
Decision Analysis to Evaluate Possible Early Allocation of Phase 3 Resources



Answers That Matter.

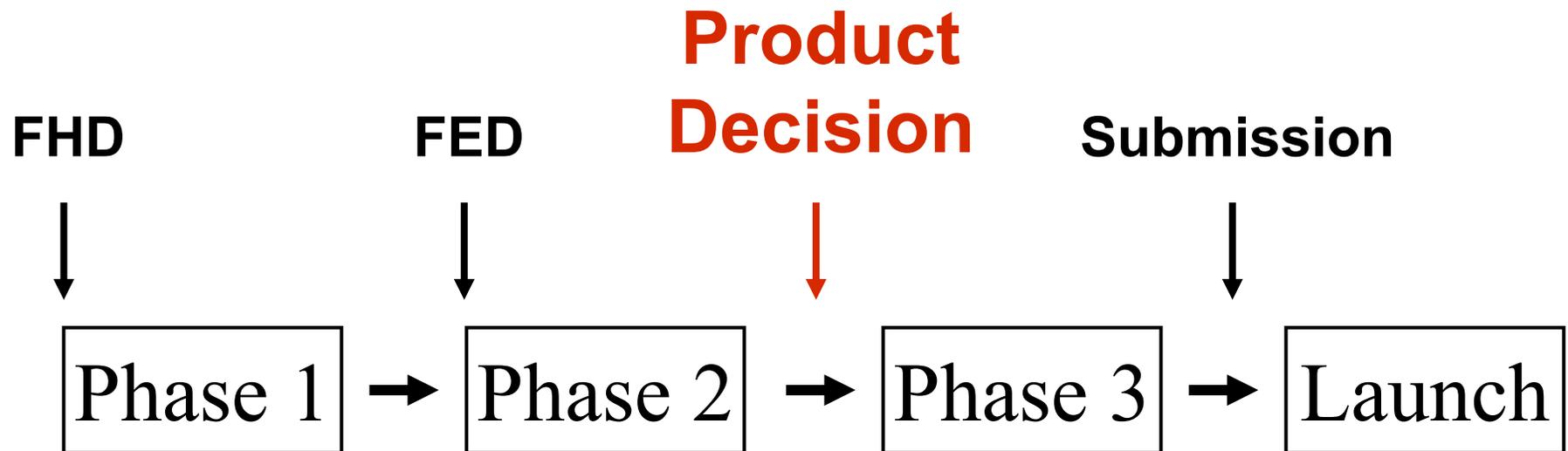
Overview

Background on drug development.

General treatment of the decision problem.

Case study: Drug XYZ--key learnings.

Clinical Development Process



What is "Product Decision"?

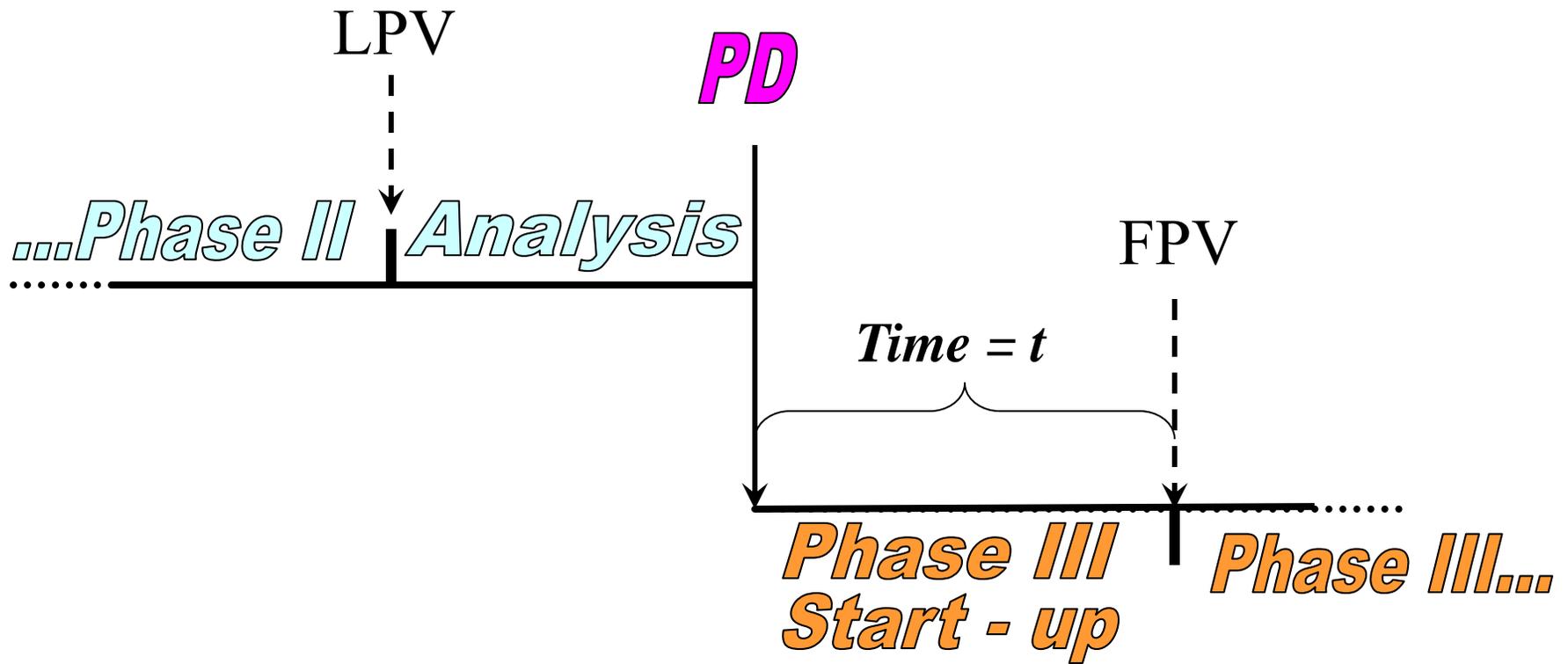
Allocation of resources toward final registration.

- Clinical
- Manufacturing
- Marketing

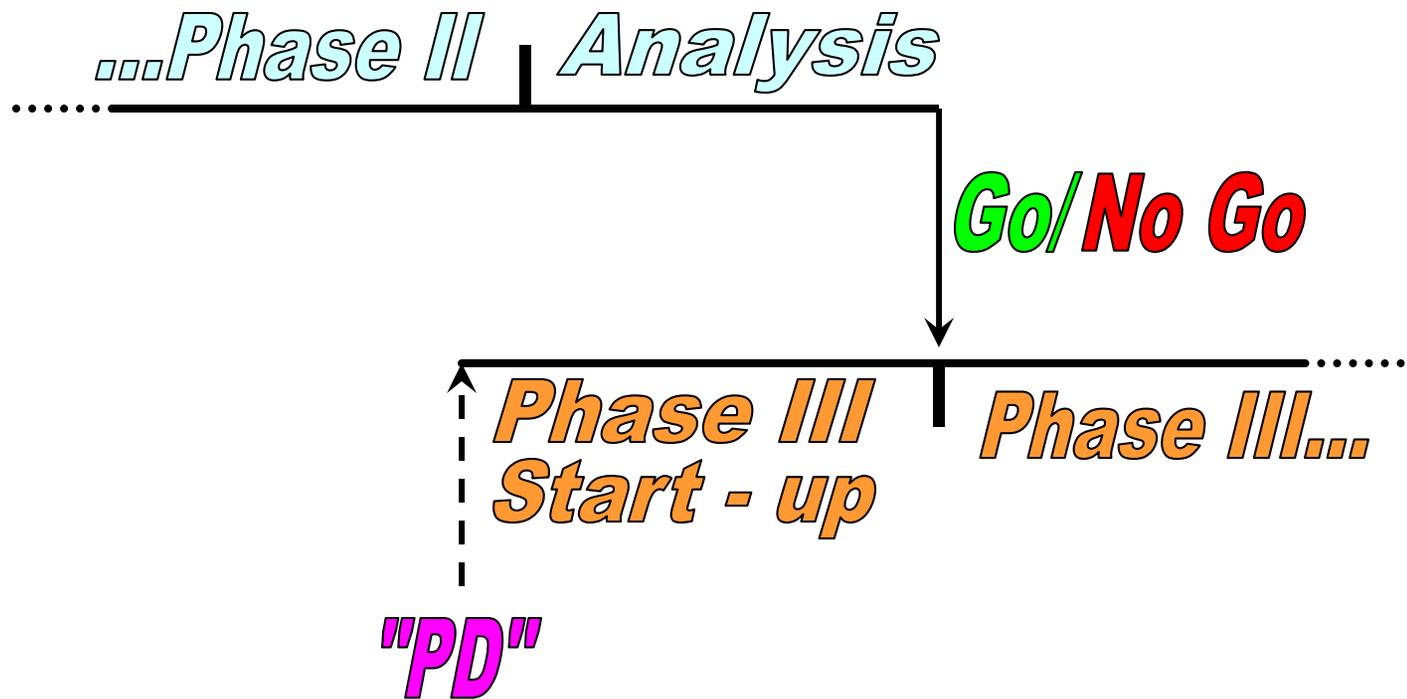
"Show me the Data!"

Completion of Phase 3 trials is almost always on the critical path from PD to submission.

Typical Timeline



Accelerated Timeline



Advantages/Disadvantages

Faster to market

- Revenue streams accelerated
- More time at peak sales
- Potential effect on market share

Phase 3 start-up money at risk

Key Variables

Difference in value between scenarios (ΔV).

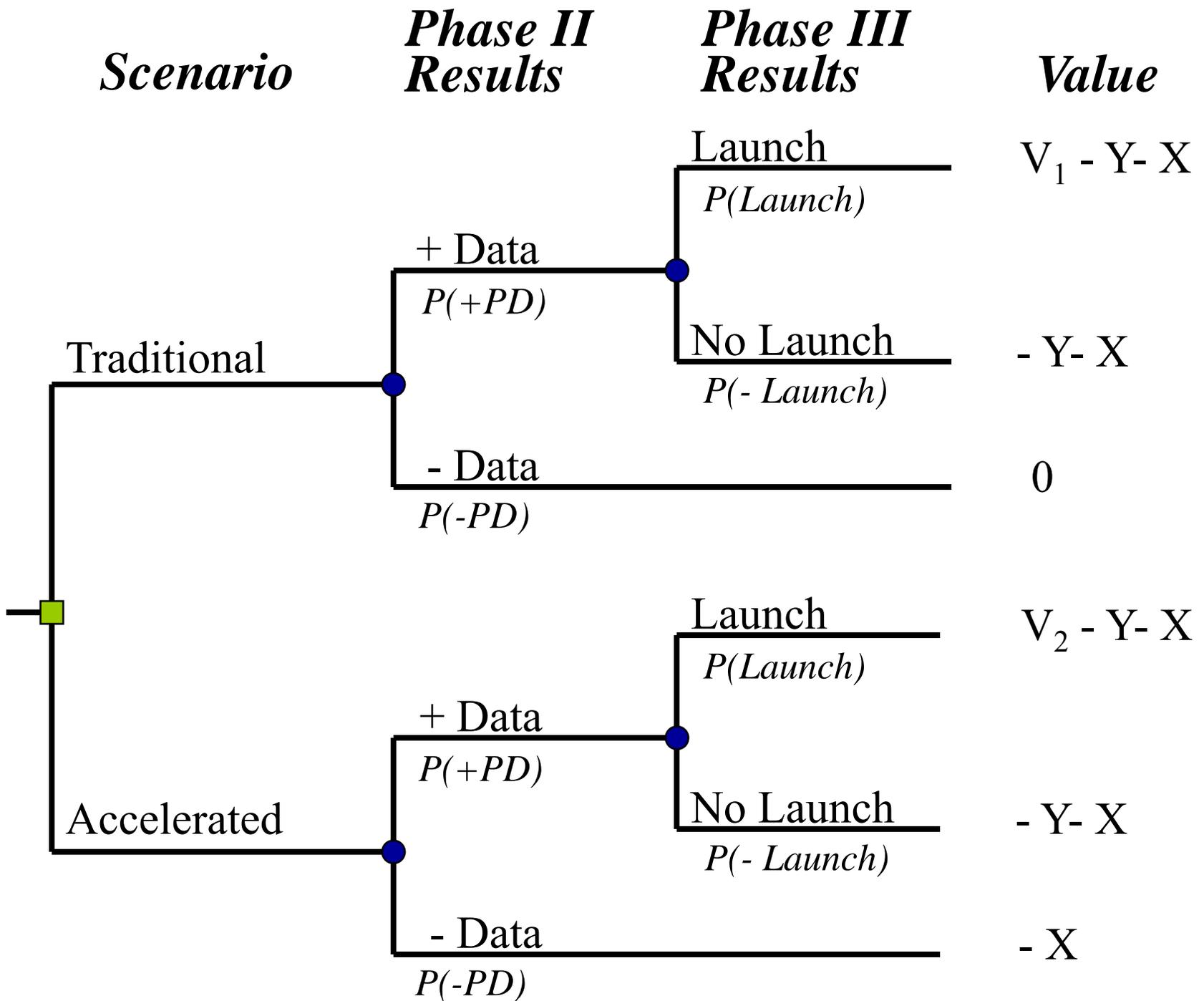
- V_1 = Value of traditional development.
- V_2 = Value of accelerated development.

Phase III costs

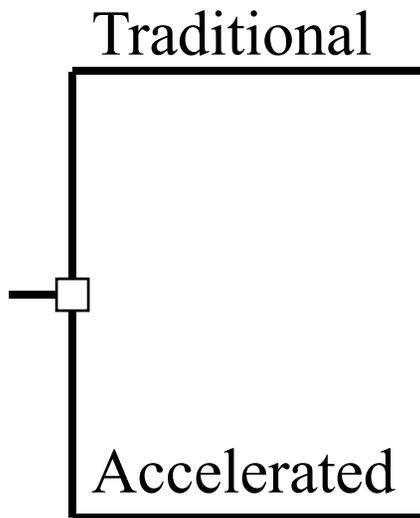
- Start up costs = X .
- Cost of completing trial = Y .

Probability of success:

- $P(+PD)$
- $P(Launch)$



Values of the Alternatives



$$V_1 P(\text{Lnch}) P(+\text{PD}) - P(+\text{PD})(Y+X) = \text{Val}_{\text{Trad}}$$

$$V_2 P(\text{Lnch}) P(+\text{PD}) - P(+\text{PD})(Y) - X = \text{Val}_{\text{Accel}}$$

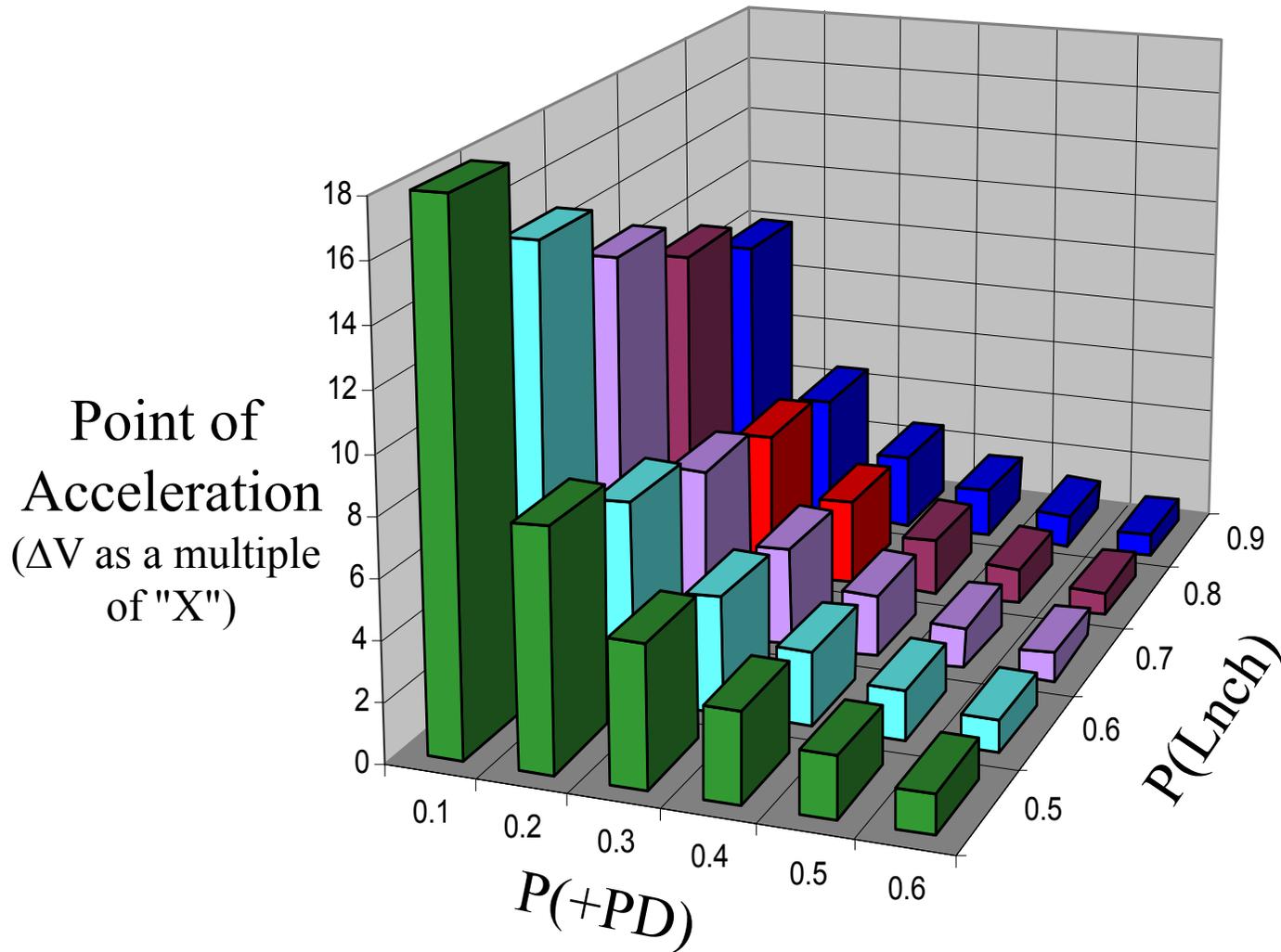
Point of Indifference

When does it make sense to accelerate Product Decision?

- Whenever $Val_{Acc} > Val_{Trad}$
- We can solve the inequality to get . . .

$$\Delta V > \frac{(1 - P(+PD))}{P(+PD) P(Lnch)} X$$

Threshold for Acceleration



Case Study: Drug XYZ

In Phase 2 clinical trials.

Meet efficacy and safety guidelines in Phase 2.

Opportunity for significant timeline acceleration.

- Acceleration in EU only.
- Medical resources "in place".
- Manufacturing and Marketing resources needed.

What's Interesting?

Alternatives

Competition as an uncertainty

Framing for the Decision-Makers

Generating Alternatives

Momentum strategy not included.

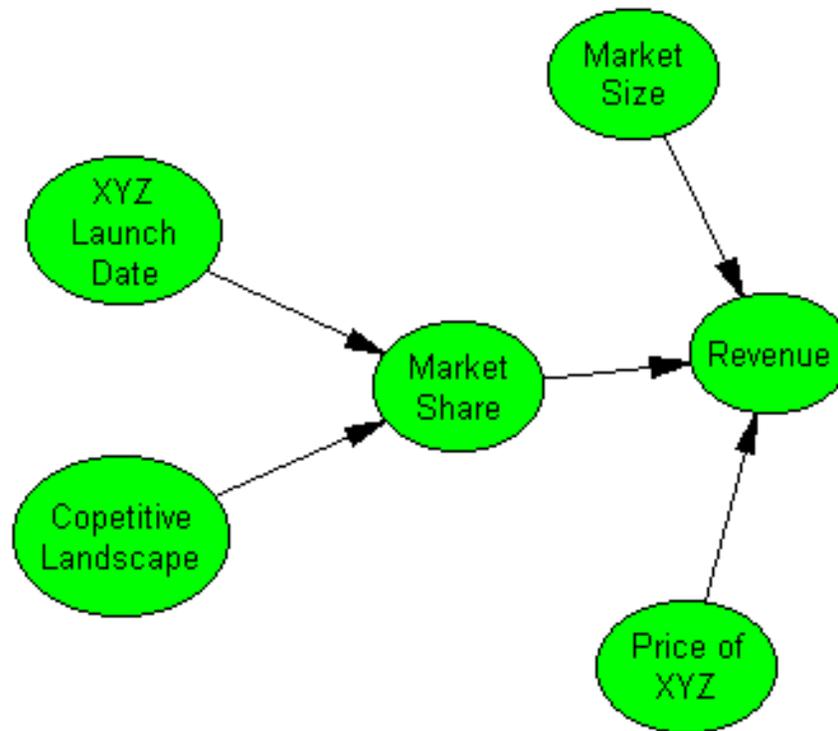
Early resource allocation.

- Marketing, Medical, and Manufacturing.
- "X" larger than typical.
- "t" larger than typical.

"Hybrid" solution: delay Marketing.

Traditional development plan.

Competition as an Uncertainty



Reducing Forecaster Workload

Assume market size does not change

Relative launch date impacts market share.

>20 forecasts reduced to 5.

Framing for the Decision-Makers

Product Decision vs. resourcing decision.

Specific resources needed.

Looking at incremental value: EU only.

The "Portfolio" perspective.

- EV vs. NPV
- Productivity
- Context

Takeaways

Create opportunity by thinking in general terms.

- Development of specific applications.
- Realization of "top-down" opportunities.

Make challenges to the alternatives up front.

Think creatively to reduce workload.

Maintain context for the decision-makers.