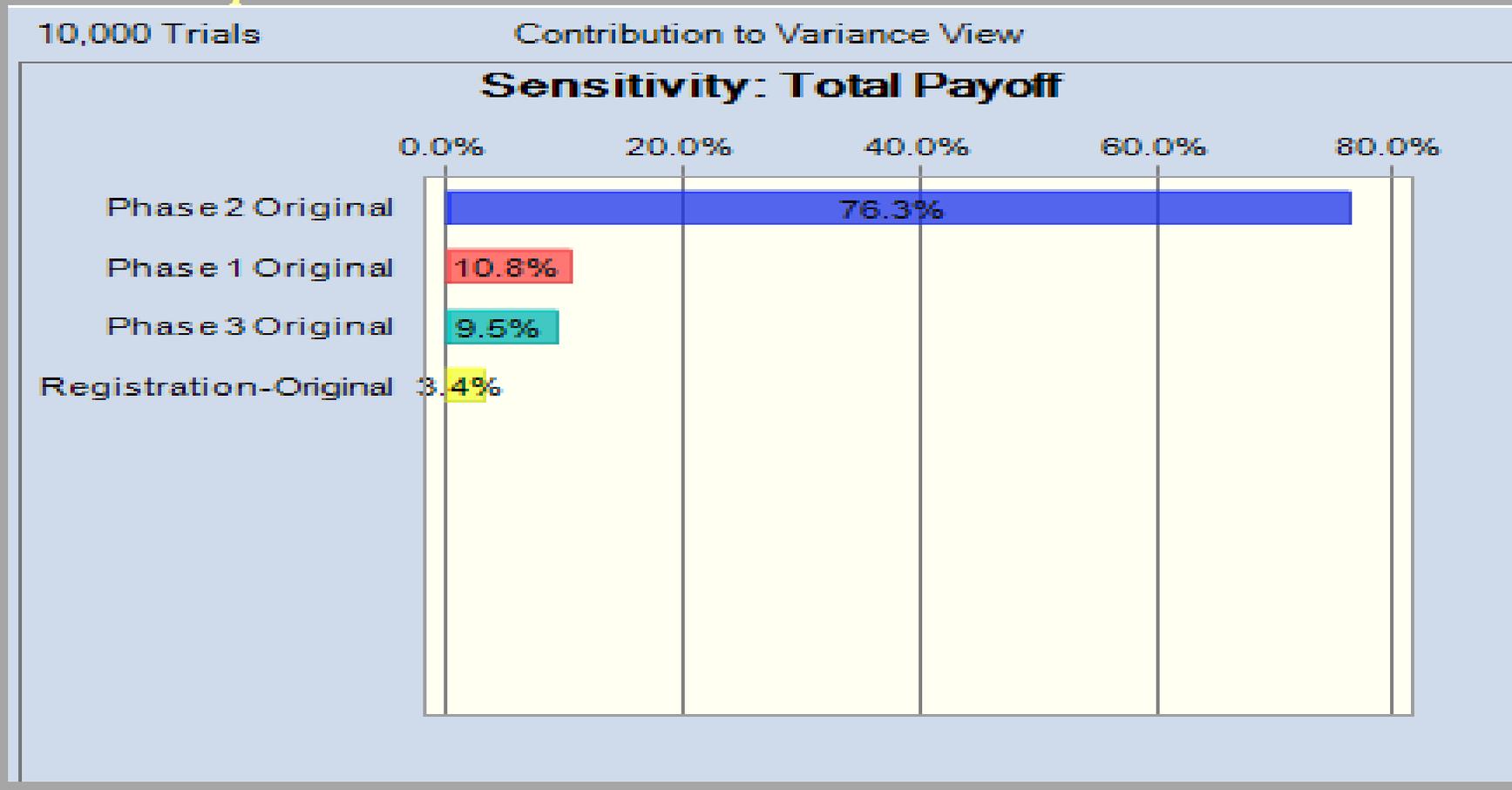
Split View

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# Sensitivity Analysis

*Based on the fitted distribution, Crystal Ball's sensitivity analysis shows that the optimal choice is to invest additional funds in Phase II.*



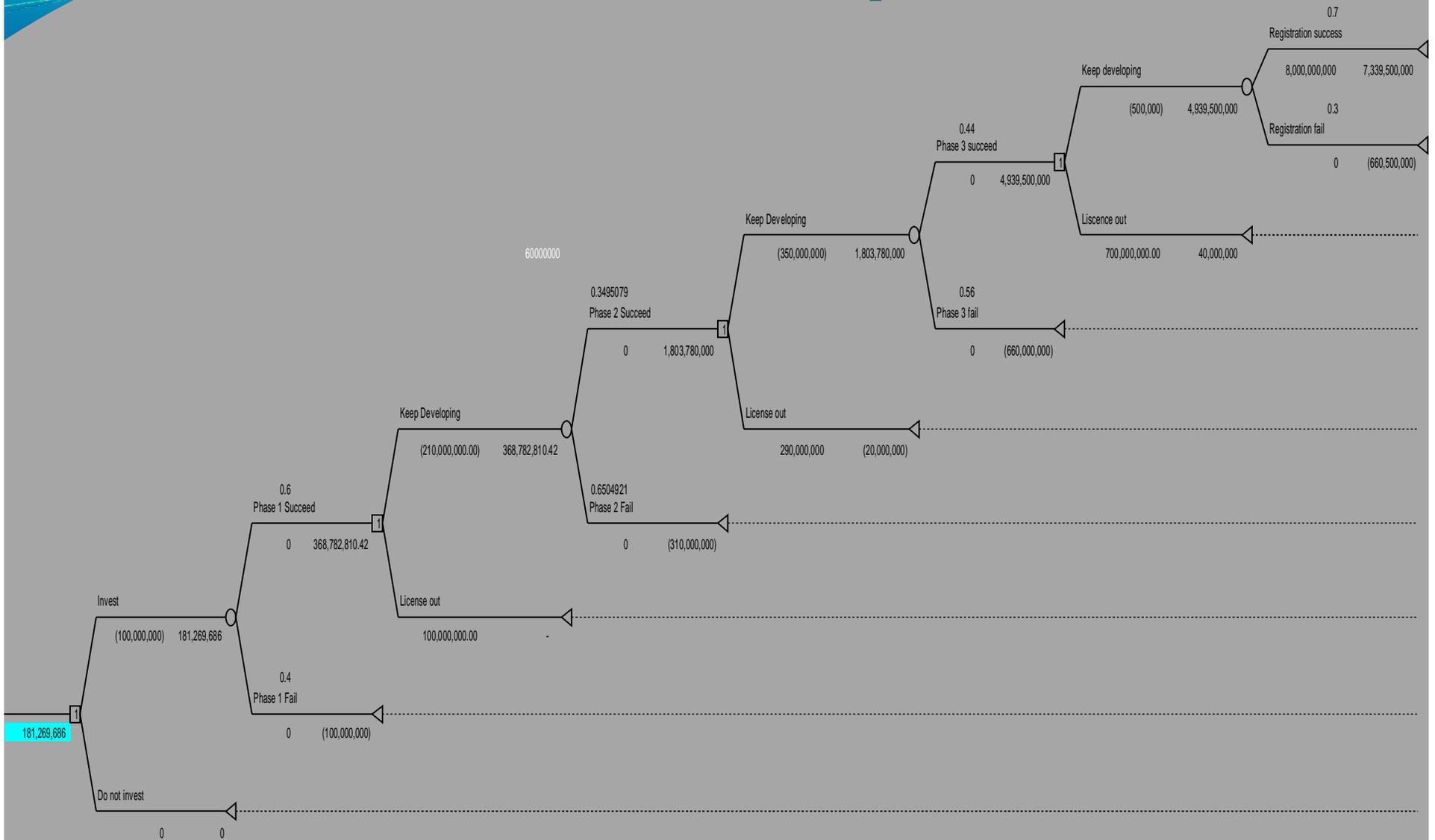
# Sensitivity Analysis

Probability	Phase 1	Phase 2	Phase 3	Registration
Original Success Probability	60%	25%	44%	70%
Increase success % factor	0%	10%	0%	0%
Adjusted Success Probability	60%	35%	44%	70%

*Based on industry averages, an investment of \$60 million results in an increase of 10% in a drug's success rate. This brings the cumulative success rate in Phase 2 to 35%.*

Oncology-Additional Investment in Phase 2		
Company	Increase Success %	Additional Capital Required \$ Mm
AstraZeneca	10.00%	60
BMS	9.51%	60
Eli Lilly	8.66%	60
Roche	9.24%	60
GSK	9.29%	60
JNJ	13.67%	60
Novartis	8.49%	60
Pfizer	13.77%	60
Shering-Plough	8.56%	60
Merck	10.33%	60
Genzyme	11.50%	60
Sandoz	8.58%	60
Abbott	11.83%	60
Biodel	9.71%	60
King Pharma	9.67%	60
Renogen	9.19%	60
Biogen	8.47%	60
Watson Pharma	9.08%	60
Charles River	9.53%	60
<b>Average Level</b>	<b>9.95%</b>	

# Precision Tree-with additional 60 mm phase 2 investment



All values are in millions

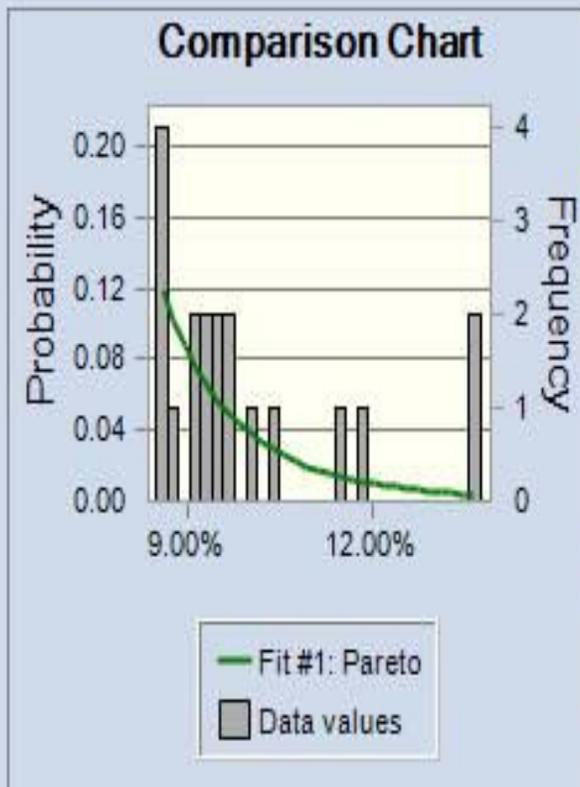
# Simulation Results

*Phase 2-additional investment distribution fit test for historical success rate*

19 Values

Split View

19 Displayed



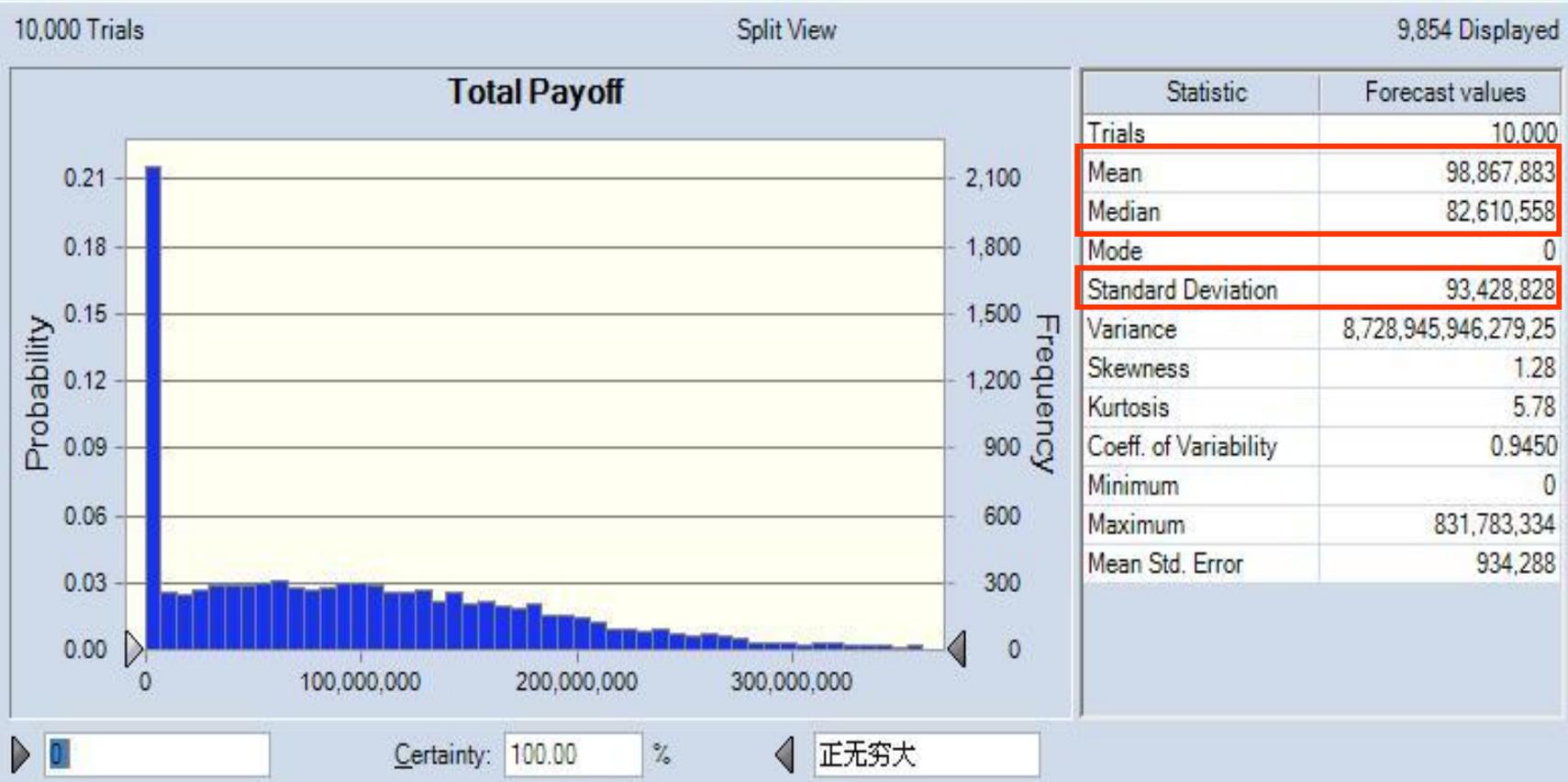
Ranked by: Anderson-Darling

Distribution	A-D	A-D P-Value	K-S	K-S P-Value	Chi-Square
Pareto	.3021	---	.1257	---	.5789
Lognormal	.4858	0.202	.1747	0.121	3.9474
Max Extreme	.7716	0.041	.1658	0.157	.5789
Gamma	.9699	0.000	.2442	0.000	9.0000
Logistic	1.1011	0.000	.1973	0.011	3.9474
Weibull	1.3616	0.175	.1367	0.000	.1579
Student's t	1.4001	---	.2468	---	3.9474
Normal	1.4299	0.000	.2442	0.000	3.9474
Min Extreme	2.0133	0.000	.2606	0.000	25.8421
Triangular	3.0583	---	.3326	---	7.7368
Uniform	5.5228	0.000	.4289	0.000	11.5263
Exponential	6.5642	0.000	.5721	0.000	57.0000

# Forecast Report

## Original Investment Scenario

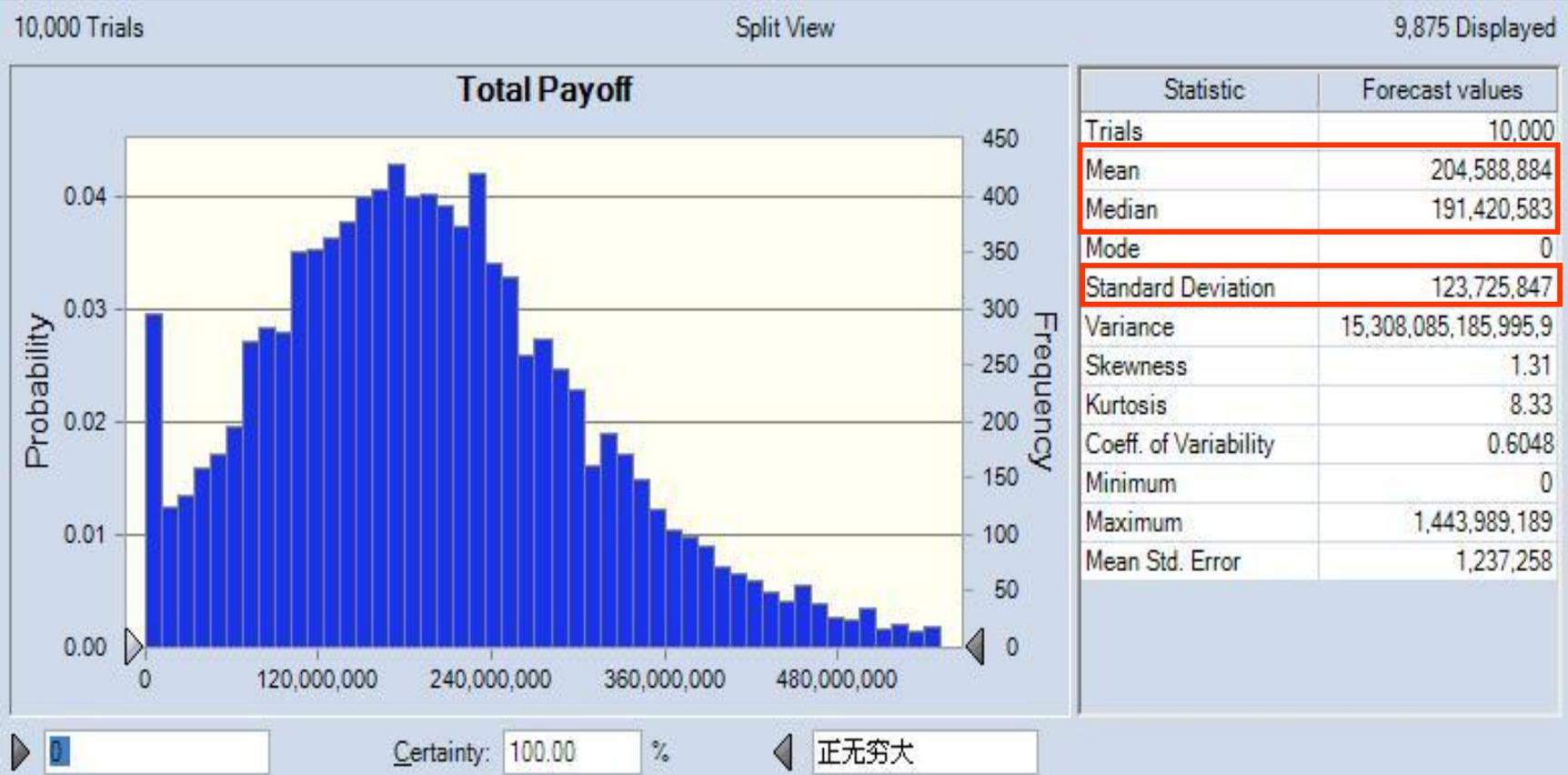
Crystal Ball simulates forecast values for key statistics



# Forecast Report

## Phase 2 Additional Investment Scenario

Crystal Ball simulates forecast values for key statistics



# Modified Sharpe Ratio Analysis

Modified Sharpe Ratio = Median/Standard Deviation

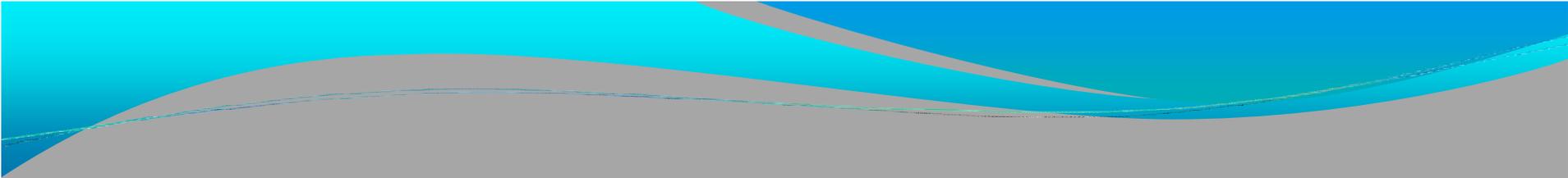
	Original Investment Scenario	Additional Investment Scenario
Median	82,610,558	191,420,583
Standard Deviation	93,428,828	123,725,847
Modified Sharp Ratio	0.88	1.55

Based on the risk adjusted return analysis above, we should choose the scenario with higher Modified Sharp Ratio

# Conclusions

- | The optimal choice is to keep developing at each phase and to make an additional investment for Phase II.
- | The median return from following this strategy is \$ 191,420,583
- | Limitations of our model





*Questions?*