MANUFACTURING RISK ASSESSMENT FOR EARLY STAGE PHARMACEUTICALS

MIT SUPPLY CHAIN MANAGEMENT

RESEARCH THESIS PRESENTATION MAY 2017

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THESIS OVERVIEW

Objective

Develop a method to assess potential manufacturing risk for early stage (pre-phase III) pharmaceuticals that can be used for molecules in the drug development pipeline

Motivation

To meet future patient demand for drugs in development now, manufacturing decisions often need to be made during the early stages of the drug development process where a high degree of uncertainty exists

Approach

Using a Discrete Event Simulation model, manufacturing risk was assessed for an individual molecule to assess maxed-capacity, under-utilization, and over-utilization scenarios based on given capacity

Conclusion

Manufacturing capacity risk for early stage molecules can be simulated through a flexible and adaptable model. With accurate inputs provided, results can influence management decisions on future capacity resources

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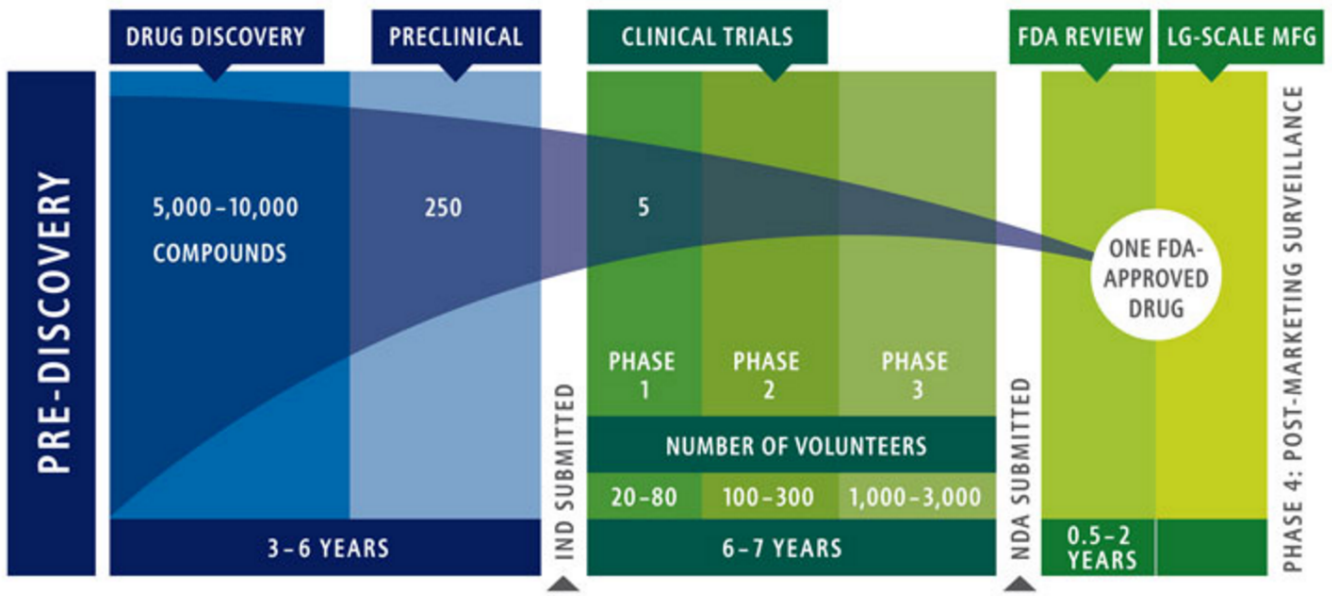
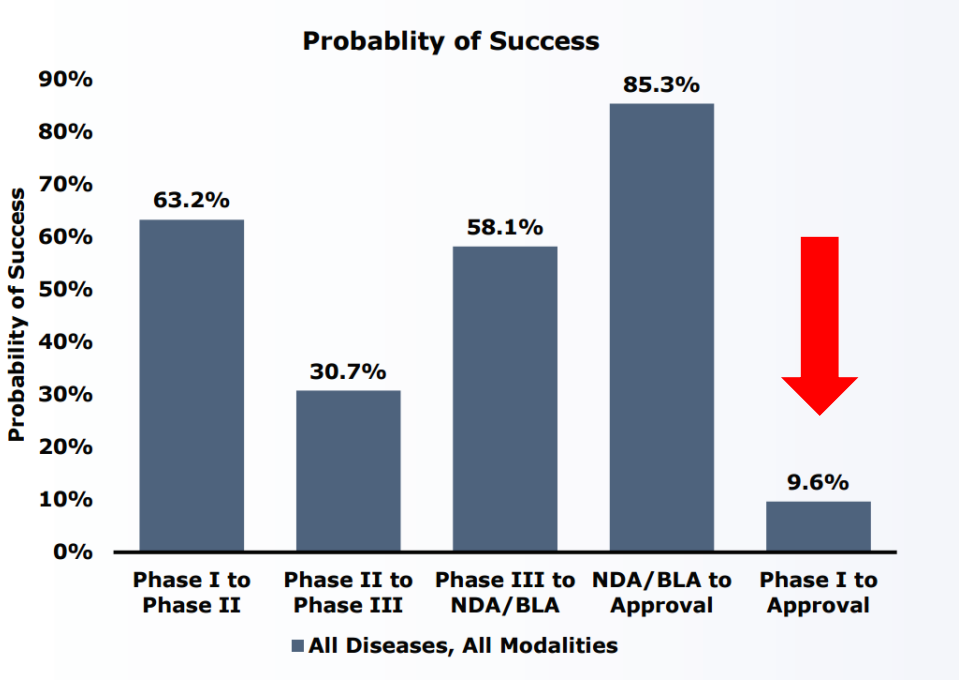
BACKGROUND AND MOTIVATION

The drug development process is long, risky, and expensive





It costs $1.4B on average to develop a new drug (Tufts CSDD)

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BACKGROUND AND MOTIVATION

Drug manufacturing is complicated and highly regulated

- FDA quality control measures – CGMP (Current Good Manufacturing Processes)
- Many decision variables involved in capacity expansion or modification
- Long timelines: 7-10 years to open a new site
- Out of stock implications

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MOTIVATION AND THE MODEL

The drug development process is long, risky, and expensive

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Drug manufacturing is complicated and highly regulated

Model needs to be adaptable and flexible

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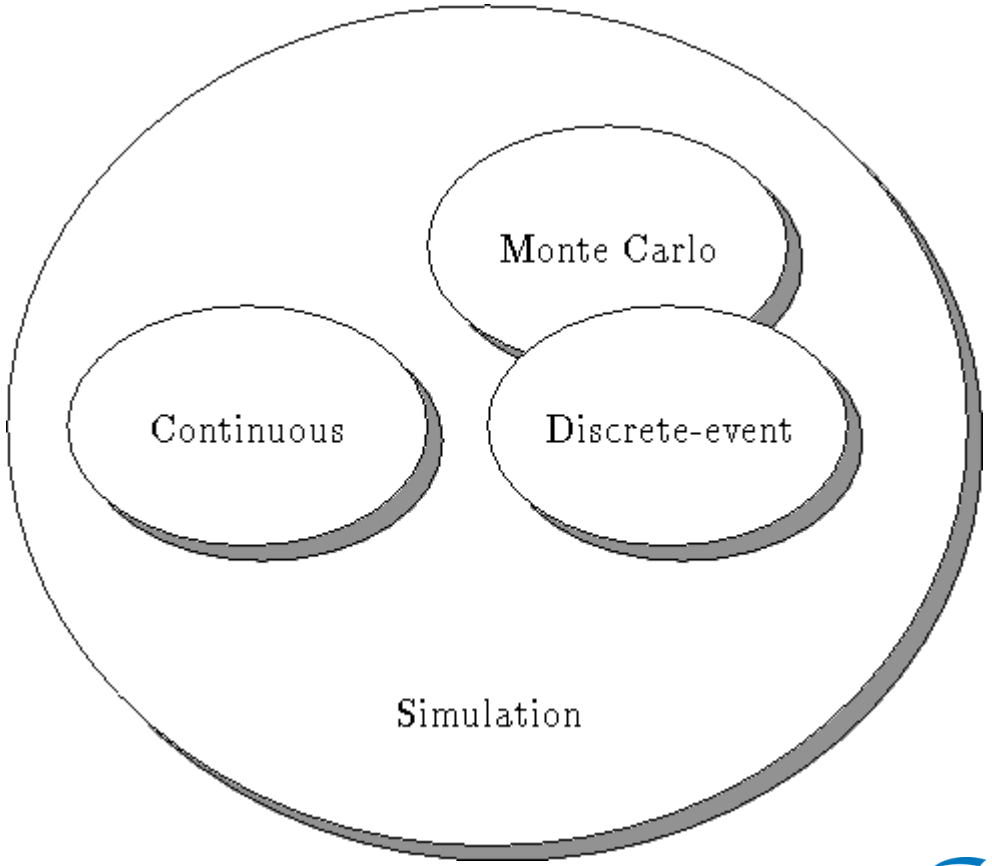
THE MODEL

Discrete Event Simulation (DES)

- Many stochastic parameters
- Differentiation and novelty to existing method
- Linearity of decisions and events



Source: Memorial University Computer Science

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THE MODEL

Stochastic parameter inputs

- Patient population
- Market share
- Patient compliance
- Dosage
- Treatment duration

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THE MODEL

Desired model outputs

Generated by model

Anticipated API quantities projected

versus

Provided by sponsoring company

Planned network manufacturing capacity

=

Assessment of manufacturing capacity risk (over, under, or target utilization)

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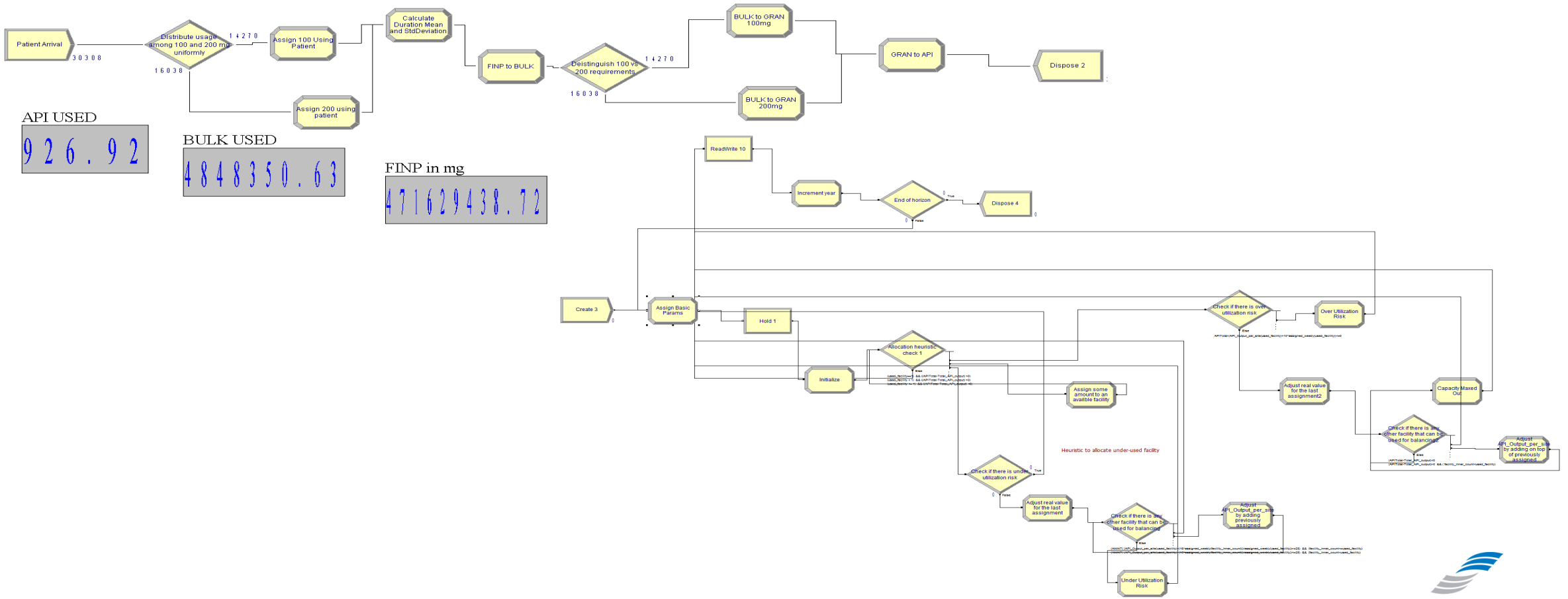
MODEL STRUCTURE IN ARENA SIMULATION SOFTWARE



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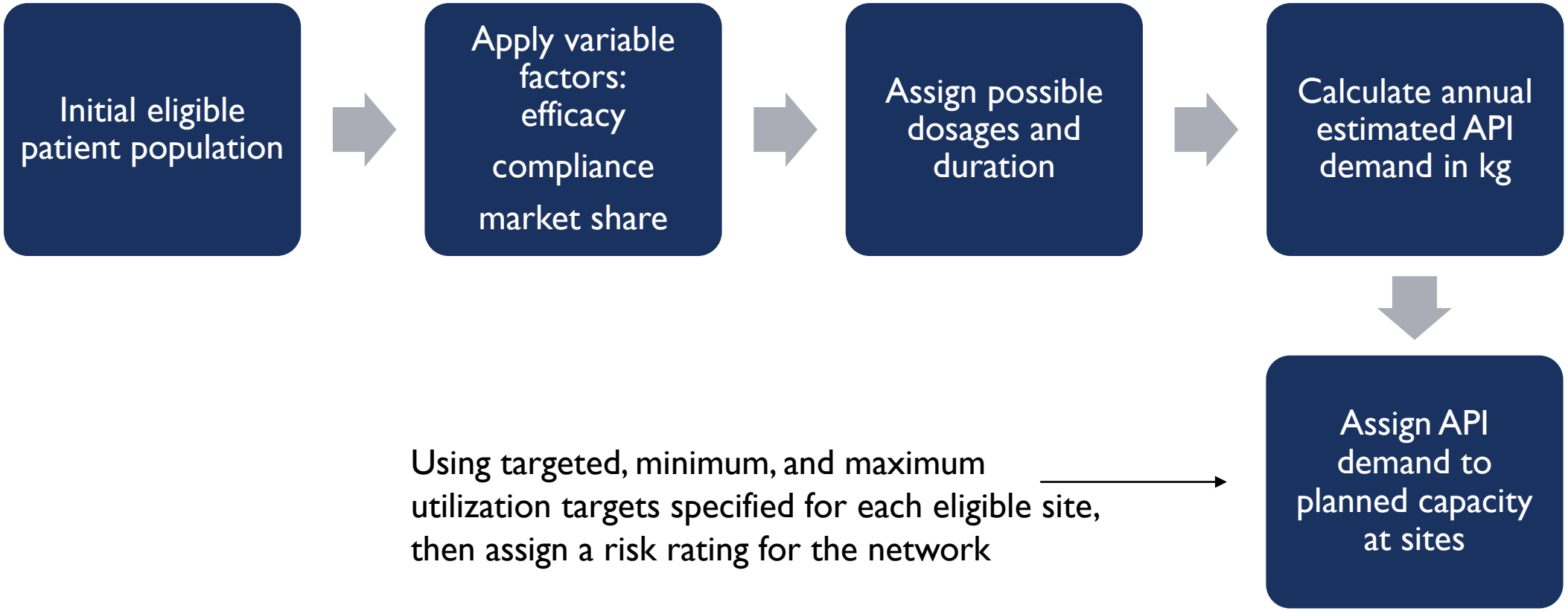
MODEL STRUCTURE SIMPLIFIED



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THE MODEL

Manufacturing risk assessment scenarios

- **None**:
  Demand is satisfied by at least target allocation to all available sites
- **Low**:
  Demand is satisfied while running some sites at under minimum capacity
- **Medium**:
  Demand is satisfied while running some sites at maximum capacity
- **High**:
  Demand is not satisfied while running all sites at maximum capacity

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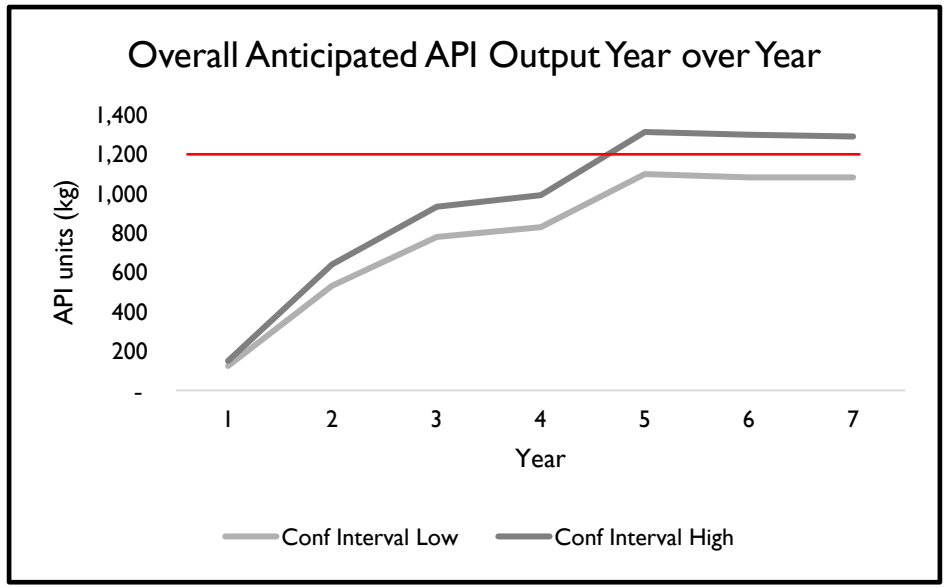
ADDITIONAL ANALYSIS OF OUTPUTS



Compliance and Market Share ANOVA

	Share1	Share2	Share3	
Comp1	177.12	189.60	195.00	187.24
Comp2	182.00	193.80	195.90	190.57
	179.56	189.60	195.00	188.90

	Df	SS	MSS	F
Compliance	1	830.00	830.00	0.98
Share	2	12495.26	6247.63	**7.39**
Comp*Share	2	687.86	343.93	0.41
Within	294	248672.97	845.83	

1. Is there enough capacity to handle anticipated demand?
2. Are there parameters that influence risk more than others?

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CONCLUSION

Biopharmaceutical companies make big bets with limited information to plan for manufacturing of drugs in early stages of development

- The model serves a **purpose**. Making safer bets to meet patient needs.
- The model is a **framework**. Adaptable, flexible, customizable.
- The model has **limitations**. There is no “one model fits all”.

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THANK YOU