



Investor Presentation

Bill Shannon, PhD, MBA

October 2011

Bill Shannon, CEO

- Education
 - MS Zoology
 - PhD Biostatistics
 - Executive MBA (In Progress)
- Profession
 - Tenured Associate Professor of Biostatistics in Medicine
Washington University School of Medicine in St Louis
 - CEO/Founder BioRankings, LLC
- Independent NIH funding to develop new statistical methods
 - Comparative effectiveness research (\$1.5M)
 - Neurology/Sleep medicine (\$1M +\$1.2M under review)
 - Ob/Gyn (\$500K)
 - Microbiome (\$600K + \$1.5M to be submitted)
 - SBIR for software development (\$700K, to be submitted)
 - ~\$750K non-statistical methods funding

Other Staff

- Alexandra McWilliams, COO and Co-Owner
- Leslie McIntosh, PhD, Director of Clinical Informatics
- Elena Deych, MS, Research Statistician
- Berkley Shands, BS, Software Engineer

Statistical Due Diligence

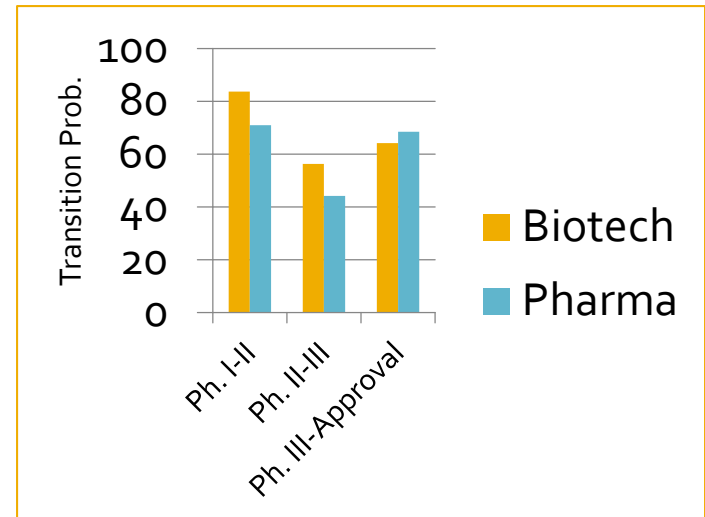
Evaluation of statistical claims and assumptions made by biotech companies concerning their drug/device pipelines

- More accurately quantify likelihood of clinical trial success/failure
- Identify flawed statistical arguments, interpretations, and analyses that undermine overly optimistic claims

Deliverables

- Identify companies with high probability to transition to the next phase

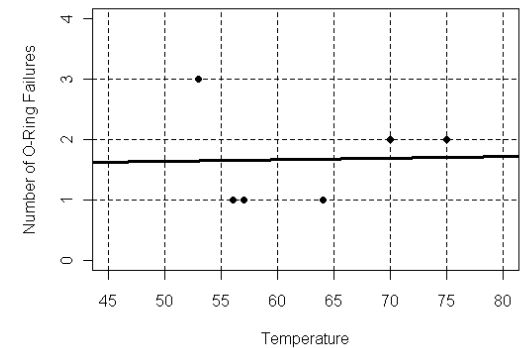
Cost per Compound (in Millions of 2005 dollars)			
Testing Phase	Mean Cost (\$)	Probability of entering phase	Expected cost (\$)
Preclinical	59.88	100	59.88
Phase I	32.28	100	32.28
Phase II	37.69	83.7	31.55
Phase III	96.09	47.1	45.26



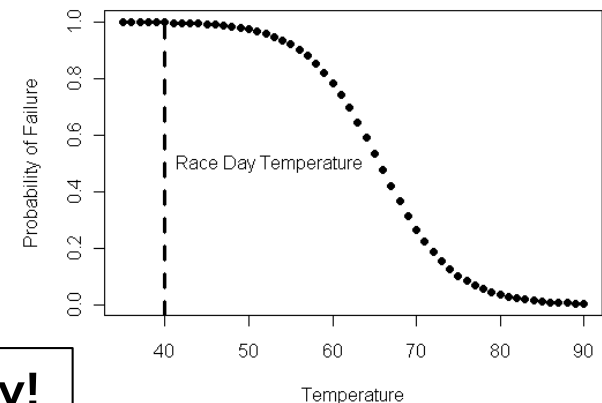
Carter Race Car (Space Shuttle)

Decision	Outcome Value	Probability	Expected Value	Probability	Expected Value
Race		Wrong Data		Correct Data	
Place Top 5	\$2,800,000	0.50	\$1,400,000	0.004	\$11,200
Place 6+	\$800,000	0.13	\$104,000	0.001	\$800
Blow Engine	-\$50,000	<u>0.29</u>	-\$14,500	<u>0.994</u>	-\$49,700
Not Finish	\$800,000	0.08	\$64,000	0.001	\$800
Subtotal Race -Current Finances Net Expected Value		1.00	\$1,553,500 -\$70,000 \$1,483,500	1.00	-\$36,900 -\$70,000 -\$106,900
Not Race					
Subtotal Race -Current Finances Net Expected Value		1.00	\$790,000 -\$70,000 \$720,000	1.00	\$790,000 -\$70,000 \$720,000

No Correlation of Failure and Temperature (Wrong Data)



Correlation of Failure and Temperature (Correct Data)



Not knowing you have the wrong data can be costly!

Pulmonary Hypertension

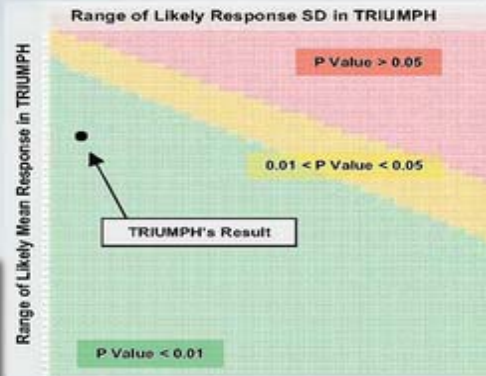
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ALTERNATIVE STATISTICS CALCULATED FROM UNITED THERAPEUTICS DATA

BioRankings predicted that Inhaled Remodulin would be successful before the company's announcement

CLINICAL TRIAL

United Therapeutics launched the TRIUMPH trial of inhaled remodulin for treatment of pulmonary arterial hypertension (PAH) in patients with NYHA Class II-IV symptoms. This is a reformulation to a more efficient drug delivery from the already FDA approved injected remodulin.



A meta-analysis of Remodulin and other treatments for PAH was used to compare the TRIUMPH study to prior studies.

P value and power look-up tables were used to define a range of means and standard deviations for the likely outcomes of the TRIUMPH trial. From these tables, most reasonable outcome results would be statistically significant.

CONCLUSIONS

We concluded from our meta-analysis that TRIUMPH was highly likely to be in the green GO region (see p value look-up table above).

Three months later (November 2007) United Therapeutics reported, as we predicted, that the TRIUMPH study achieved the primary endpoint of overall 6 minute walk test improvement ($p < 0.0006$).

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William D. Shannon,
PhD

(314) 704-8725

Prostate Cancer

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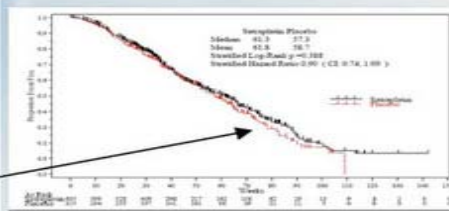
ALTERNATIVE STATISTICS CALCULATED FROM GPC DATA

BioRankings predicted that GPC's Satraplatin would fail before the company's announcement

Clinical Trial

The SPARC trial, funded by GPC Biotech, studied satraplatin in hormone refractory prostate cancer. They filed an NDA for accelerated approval, but it was withdrawn based on vote by ODAC on July 24, 2007 that the FDA should wait for final survival analysis before deciding on approval.

Using the data from the overall survival curve (as shown), GPC focused on patients who survived twelve months. Based on this, they predicted a positive outcome.



BioRankings showed GPC's argument was flawed. By examining different possible mortality rates for the two study arms (refer to table) we were able to calculate p values that could be achieved in their ongoing trial. From this analysis, no p values reached statistical significance.

BioRankings Statistical Analyses

Mortality rate		# Dead	# Alive	P value
0%	Satraplatin	309	326	0.99
0%	Placebo	154	161	
30.4%	Satraplatin	362	273	0.41
20.2%	Placebo	170	145	
20.2%	Satraplatin	344	291	0.60
30.4%	Placebo	177	138	
30.4%	Satraplatin	362	273	0.24
50.0%	Placebo	193	122	

Conclusions

Our calculations showed conclusively that the SPARC trial would fail to achieve an overall survival improvement.

Three months later (October 2007) GPC and partners reported, as we predicted, that the trial did not achieve the endpoint of overall survival ($p=0.80$).



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William D. Shannon, PhD (314) 704-8725

Diabetic Nephropathy

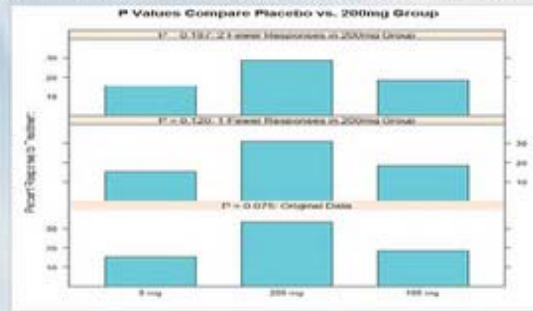
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ALTERNATIVE STATISTICS CALCULATED FROM KERYX DATA

The BioRankings method showed the data was too close to warrant a guaranteed pass or fail for Keryx's Sulodexide

Clinical Trial

Keryx's lead compound under development, Sulodexide, was a first-in-class, oral heparinoid compound for the treatment of diabetic nephropathy. Sulodexide was in a pivotal Phase III /Phase IV clinical program under a Special Protocol Assessment with the FDA.



BioRankings performed a sensitivity analysis of previously published Sulodexide data used to design Keryx's study. By varying the response-to-treatment rates (see histograms) slightly, we showed that the prior data quickly became highly non-significant.

Conclusions

Our sensitivity analysis calculations could not be used to definitively predict success or failure of the trial. However, this analysis did raise a red flag about the possibility of this trial not being significant.

In March 2008, Keryx reported that Sulodexide did not achieve statistical significance.



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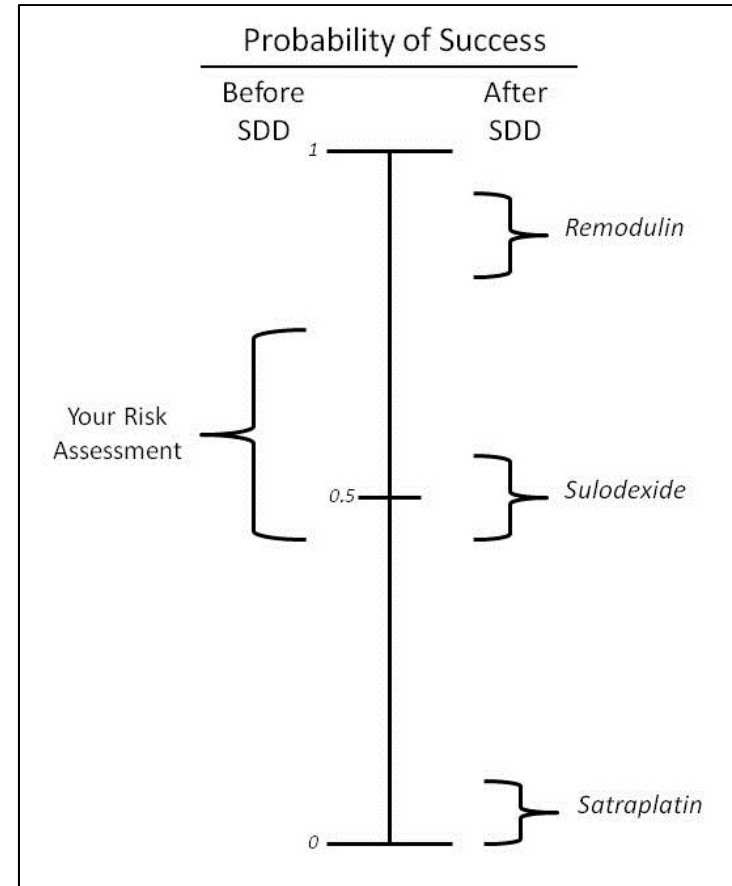
William D. Shannon, PhD (314) 704-8725

Sequenom

- Back in the news with a Trisomy-21 blood test
- Statistical due diligence ~2 years ago raised alarm
 - Initial report was one marker accurate for diagnosis
 - Markers added to improve test sensitivity/specificity
 - Appeared to violate statistical practice
 - Produce overly optimistic estimates of test accuracy
 - Was corporate fraud which played out through the pattern of statistical reports indicating something wrong

Value Proposition

Achieve higher profits
by improving your risk
assessment through
statistical due
diligence



Proposal

- Form an alliance with 5 investment firms each contributing \$200,000/yr for 3 years
- Work together to develop personalized and automated processes for statistical due diligence
- Recover your costs through better investing and higher profits