

## Crossing the Biotech-Pharma Chasm

June 17, 2009



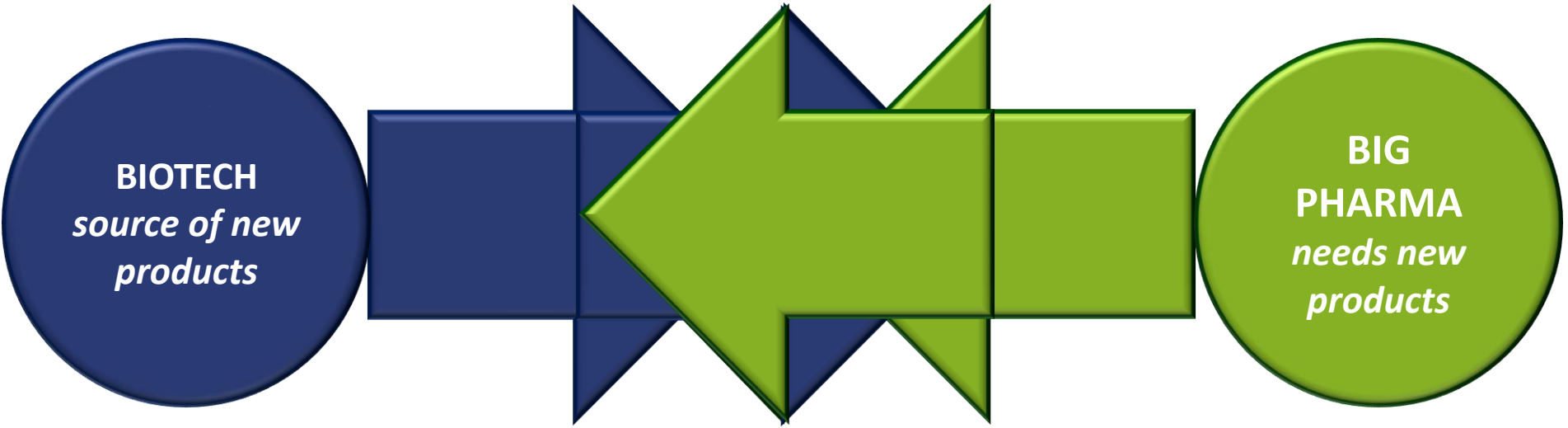
Presented by Harris Kaplan, CEO

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410-215-9595

- How Biotech and Pharma View The World
- What It Takes To Get A Deal Done in the World of *“He Who Hath the Gold Makes the Rules”*
- Steps Your Company Can Take to Assure You Get Maximum Value for Your Product Assets

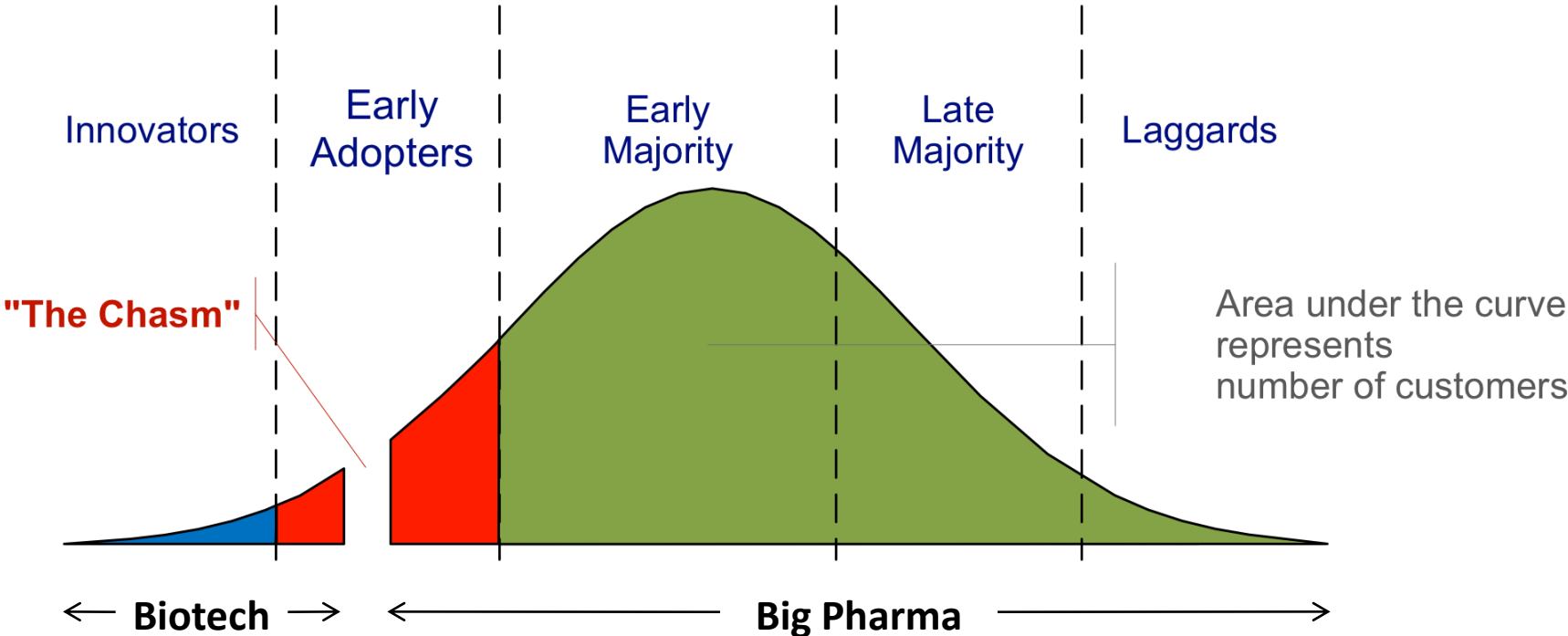
# In theory, biotech and pharma are completely symbiotic



*But it doesn't always work out that way!*

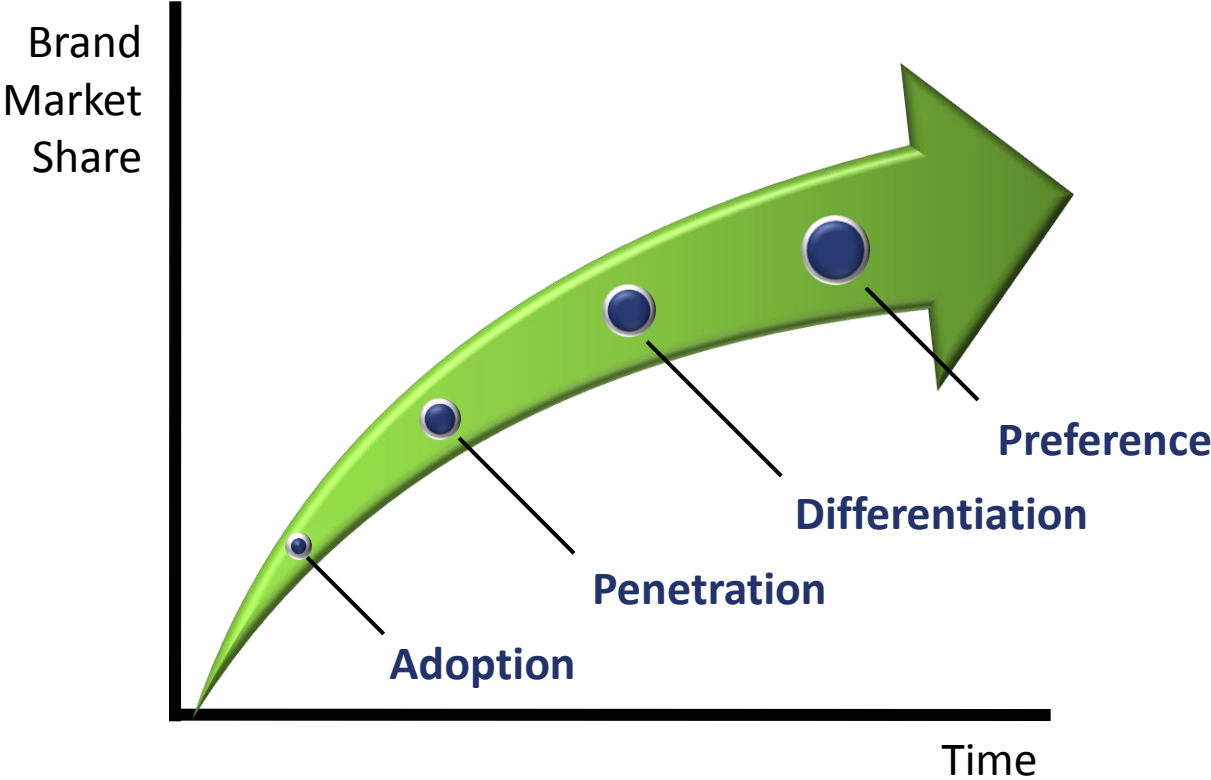
Biotech and big pharma have different perspectives when they view an opportunity...

Diffusion of New Product Innovation



...which impacts how they perceive future product value

**Cumulative Product Adoption / Revenues Over Time**

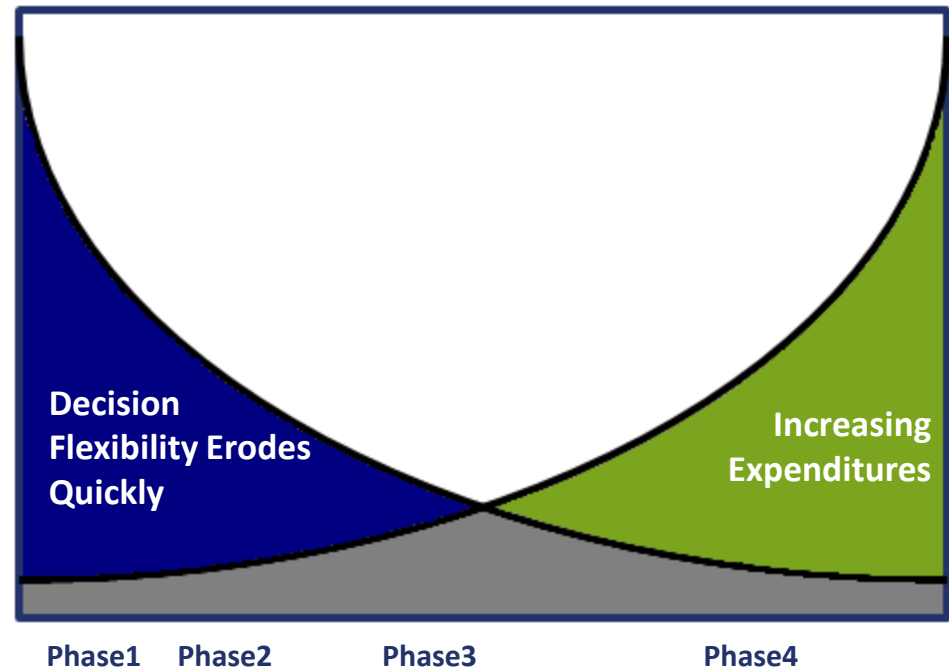


# Lessons Pharma Has Learned (Deal Making 101):

## The battle for market share is increasingly won prior to Phase 3

- Recognize that decision flexibility erodes very rapidly
- Getting a molecule back on track is expensive, time consuming, and significantly depreciates valuation and market potential
- Cannot recoup the cost of a suboptimal label with good marketing
- Pharma wants a partner who understands these points and has reflected these in their thoughts and actions
- At \$1B to get a drug to market, for pharma the choice simple:

### Long Term Product Value Gets Created Early



***Pay To Get It Right or  
Pay The Company Because They Got It Right!***

- A cashing out entrepreneur or VC is hardly objective about their product
- MOA probability of success is probably lower than you project
- Competition is usually smarter and further ahead you think
- A KOL is every company's friend and too much time and money gets spent drinking the KOL-Aid

# The higher the potential valuation, the more rigorous pharma's questions and process become

## Biotech

- MOA
- 95% of value is in the MOA
- Regulatory approval
- Science sells itself
- Let's get to first base
- Top-down valuation
- Analogue
- Up front payment
- Single product focus
- Sizzle sells stock

## Pharma

- What are the target indications?
- How much of the value is still to be created?
- What are the label and claims?
- What price and SG&A spend is required?
- Is this product a home run?
- Will physicians prescribe? Payers reimburse? Patients pay to use?
- What's the saleability at time of launch?
- What's the potential revenue and market share?
- How does this fit with our portfolio?
- How robust is this deal? –  
*Will this deal get me promoted?*

# As emphasis on external deals grows and deal prices continue to escalate, pharma is beefing up its due diligence process

- **Currently, many buy-side companies are organized by therapeutic category (in line brands through emerging)**
  - Emerging assets under-analyzed
  - Overpayment for external deals
  - Risk not fully appreciated
  - Pharma licensing and BD people rewarded for getting deals done
  
- **Buy-side beginning to reorganize to focus on emerging assets**
  - Dedicated personnel and budget
  - Detailed opportunity assessment
  - Clear go / no go criteria in advance of a deal
  - Move more quickly to decision and valuation
  - AZN, JNJ, PFE are examples

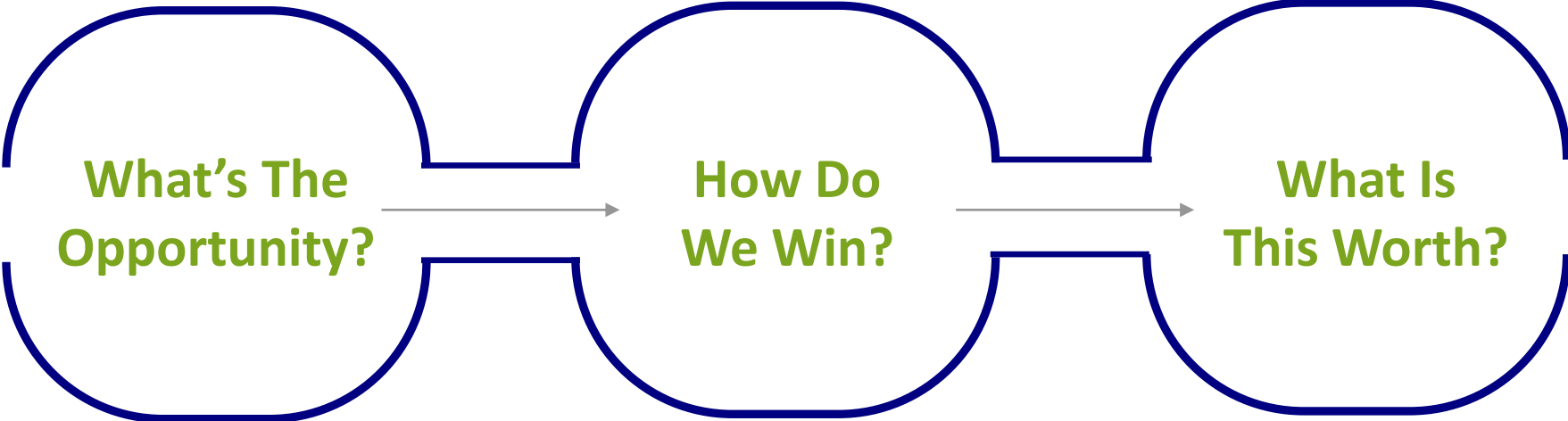
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# WHAT IT TAKES TO GET DEALS DONE

The logo for HEALOGIX is positioned on the right side of the slide. It features the word "HEALOGIX" in a dark blue, sans-serif font. The letter "O" is replaced by a blue circle with a white dot in the center. The logo is set against a background of two horizontal bars: a top bar in dark blue and a bottom bar in olive green.

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# You need to answer these critical business questions



## Market

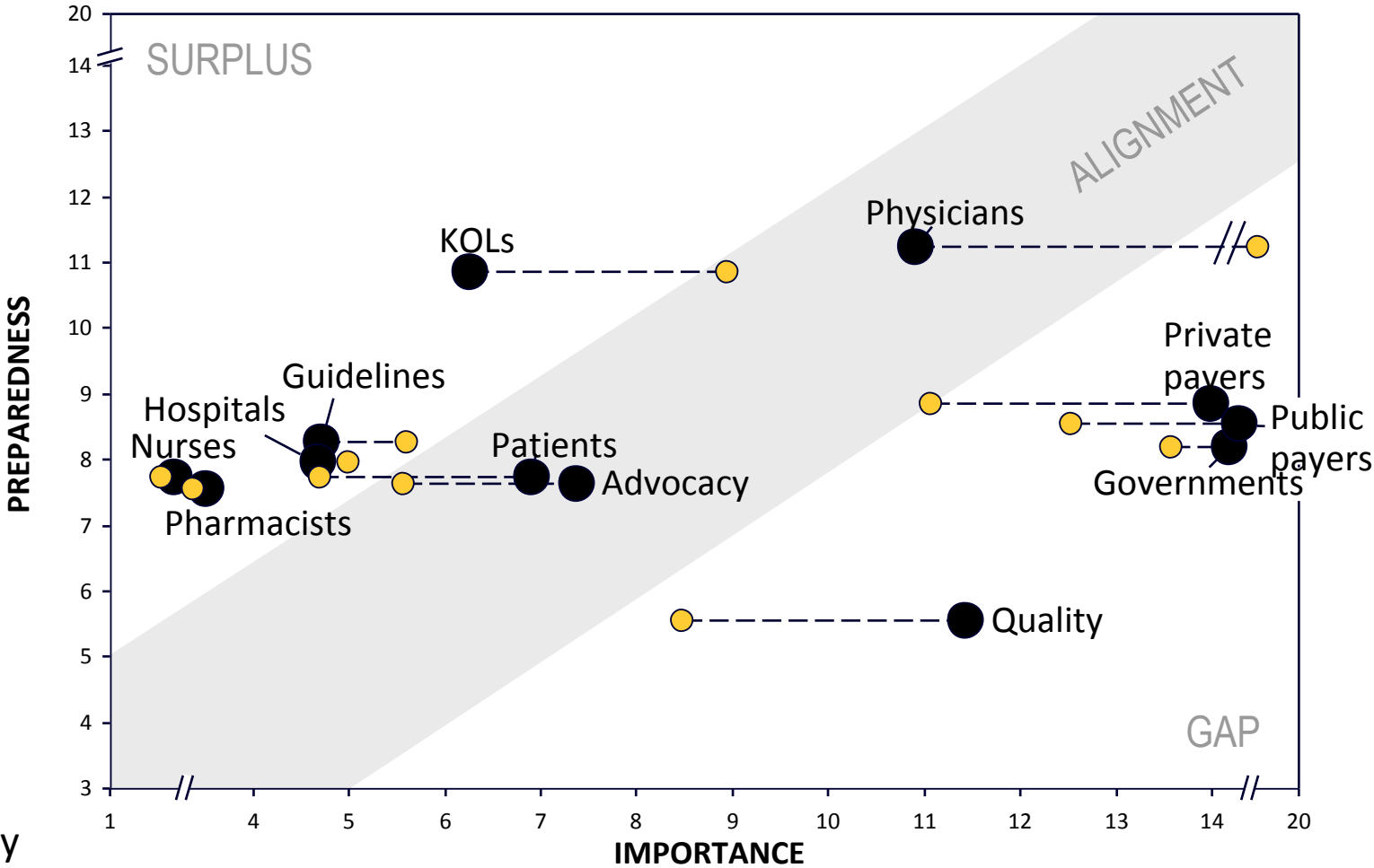
- How do you know the market will grow to be >\$X Billion?
- Won't the presence of other products in the market in 2012 impact sales potential?
- What is the impact of <BRAND> going generic?

## Your Product

- Why do you feel your product will be best-in-class?
- As you don't have Phase 3 data yet, why can't I wait until you do to consider partnering/buying?
- What are the barriers to prevent a later entrant from stealing market share after you've built the market?
- How will this product perform if it is awarded Tier 4 status with a step edit or PA required before it can be used?

# How well will your product perform in the new landscape?

Stakeholder Importance vs. Industry Preparedness, In 2 – 3 Years\*



\*Source: Capgemini

# Pharma wants partners with an aligned vision and realistic sense of value

- Realistic appraisal of MOA success
- Realistic estimates of market potential, pricing, and reimbursement strategies based on direct external stakeholder input: credible and anchored in the future
- A revenue forecast with transparent and customer based assumptions
- Clinical plan tied to commercially valuable endpoints
- Clear perspective on the strengths and weaknesses of future competition
- Longer term development plan to fully exploit the value of a compound

“

*What we're looking for are partners who can clearly show us the value they want us to pay for...  
We dislike opacity and fear buying blind...*

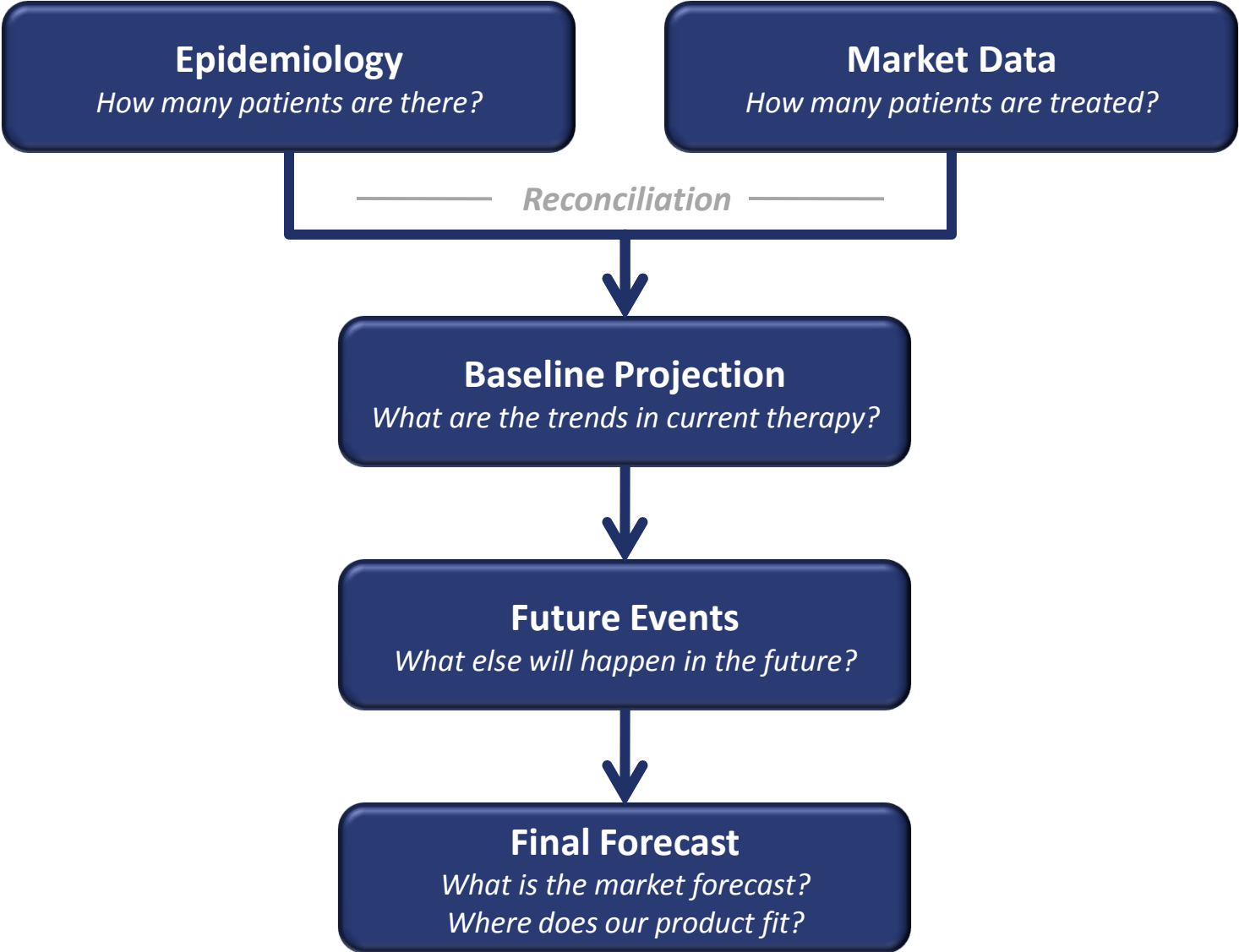
**James Hall, VP CVGI Emerging AZ**

“

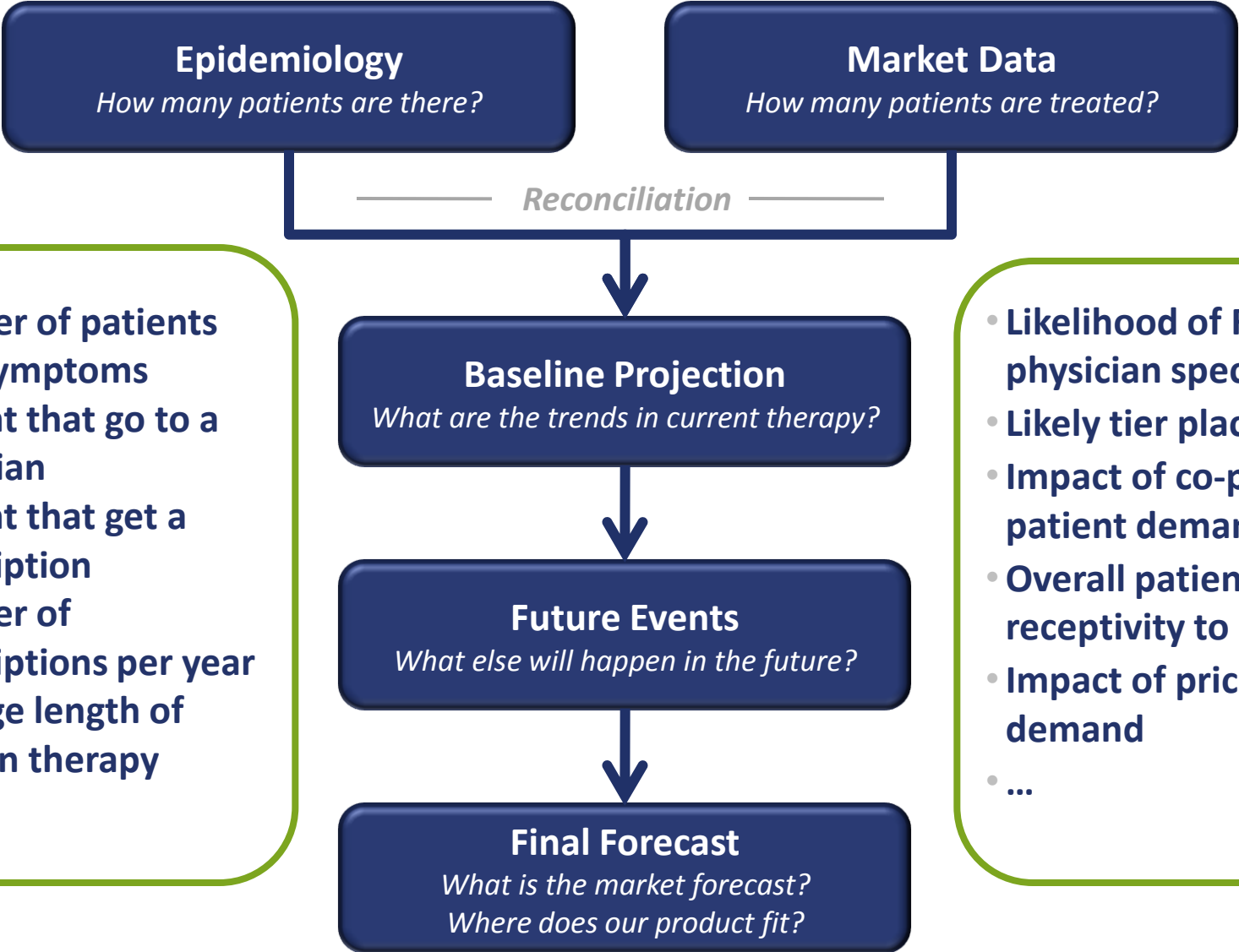
*There have been certain deals that we've looked at, where the company had valuations in mind that we just didn't think the product could support...*

**Deborah Dunsmire, CEO Millennium Pharmaceuticals**

# A standard forecasting template — what's missing?

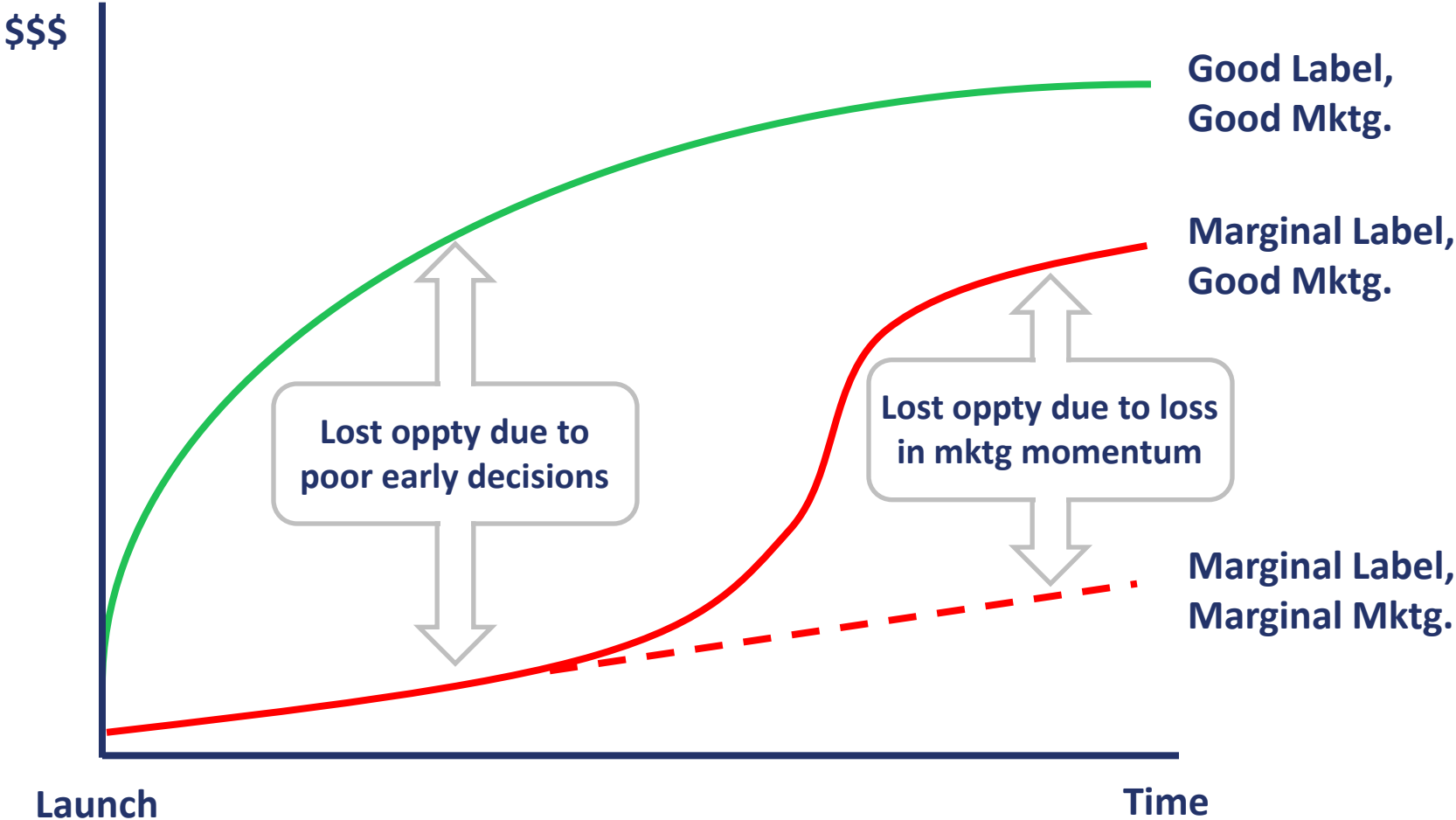


# Forecasting: The devil is in the details



To pharma, it's not about up-front payments – it's about downstream royalties and total deal value

A Variety of Deal Value Scenarios



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# STEPS YOU CAN TAKE TO MAXIMIZE YOUR VALUE

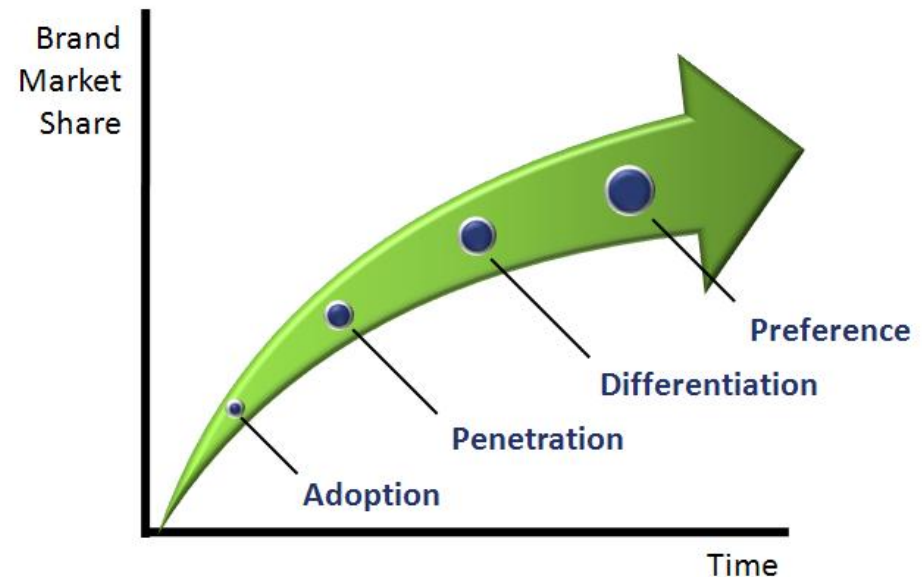


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# The best offense is a good defense

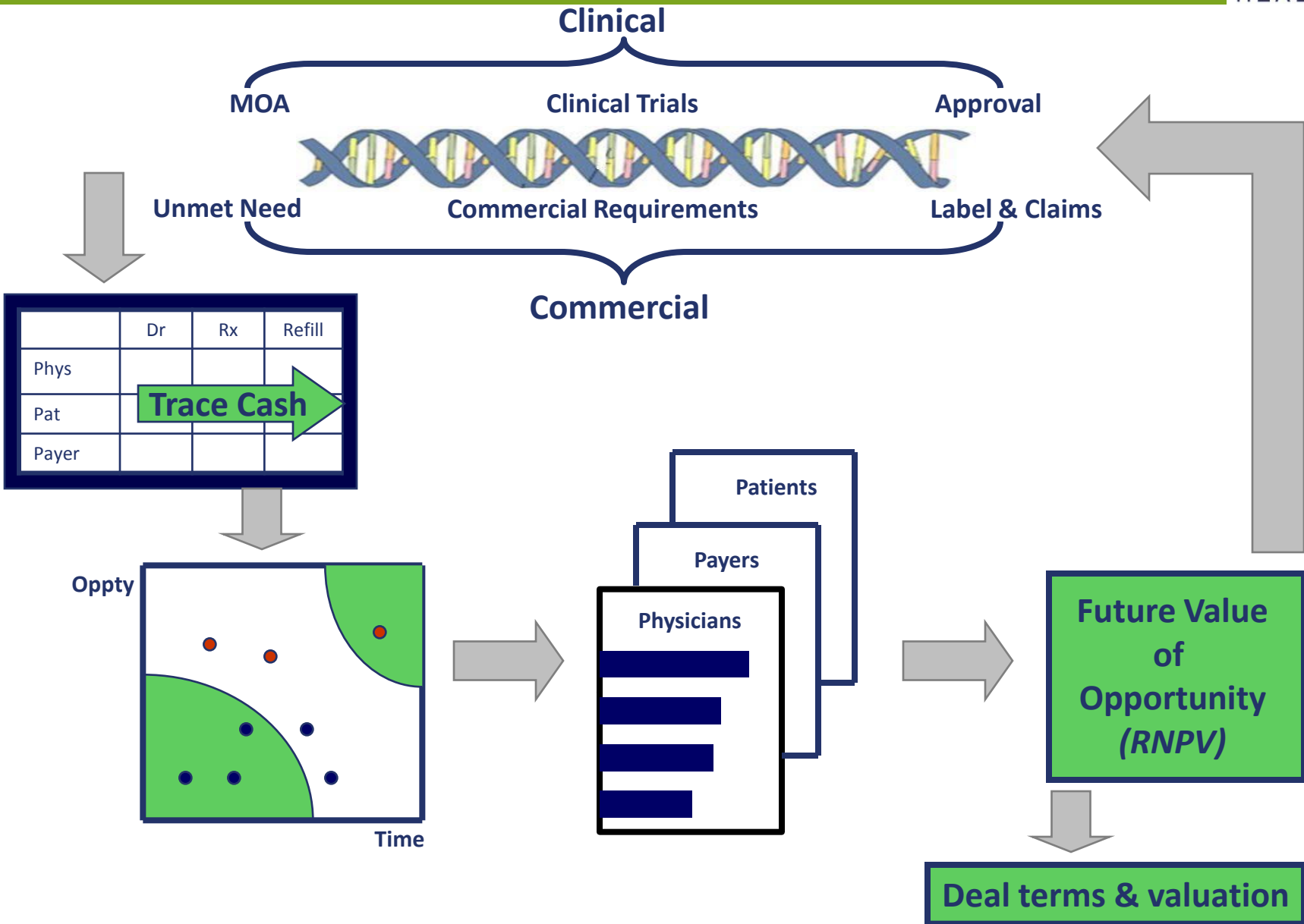
- Get an objective and projectable view of your product from the perspective of the customer
- Fast forward your thought process to the time of market entry
- Pretend you were marketing the product

## Cumulative Product Adoption / Revenues Over Time



***You will be a better negotiator, better judge of prospective partners, and a better partner.***

# Doing your own due diligence: Begin with the end in mind and work backwards

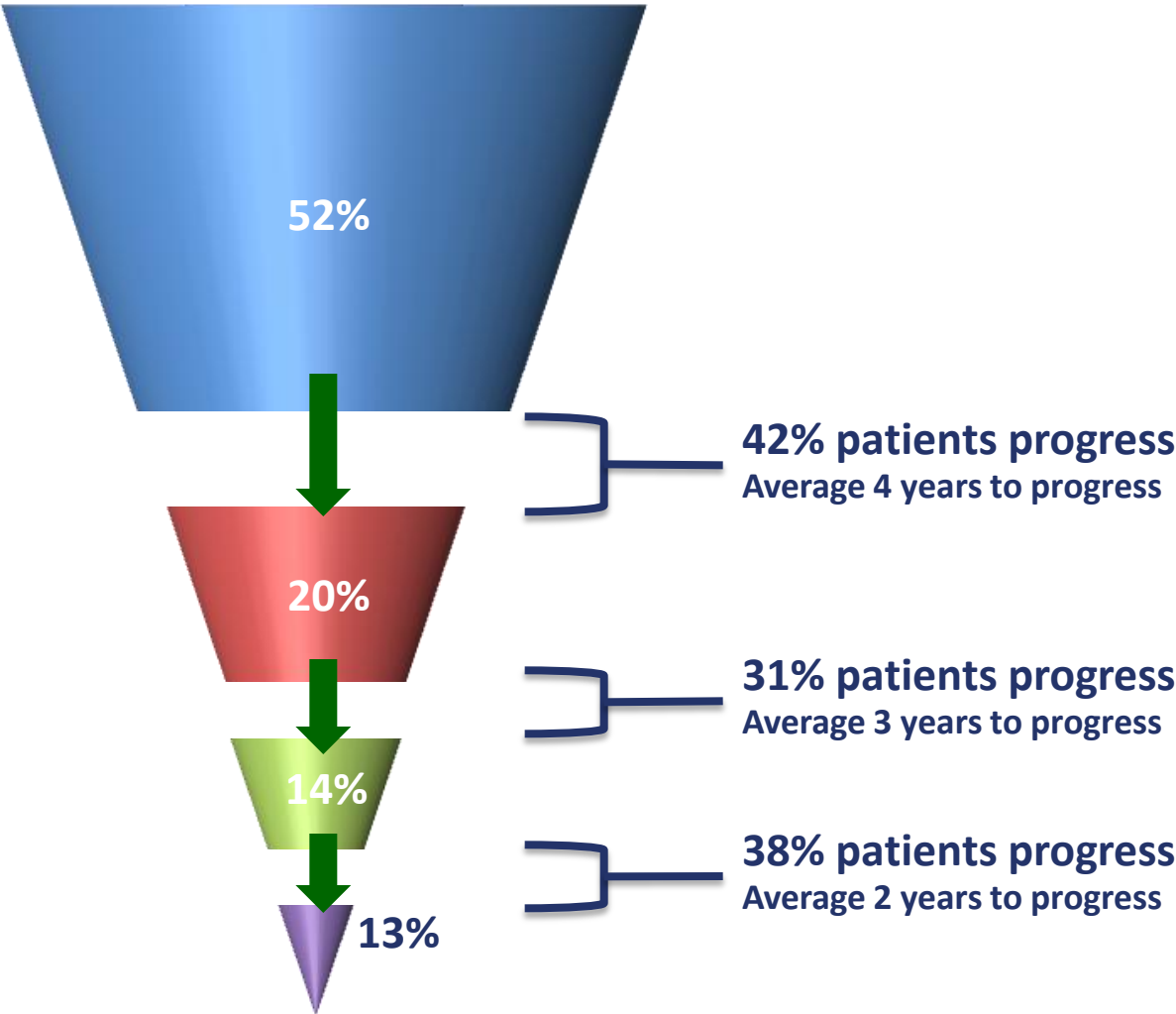


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# REAL PROOF: DIABETIC RETINOPATHY

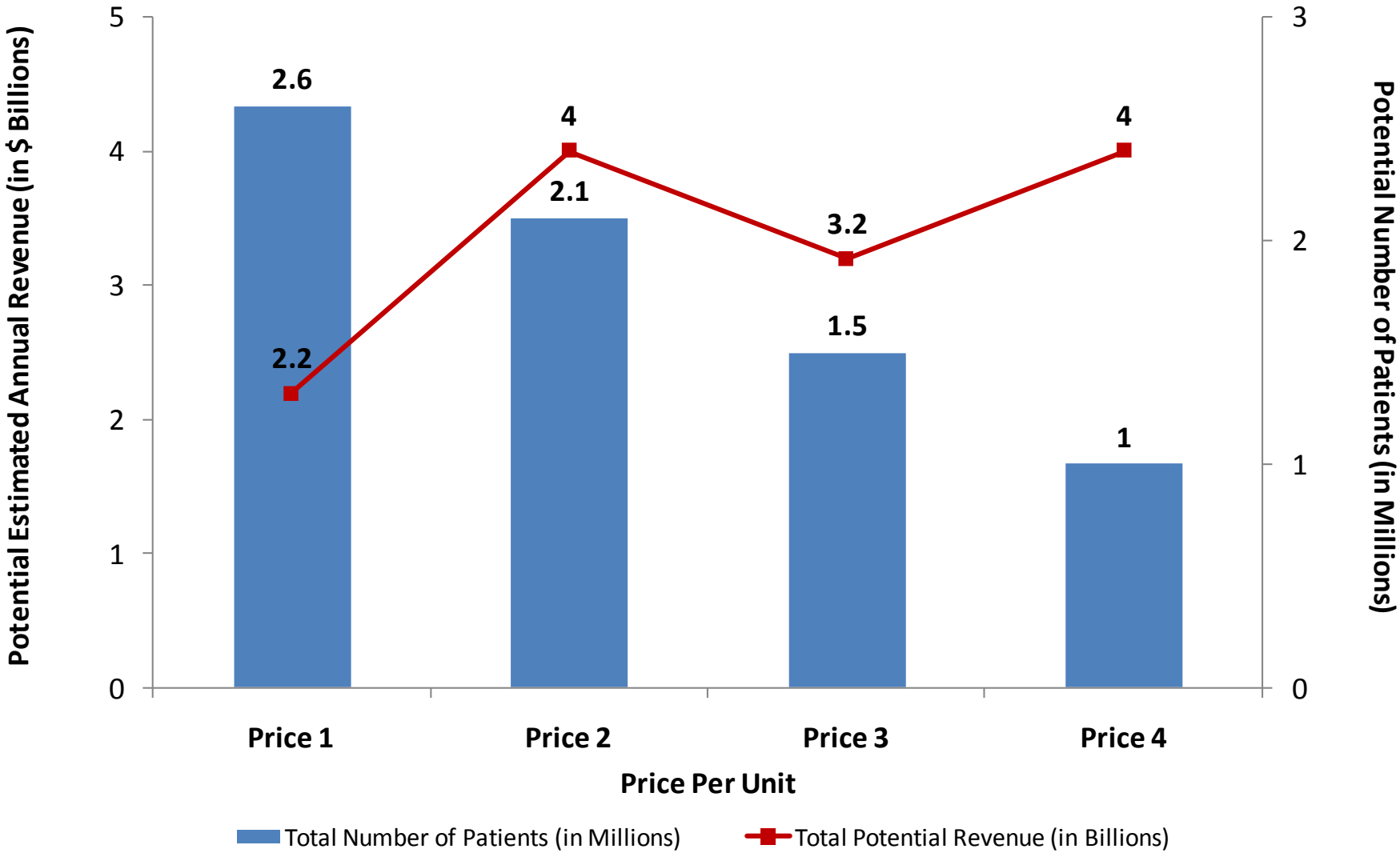
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Determining which patients are part of the treatable patient population is the first task that has to be accomplished.



■ Mild Non Proliferative ■ Moderate Non Proliferative ■ Severe Non Proliferative ■ Proliferative

# And a larger target population doesn't necessarily translate to higher potential revenue



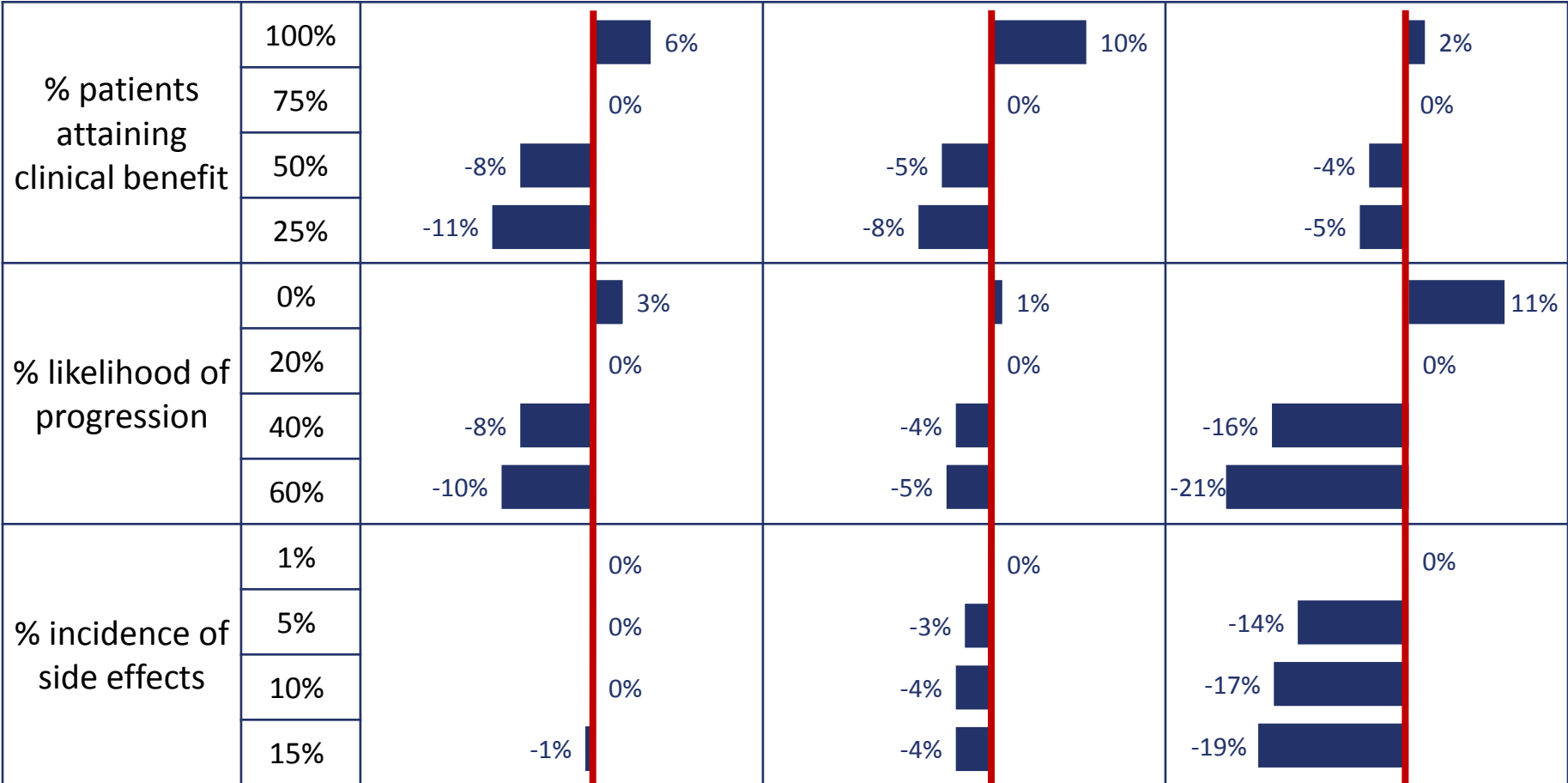
# How a miss on clinical endpoints impacts baseline uptake

*(what are the key drivers and how much downside protection do we have?)*

## PHYSICIAN

## PATIENT

## PAYER



Baseline  
40%

Baseline  
70%

Baseline  
80%

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# REAL PROOF: RHEUMATOID ARTHRITIS

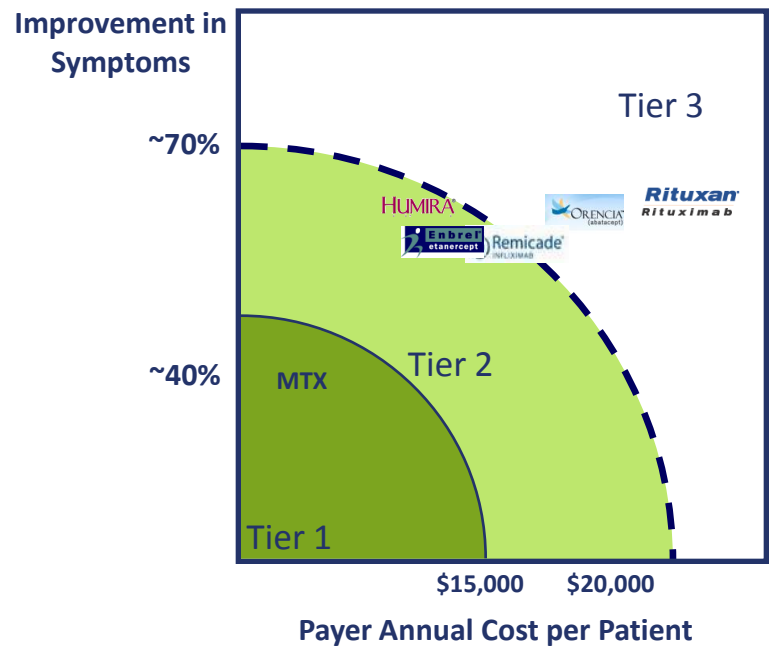
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# The devil or the opportunity is in the details

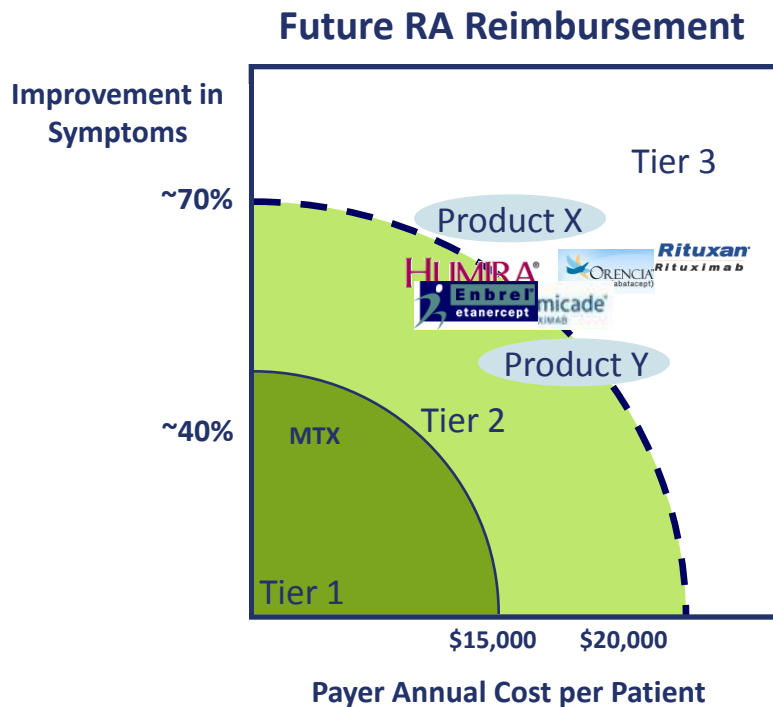
- The cost of RA treatment continues to grow (\$15,000-\$20,000/patient/yr)
- Currently, few access restrictions on Anti-TNFs in the US
- Most Anti-TNF agents are either on Tier 2 or some mode of capped co-payment (20% up to \$2,500)
- Drugs like Orenzia & Rituxan are typically on Tier 3

## Current RA Reimbursement



*What will happen when two new TNF competitors enter the market?*

# Similar competition increases leverage of payers relative to product manufacturers



- Payers
  - Requiring MTX use before Anti-TNF
  - New plan design – Higher co-payments to patients (the new payer)
  - Step edit – one or two TNFs on tier 2, lower prices
- Market size drops by about 30%

# So let's assume your company has a new oral compound for the treatment of RA

- What are some of the key commercial questions?
  - Where does this product fit relative to current treatment?
  - What is the appropriate efficacy / side effects / dosing / price required to occupy that position?
  - Who is the candidate patient(s)?
  - What assumption do we make about co-payments from patients?
  - How does our compound compare vs TNFs? Vs other orals?
  - What claims can we make that would support our positioning and competitive differentiation?
  - How does our clinical trial or outcomes strategy support that requirement?
  - What's the required investment? What would peak year sales be? How fast would this product ramp?

# Companies having gone through the process make hard & expensive decisions with confidence

## Company Situation

## Company Action

<b>Opportunity assessment and definition of entry criteria into major primary care market</b>	Resulted in joint development & marketing deal valued at over \$1B
<b>Client considering several new additional product enhancements in oncology market</b>	One of potential opportunities moved forward, others were no/go
<b>Client had phase 2 compound in CV market for severe condition</b>	Client decided not to move forward with phase 3 development
<b>Client evaluating several fixed dose combinations in view of impending generic competition</b>	Resulted in a co-development deal to create a FDC that will be introduced in 2009
<b>Client evaluating next generation product in CNS market - licensing deal in process</b>	Client made decision to not move forward on licensing deal
<b>Client needed to develop clinical endpoints and pricing for new product for oncology</b>	Identified potential of wrong comparator being used for one tumor type  Identified significant price upside given development strategy

- MOA and breaking science are necessary but no longer sufficient
- It's increasingly about indications, label & claims, pricing, marketing and market access
- The battle for market share is won/lost prior to Phase 3
- The best offense is a strong defense
  - Know your customer's customer
  - Don't underestimate your competition
  - Don't underestimate big pharma
- Big pharma will pay to get it right or will pay you because you got it right

- He who hath the gold makes the rules.
- Gain an understanding of what it will actually take to commercialize your product...

*before you develop your pivotal trial strategy!*

*before you begin your partnering negotiations!*

- Being “smart” about your product only enhances the probability of a successful negotiating outcome

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