



Back of the Envelope Analysis

An Example, from the Pharmaceutical arena
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Situation

- Project team to create and recommend a clinical drug development option
- But team was given less than a week!
- Some basic risk and value data were available but specifics needed to be assessed
- Estimated full analysis might take a month to complete
- How do we help the project team given the time constraint?

“Back of the Envelope” Analysis?

- Do “sensitivity” or “what-if” analysis using existing data and extreme cases to explore whether the decision is likely to be obvious/robust
- Analysis can be done very quickly
- If robust, share results with team for validation and explore implications
- If not robust, focus team on key issues to accelerate more rigorous analysis

A Multiple Indication Example

- New drug for two related indications ('A' and 'B')
- Success in one indication likely to significantly increase confidence in the other
 - Indications share common requirements/risks with respect to safety, manufacturing, etc.
 - Efficacy also likely to be partially 'correlated'
- Both indications are valuable (>\$500M) and risky (~10% probability of success)

Develop Indications Concurrently or Staggered?

Indication 'A'

Stage 1

Stage 2

Launch A

Indication 'B'
Options

Staggered Option-
Less At Risk Spend

Stage 1

Stage 2

Launch B

Concurrent Option-
Earlier Launch

Stage 1

Stage 2

Launch B

Data Already Available

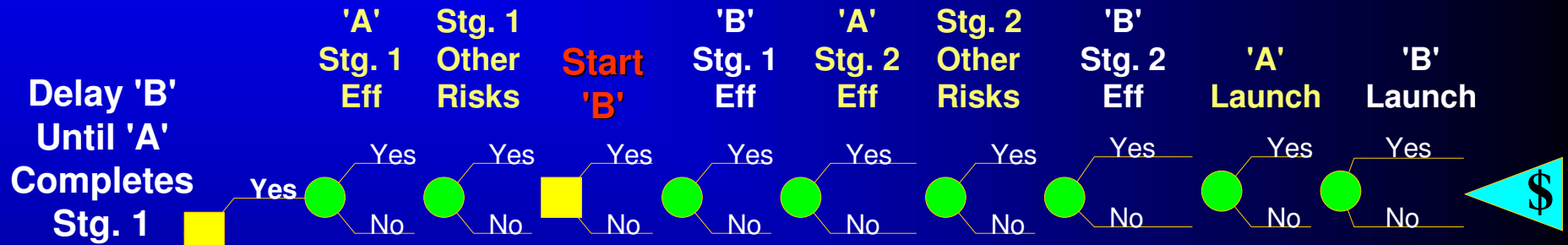
- Some data available from portfolio review:
 - Unconditioned probabilities of success
 - Value of success
 - Preliminary study costs and timings
- No data on conditioned probabilities
- Methodological approach for this type of problem already existed

Assumptions/Features of the Model

- Indication 'B' Stage 1 and 2 Efficacy conditioned upon Indication 'A' Stage 1 and 2 Efficacy result, respectively
- “Other” risks required for success of both Indications 'A' and 'B'
- The NPV of success changed a constant amount per year of delay to Launch (~ 20%/year)

The Model

Staggered Option



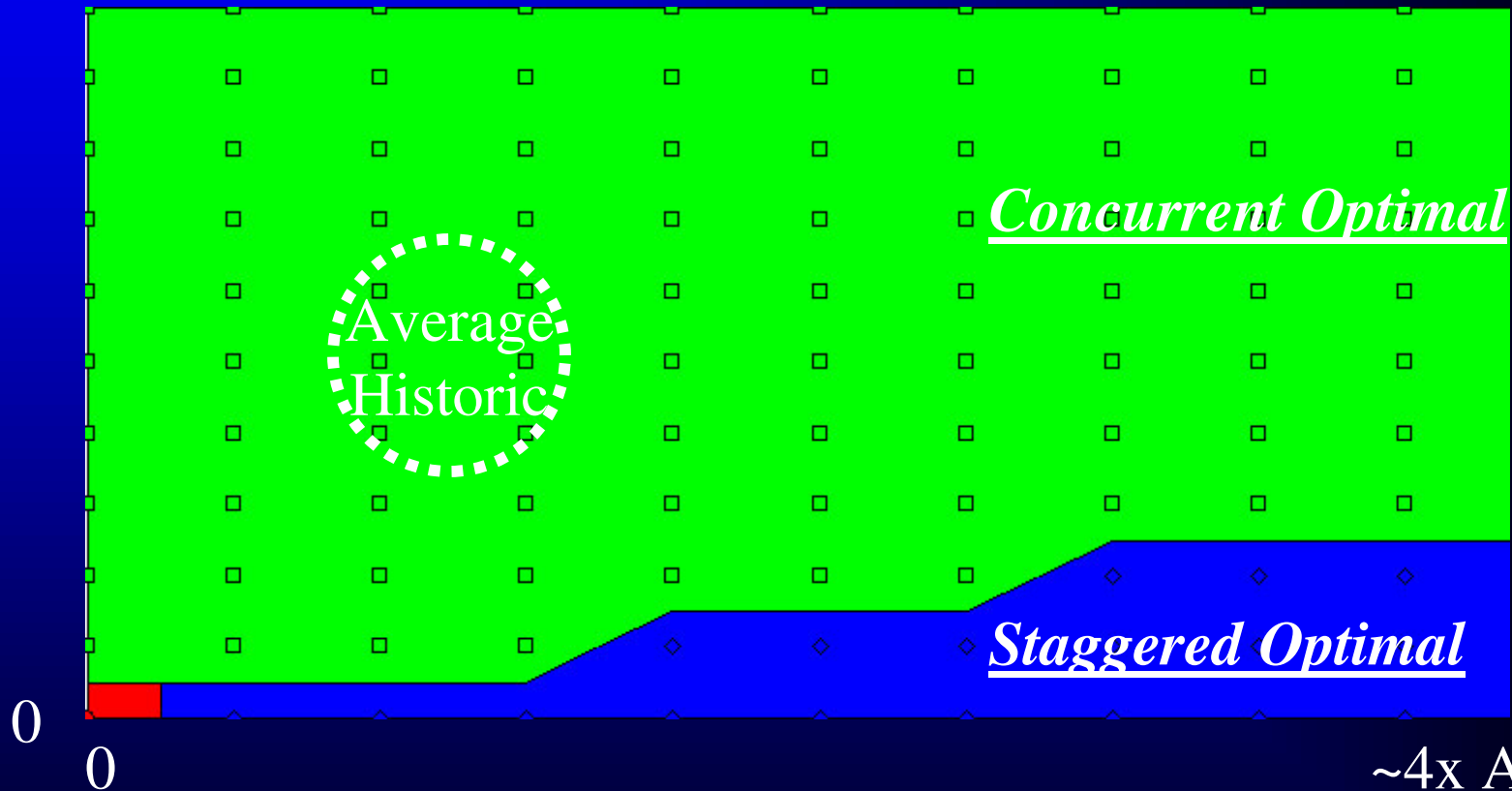
Concurrent Option



Even with High Efficacy Interaction Delaying Launch of 'B' Doesn't Pay!

~2x Avg.

'A' Stage 1 Duration

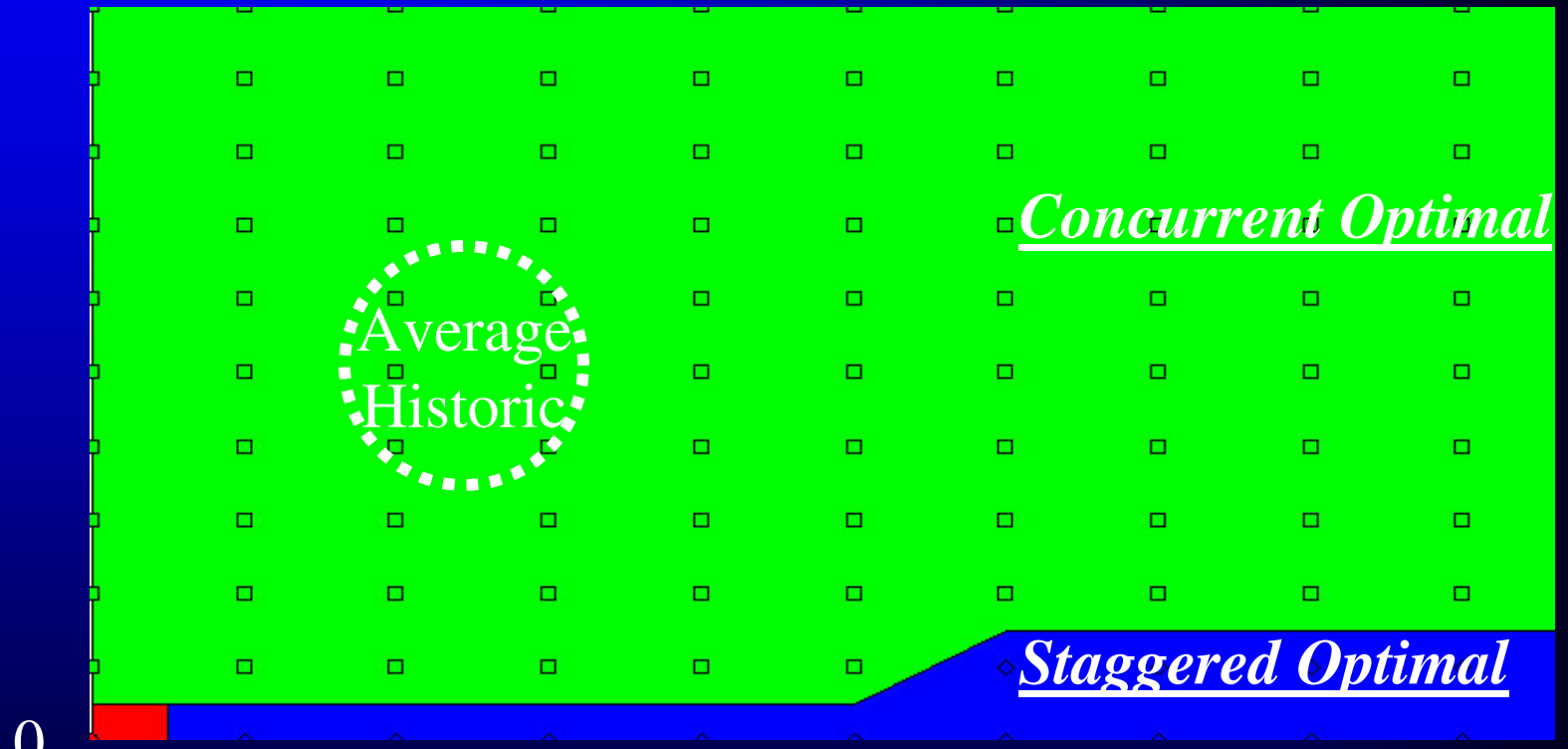


'B' Stage 1 Cost

If There Were No Efficacy Interaction Speed is Almost Always Favored

~2x Avg.

'A' Stage 1 Duration



Concurrent Optimal

Staggered Optimal

~4x Avg.

'B' Stage 1 Cost

Findings for the Team

- Value lost by delaying launch of Indication 'B' was unlikely to be offset by the value of information gained from waiting for outcome of Indication 'A'
- Concurrent start best strategy over entire range of reasonable study costs and durations, even when success of 'B' highly 'correlated' with 'A'

The Team accepted that time to Launch was paramount and focused on strategies that minimized delay.

Almost Instant Gratification for the DA Practitioner and Team

- The Team had an objective value framework before they created detailed clinical development plans.
 - They had an answer when they needed it!
 - Minimal team member time was required.
 - Moreover, the team did not have to provide probability of success for 'B' given success of 'A' which they “feared”
- Analysis only required about one day of analysis time

The Price of Speed

- Minimal framing of the problem/model with team can lead to doubts about the results
 - Especially true if results are greatly different from the momentum case
 - Can result in lack of team buy-in.
- Some teams spend significant time debating the “off the shelf” ranges of assumptions
- Teams may come to expect ‘Instant’ gratification!
- If a full analysis is required the team may “game” the data/Analyst - they may bias the data provided.

Conclusions

- In this example, quick delivery of the DA results was paramount and so a “Back of the Envelope” analysis was probably appropriate
- Back of the Envelope analyses are very likely to help the DA practitioner guide the process but they may not suffice to replace a complete analysis...