

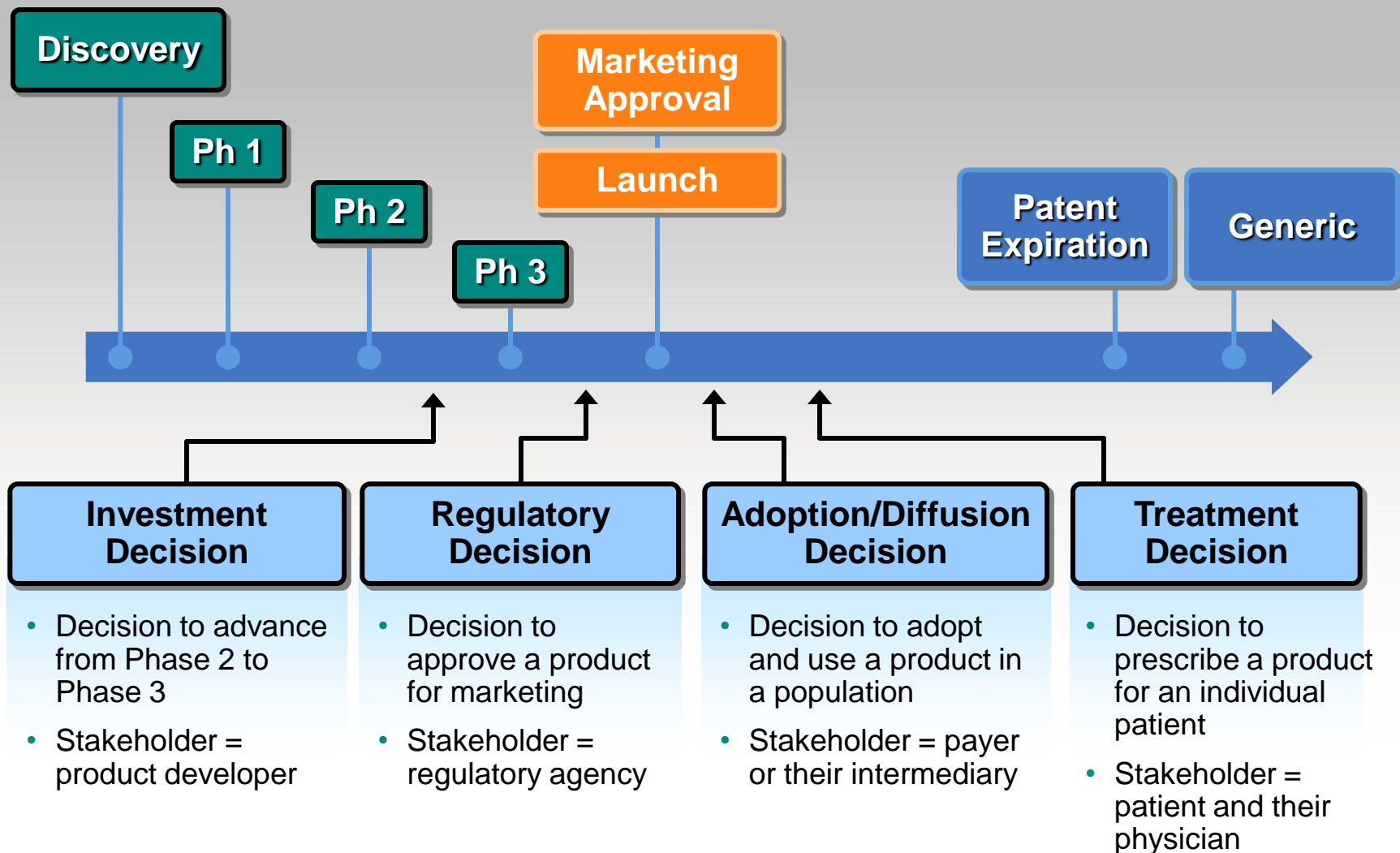
Panel 3

Business Implications of Comparative Effectiveness

Research with stratified populations

Newell McElwee, PharmD, MSPH
U.S. Outcomes Research
Merck & Co., Inc
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Key Decisions in the Lifecycle of a Pharmaceutical Product



Investment Decisions

- Phase 2 – Phase 3 investment decisions are informed by financial analyses (eNPV, real options, etc.)
 - Decisions based on opportunity costs for the portfolio
 - eNPV calculations historically based mostly on PTRS*
 - Best guess estimates of the probability of adoption and treatment use
- Increasing emphasis on more granular input for prediction of adoption/diffusion and treatment decisions
 - Simulation modeling to estimate the impact of policies such as CED on adoption/diffusion and eNPV (example follows)
- Need to minimize the risk (under uncertainty) of a:
 - *False Positive*: Developing something we can't sell
 - *False Negative*: Stopping development of a beneficial treatment

Bottom Line: Need More Accurate Estimates of eNPV

Simple Example of a Hypothetical “Asset” in the Investment Portfolio

Year	Expenses*	Revenue	Net	Phase
1	\$10	0	-\$10	1
2	\$10	0	-\$10	1
3	\$20	0	-\$20	2
4	\$20	0	-\$20	2
5	\$50	0	-\$50	3
6	\$70	0	-\$70	3
7	\$70	0	-\$70	3
8	\$50	0	-\$50	3
9	\$100	\$400	\$300	4
10	\$100	\$600	\$500	4
11	\$80	\$730	\$650	4
12	\$80	\$760	\$680	4
13	\$80	\$800	\$720	4
14	\$80	\$820	\$740	4
15	\$80	\$840	\$760	4
16	\$60	\$750	\$690	4
17	\$1	\$300	\$299	5
18	\$1	\$100	\$99	5
19	\$1	\$50	\$49	5
20	\$1	\$40	\$39	5

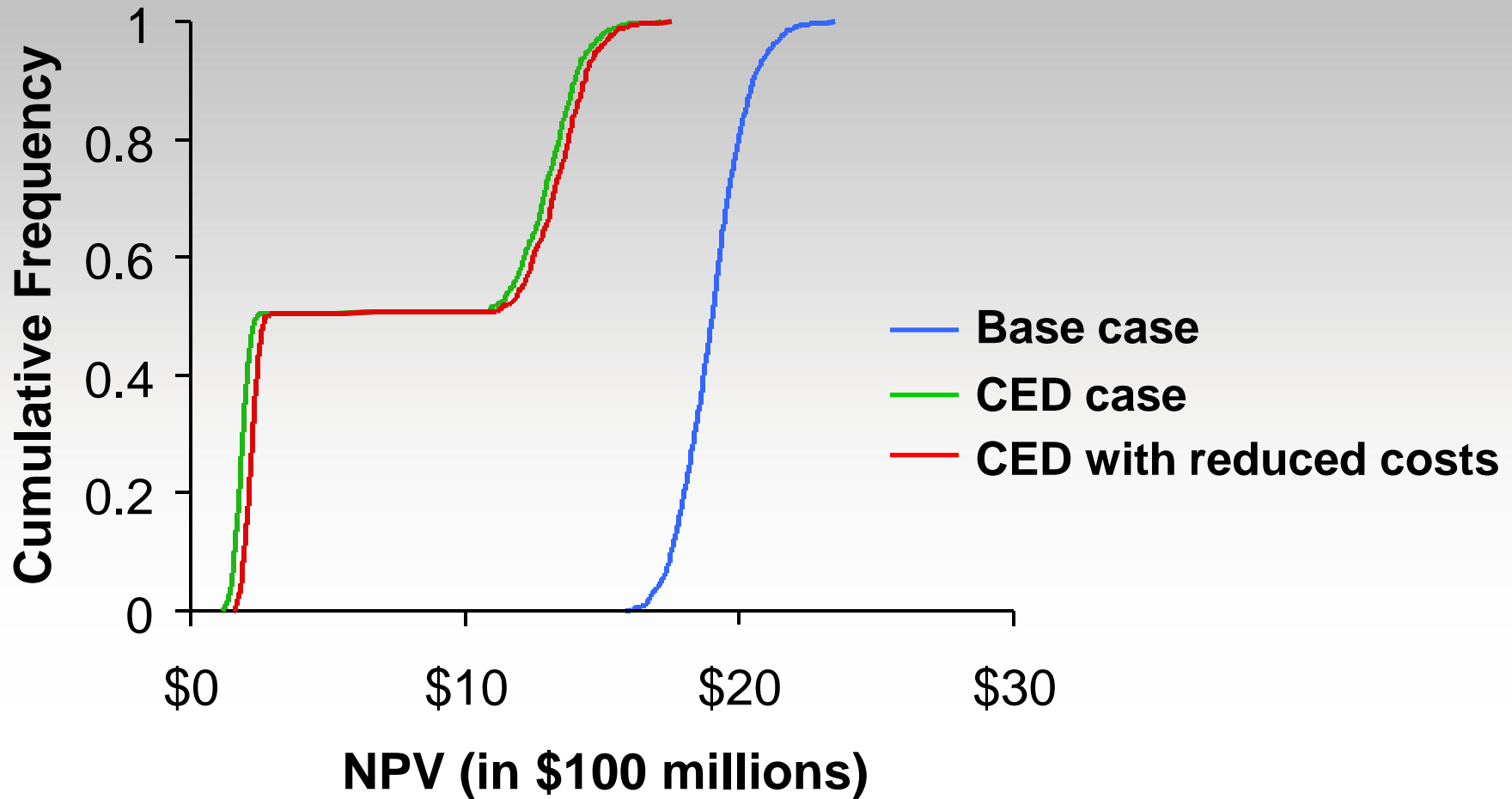
* \$ values in millions

** Values hypothetical, made up by me

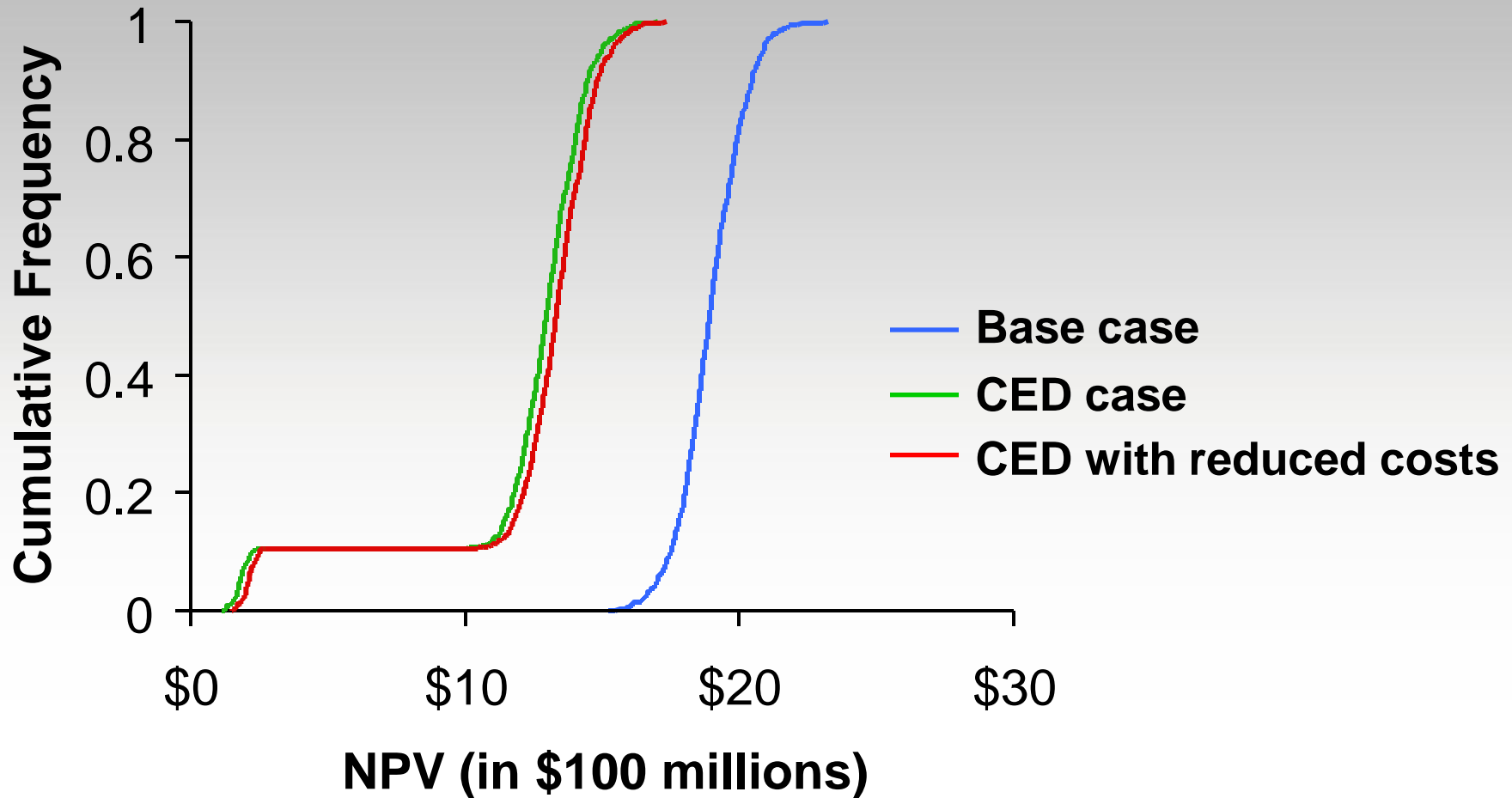
Brief Illustration: The Impact of CED on eNPV

- **Estimated Base Case eNPV* and the impact of Coverage with Evidence Development in years 9 - 11**
 - **Scenario 0 = Base case + probability of trial success of 0.5**
 - **Scenario 1 = Base case + probability of trial success of 0.7**
 - **Scenario 2 = Base case + probability of trial success of 0.9**
- **Winners get 5% “prize”, losers get 75% “penalty” in years 12 - 16**
- **Estimated the impact of more efficient drug development (production) costs for each scenario**
- **Monte Carlo simulation with 1,000 trials**

Scenario 0 (p trial success = 0.5)



Scenario 2 (p trial success = 0.9)



Conclusions

- **Loss of revenue during CED decreased eNPV from base case**
- **eNPV partially, but not completely, restored by better predicting “winners”**
- **Improved production efficiency had little impact on eNPV**

Treatment Decisions: Are you like the average?



Will “niche” indications decrease eNPV?

- Number of treated patients will decrease
- Effectiveness in treated patients will increase
- Value-based pricing could maintain economic value
- Additional value created by avoidance of adverse events in patients who are not treated because they are unlikely to respond

Niche indications will NOT NECESSARILY decrease eNPV