

# Feasibility study of investing in innovative pharmaceutical products

**Workshop on Innovation Commercialization and Entrepreneurship**

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# Feasibility study and innovation



Viability



Feasibility (Technical)



Desirability



# What is feasibility study trying to answer?

“Is it feasible?”

“Is it possible?”

“Is it worth pursuing?”



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# What factors could impact the results?



What is an alternatives being compared?



What is the perspective of the analysis? Or “Who would use the results?”



What is the time horizon of the project?



Feasibility study depends a lot on assumptions (guesswork).



Bad assumptions means uninformed decision making by those who use the data.

# Who are the users of feasibility study?

- Public decision maker

Question:

Should I fund this innovation?

What is the overall impact of this innovation?

Perspective employed:

Societal perspective

- Entrepreneur/Private

Question:

Is this innovation viable from a business perspective?

Perspective employed:

Company/Investor/Venture Capital  
Lender (Bank)

# Major components of feasibility study

1

## ***Product feasibility***

Can the product work?  
Does this product respond to consumer's need?

2

## ***Market feasibility***

Does the product has market?

3

## ***Organization feasibility***

Does the organization has sufficient skills and resources to bring a product to market successfully?

4

## ***Financial feasibility***

How much is an investment?  
What is the financial performance of this business?

Other components e.g., Social and environmental considerations

# Product feasibility

- HIV Prevention tools
  - Use of condom



# Target Product Profile (TPP)

- first used in 1997
- A mean to **improve sponsor and FDA interactions during the drug development process**
- **beginning with the goal in mind**
- the goals of the drug development program
- documents the specific studies intended to support the labeling concepts
- **The use of the TPP has evolved**
  - not only facilitate the dialogue between the sponsor and the FDA
  - but with other stakeholders (such as **physicians and payers**)

## **Guidance for Industry and Review Staff Target Product Profile — A Strategic Development Process Tool**

*Additional copies are available from:*

*Office of Training and Communications  
Division of Drug Information, HFD-240  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857  
(Tel) 301-827-4573  
<http://www.fda.gov/cder/guidance/index.htm>*

**U.S. Department of Health and Human Services  
Food and Drug Administration**



Product class:	
Product name:	<i>To be completed once product approaches phase 2b</i>
Date of TPP endorsement	
Dates of TPP revisions	

	Desired		Minimally acceptable		“Insert Product Name” profile (Completed as product approaches phase 2b)	
	Target	Rationale	Target	Rationale	Target	Rationale
Indication						
Expected efficacy						
Target population(s)						
Route of administration						
Formulation & presentation						
Dosage schedule						
Safety profile						
Co-administration						
Shelf-life & storage						
Manufacturability						
Price						
Product registration and WHO prequalification						

- ***Desired: Best case***
- ***Minimally acceptable: Worst case***
- ***The product: Acceptable***
- Factors are different based on the product
- The factors would effect the pricing strategy of the product

# TPP for vaccine product (1)

Bruce Y. Lee, Kristina M. Bacon, Angela R. Wateska, Maria Elena Bottazzi, Eric Dumonteil & Peter J Hotez (2012)  
Modeling the economic value of a Chagas' disease therapeutic vaccine, Human Vaccines & Immunotherapeutics, 8:9,1293-1301

**Table 2.** Desired and minimally acceptable target product profiles (tpps) baseline assumptions for desired and minimally acceptable vaccine targets

Input parameters	Desired TPP	Minimally acceptable TPP
<b>Target population</b>		
Age	Children (> 2y)	Adults (> 16 y)
Disease Stage	Indeterminate	Indeterminate
<b>Vaccine characteristics</b>		
Cost (all doses)	\$46	\$200
Indication	Prevent cardiomyopathy	Delay the onset of cardiomyopathy
Efficacy	80%	80%
Dosage	One-dose	Two-dose
Duration of protection	Lifetime	Lifetime
Delay of cardiomyopathy	-	10 y
<b>Side effects</b>		
Urticaria	0.001%	0.1%
Carditis	0%	5%
Vaccine induced cardiomyopathy	3%	3%

# TPP for vaccine product (2)

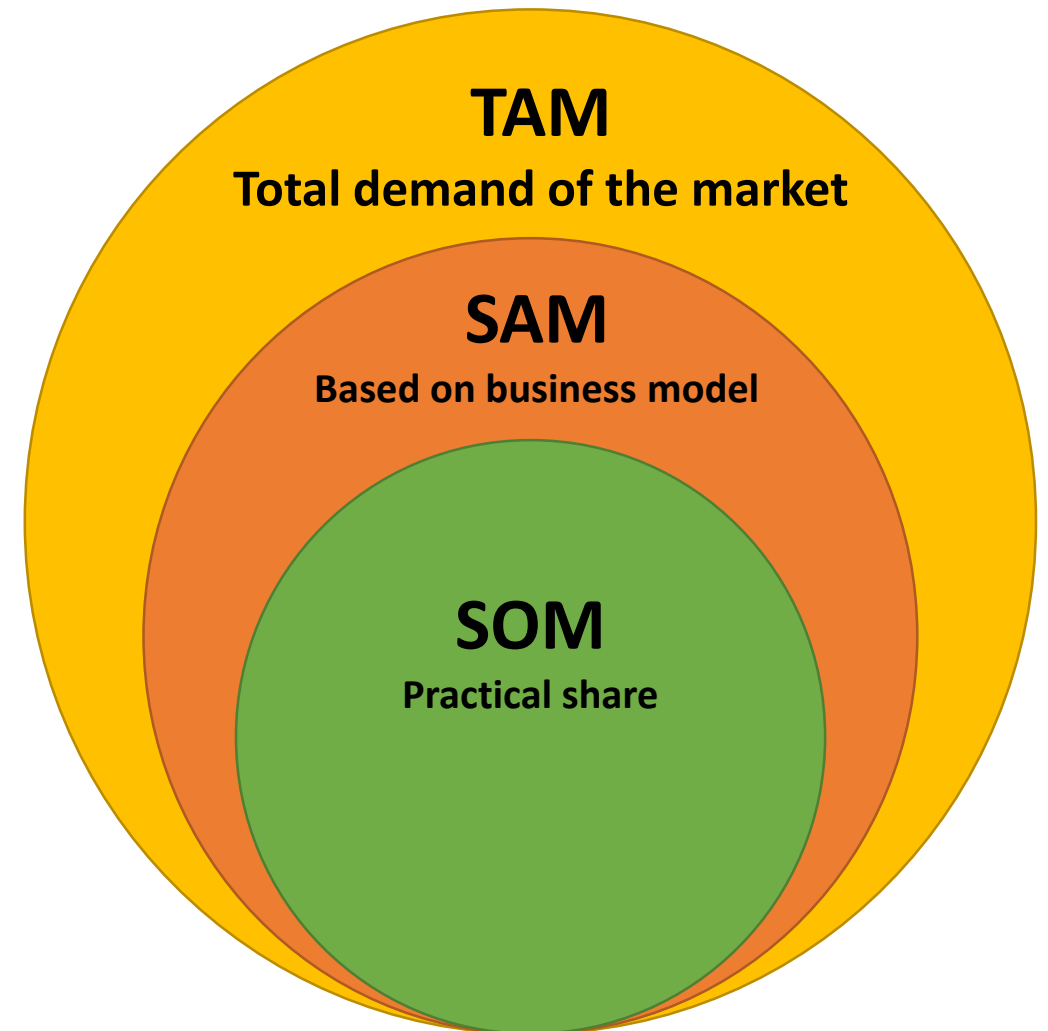
Mahmood, Kutub, et al. "Hexavalent IPV-based combination vaccines for public-sector markets of low-resource countries." *Human vaccines & immunotherapeutics* 9.9 (2013): 1894-1902.

**Table 1.** Target product profile (TPP) for a IPV based hexavalent vaccine for developing world markets

Product profile		Hexavalent pediatric combination vaccine for public market in developing world		
Disease area		Pediatric infectious diseases		
Possible Franchise		EPI routine immunizations		
Possible concomitant vaccinations		EPI schedule (BCG, measles), MenAfrivac, Quadrivalent Meningococcal conjugate, pneumococcal conjugate or common protein pneumococcal vaccine, measles, mumps, rubella, rotavirus		
Indication		Prevention of diseases caused by <i>C. diphtheriae</i> , <i>B. pertussis</i> , <i>C. tetani</i> , <i>H. influenzae</i> type b, Hepatitis B virus, polio viruses type 1, 2, 3		
Targeted segments of population		Immunization of infants under 1 y of age with primary series, may be followed by booster in second year of life		
Business case		Worst case	Acceptable	Best
Claim 1		D, T, Hib, HBV responses inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV only after booster	D, T, Hib, HBV responses after 3 dose primary series not inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV	D, T, Hib, HBV responses after two dose primary series not inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV
Claim 2		PT, FHA, pertactin response inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV only after booster	PT, FHA, pertactin response after 3 dose primary series not inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV	PT, FHA, pertactin response after two dose primary series not inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV
Claim 3		Polio response inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV only after booster	Polio response after 3 dose primary series not inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV	Polio response after two dose primary series not inferior to current pentavalent vaccine (wP or aP as appropriate) plus separate IPV
Safety/contra-indications		Serious AE's more frequent than individual components given together	Serious AE's no more frequent than components given together	Serious AE's less frequent than components given together
Tolerability		Mild to moderate AE's more frequent than individual components given together	Mild to moderate AE's no more frequent than individual components given together	Mild to moderate AE's less frequent than individual components given together
Delivery route		IM	IM	IM
Dosing regimen		6, 10, 14 weeks of age with more booster(s) required in second year of life	6, 10, 14 weeks of age with optional booster in second year of life	6, 10, weeks of age with optional booster in second year of life
Presentation		1 mL, dual chamber syringe	0.5 mL full liquid or liquid/lyo, pre-filled syringe, single dose vial	0.5 mL full liquid, pre-filled syringe, Uniject®, or multi dose vial, can use jet injector
Stability storage		≤ 2 y, 2–8°C	2 y, 2–8°C	≥ 3 y, 2–8°C + 2–25°C last 1–3 mo
Use setting		Same as EPI	Same as EPI	Same as EPI

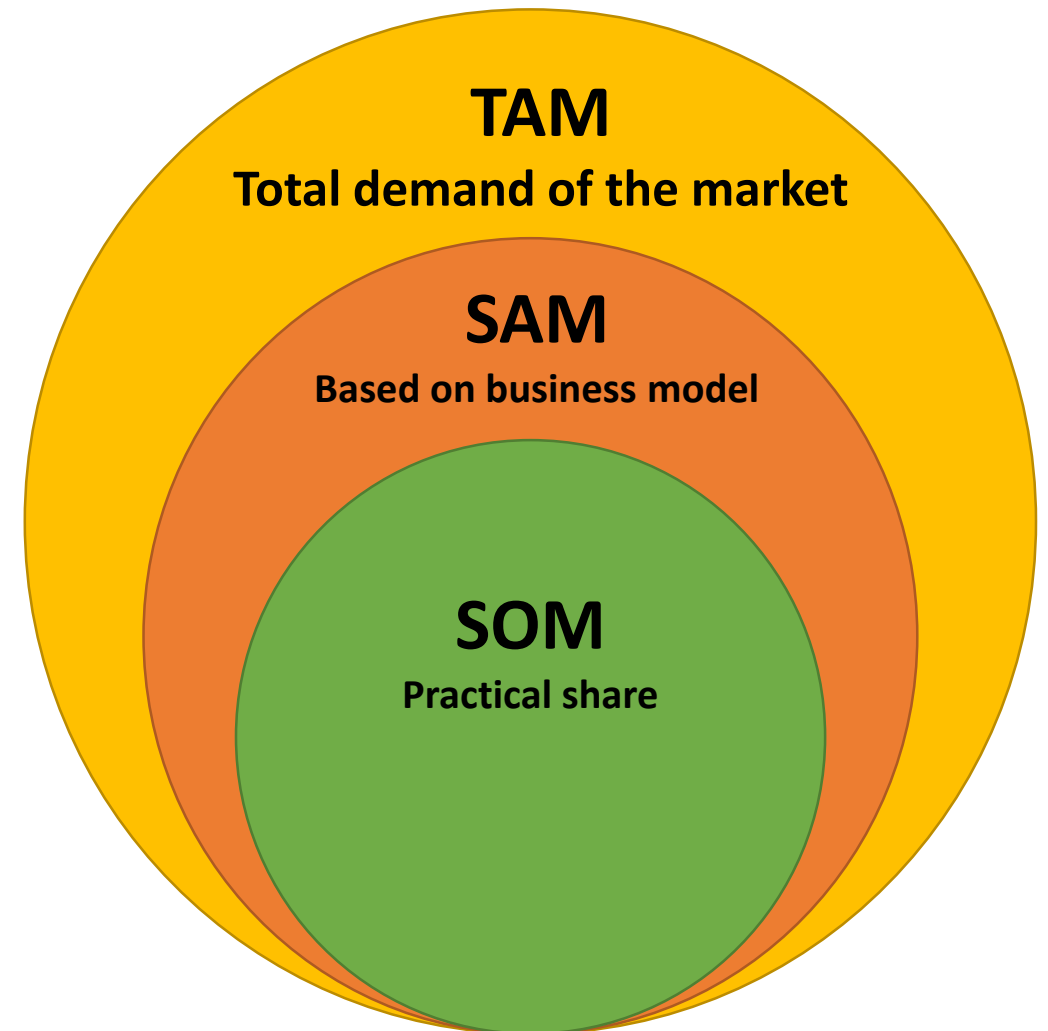
# Market feasibility: Is there a market for the product?

- Customer segments on business model canvas
  - **TAM** = Total Available Market
  - **SAM** = Segmented Addressable Market
  - **SOM** = Share of the Market
- Industry attractiveness
- Market timeliness
  - First mover
  - Second mover
  - Late mover



# Organization feasibility

- Non-finance aspects on feasibility
  - Management ability
  - Resource sufficiency
- **Determine your SOM** = Share of the Market
- Practical share that is feasible for your organization



# Financial feasibility

- Objective:

To test whether the project's return will exceed opportunity costs



- The feasibility study estimates value based on market prices
- Some feasibility studies weigh social costs and benefits in addition to monetary values.
- The results should also help identify potential risks and criteria for success.

# What do we need to know in financial feasibility?

## **What is normally need for project's financial performance?**

- Capital requirements
  - Total start-up cash needed
- Rate of return
  - Internal Rate of Return (IRR)
  - Net present value (NPV)
- Break even points

## **What is also important?**

- Project Cash flow
  - Expected cash inflows
  - Expected cash outflows



## Entrepreneurial

- The financial feasibility as required factor to obtain a sufficient capital in relation to the financial need covering.
- The profitability as necessary result in relation to the survival and development of the business.

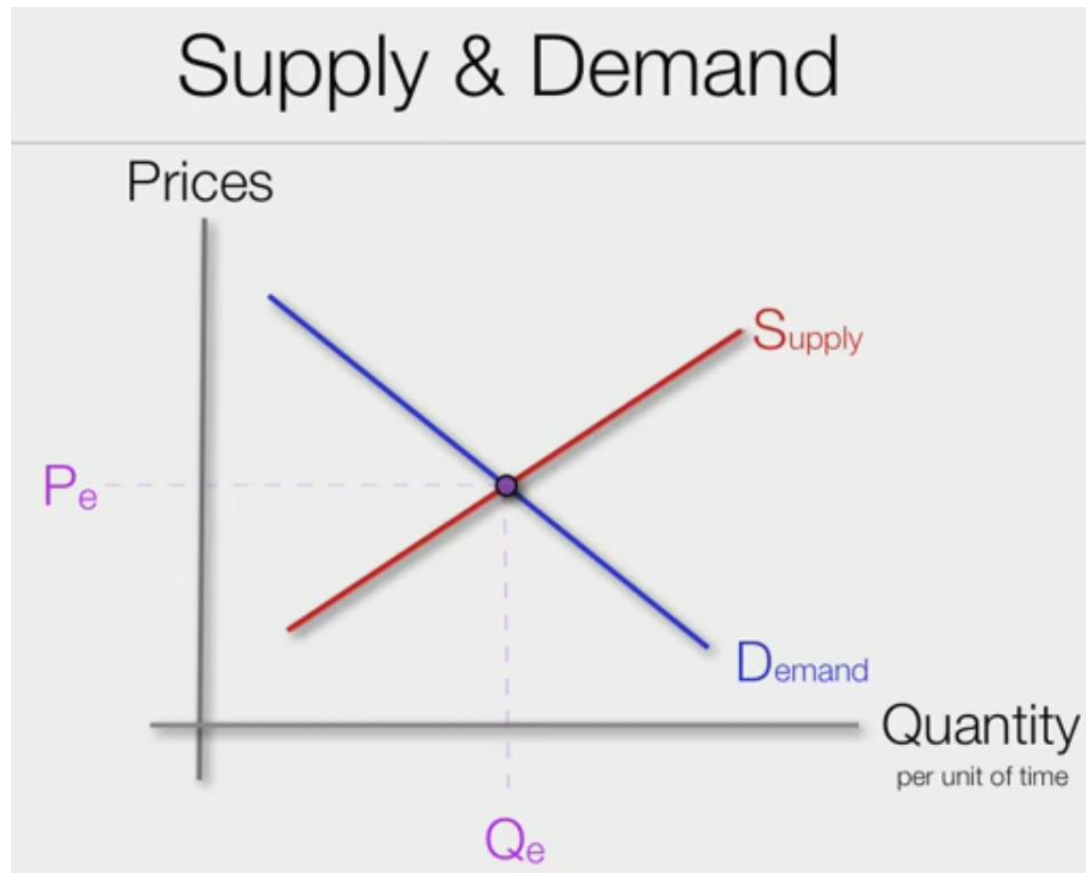


## Investor

- Project capacity to reward the initial investment within a certain period.



# Two categories of data needed for financial feasibility analysis



- Supply: How would we produce the product we would like to produce?
- Demand: Who would we sell the product to at what price and how many people would buy it?

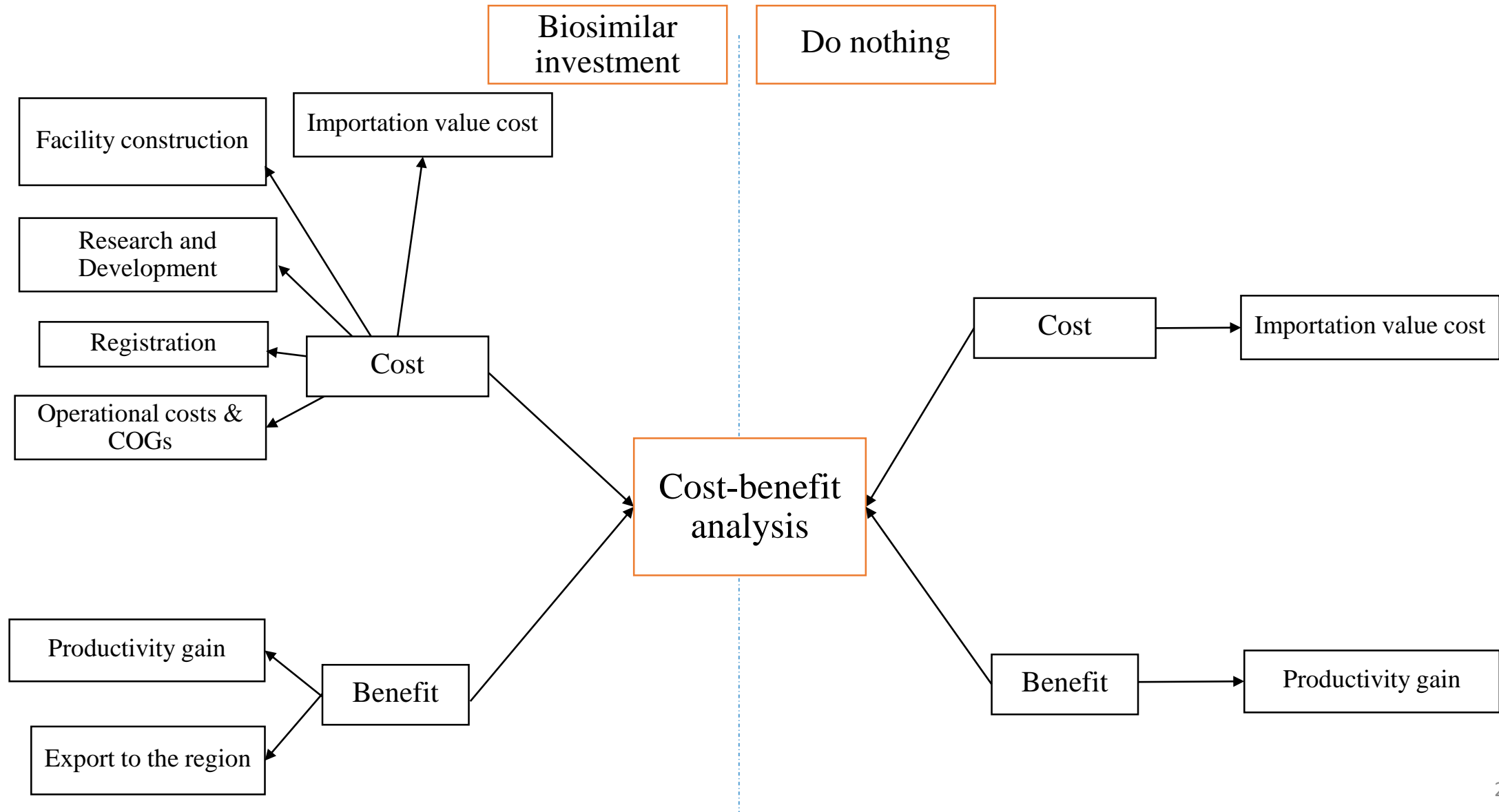
# What we need to know before conducting financial feasibility?

- What product?
- Planned supply: How much to produce? Batch size?
- How to produce? Or How to get the product out to the market?
  - Build a plant for that specific product (from upstream to downstream)
  - Build a plant for that specific product (from downstream)
  - Get a contract manufacturing organization produce the product under your brand
- What activities are needed for product to be marketed?

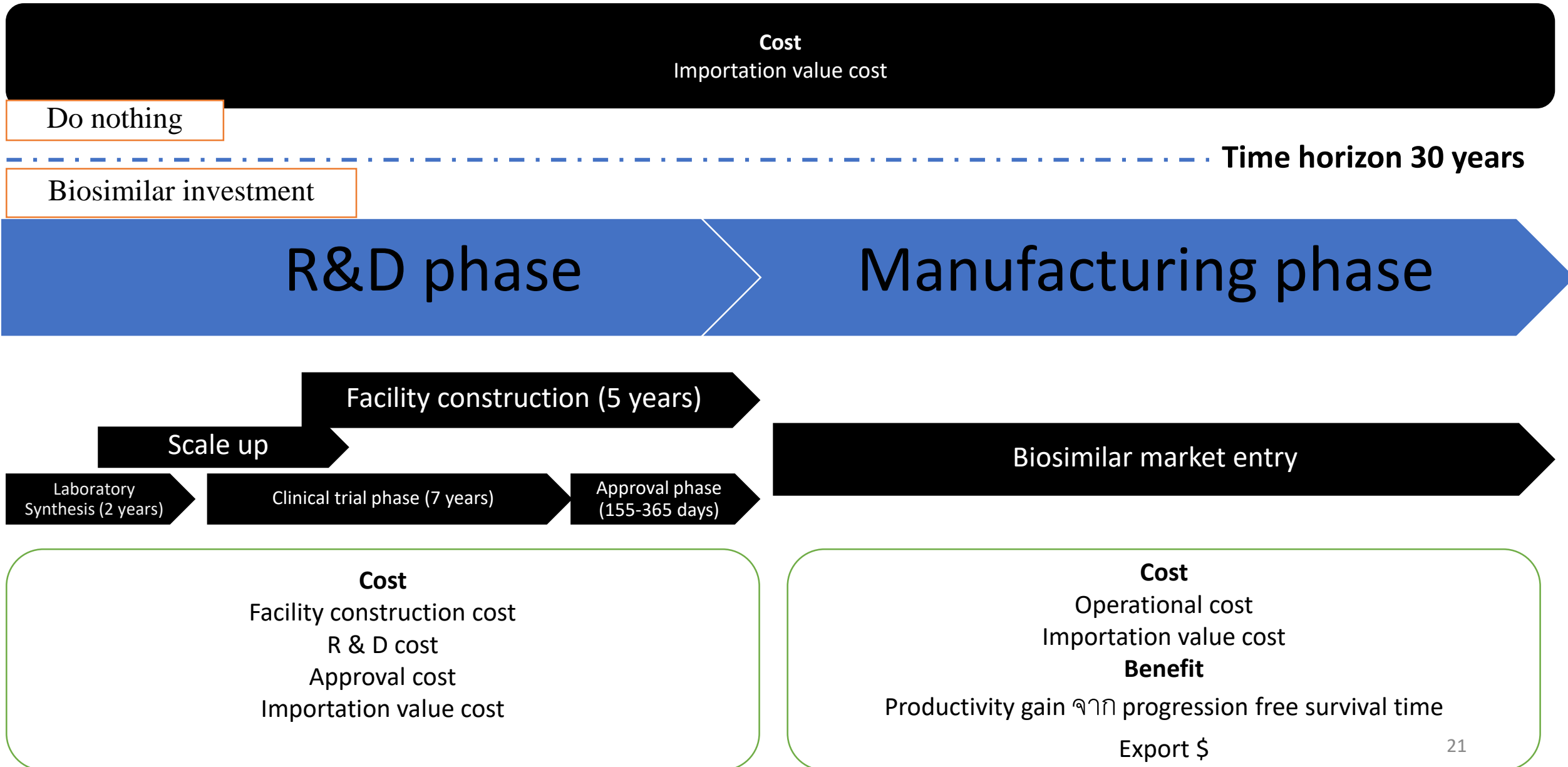
# Case: Financial feasibility of investment in biosimilar production in Thailand

- Defining the scope of the analysis
  - Decision problem
    - Should Thailand invest in production of bevacizumab biosimilar?
  - Decision choice
    - Build a plant for bevacizumab biosimilar production from upstream process
    - Do nothing
- Cost-benefit analysis
- Societal perspective

# Conceptual framework



# Timeline of the Biosimilar investment project

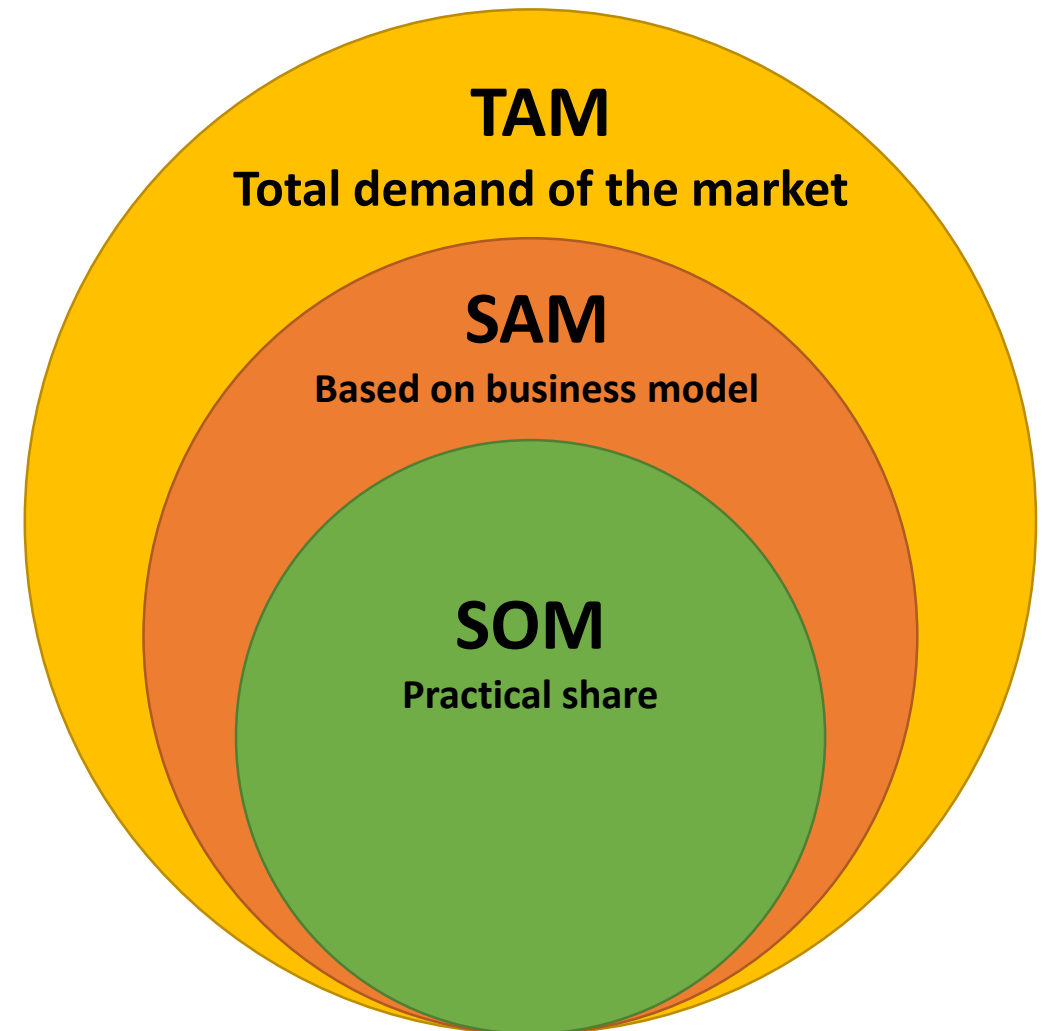


# Costs

- Capital investment
  - Research & Development
    - Licensing fee for Product prototype
    - Scale up
    - Pre-clinical study
    - Clinical study
  - Facility construction
    - Location
    - Size
  - Registration
- Fixed costs
  - Rent
  - Electricity
  - Minimum personnel for facility
- Variable costs/Ongoing operating costs
  - Cost of Goods Sold (COGs)
    - Raw material
  - Operation costs
    - Personnel

# Benefits

- Sales forecasting = Market feasibility
- Customer segments on business model canvas
  - **TAM** = Total Available Market
  - **SAM** = Segmented Addressable Market
  - **SOM** = Share of the Market
- Directly link to the cost estimations
  - The scale of the production
  - Strategy to target the market



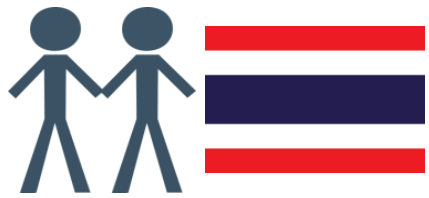
# Bevacizumab example

- Total available market for Bevacizumab in **Thailand**
- Widely use biologic drug in Thailand: indications of Bevacizumab
  - Cervical cancer, persistent/recurrent/metastatic
  - Colorectal cancer, metastatic
  - Glioblastoma
  - Non-small cell lung cancer, nonsquamous
  - Ovarian (epithelial), fallopian tube, or primary peritoneal cancer (platinum-resistant recurrent), Ovarian (epithelial), fallopian tube, or primary peritoneal cancer (platinum-sensitive recurrent)
  - Renal cell carcinoma, metastatic
  - Off-label indications are **Age-related macular degeneration\***; Breast cancer, metastatic; Endometrial cancer, recurrent or persistent; Soft tissue sarcoma, angiosarcoma; Soft tissue sarcoma and hemangiopericytoma

*TAM:  
# of patients  
with the  
diseases*

*Incidence Vs  
Prevalence*





# TAM: what makes it complicate: Payer is not the patient



สวัสดิการข้าราชการ

ครอบคลุมอย่างน้อยตามบัญชียาหลักแห่งชาติ หากมีความจำเป็นต้องใช้ยา  
นอกบัญชีต้องมีคณะกรรมการแพทย์รับรอง  
มีการบริหารจัดการยาราคาแพง เช่นยามะเร็ง บางรายการ โดยเบิกได้ตาม  
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# Pricing decision

- Price of Avastin® approx. 47,000 Baht per vial (at the time of analysis)
- Prices of biosimilar product were reported to be 30 – 40% cheaper than the original biologics
- Price used in the analysis is the projected price
- Factors that would influence the price of the product
  - Patent expiration
  - Competition from other biosimilars
  - Other novel products in the same therapeutic group
- Pricing is a strategy and would determine the target customer of the product

# Pricing structure and strategy

Strategy	Price	Circumstances/Comments
<b>Cost-Based (pricing based on cost of product)</b>		
<b>Cost-Plus</b>	<i>Cost + Desired Profit Margin</i>	<ul style="list-style-type: none"> <li>• Guarantees profit</li> <li>• Inelastic-demand and little competition</li> </ul>
<b>Target-Return</b>	<i>Cost x Desired Return on Investment</i>	<ul style="list-style-type: none"> <li>• Guarantees profit</li> <li>• Inelastic demand and little competition</li> </ul>
<b>Geographic/ Seasonal/Population</b>	<i>Different price for different locations, groups or seasons</i>	<ul style="list-style-type: none"> <li>• Different costs for different locations, groups or seasons</li> </ul>
<b>Competitor-Based (pricing based on prices of competing products)</b>		
<b>Price-Matching</b>	<i>Price = competitors</i>	<ul style="list-style-type: none"> <li>• Other advantages (e.g., lower cost) over competitors</li> <li>• Large target population</li> <li>• May want to maintain status quo</li> </ul>
<b>Price-Undercutting</b>	<i>Price &lt;&lt; competitors</i>	<ul style="list-style-type: none"> <li>• Elastic demand</li> <li>• Maximize quantity sold</li> </ul>

Lee, Bruce Y., and Sarah M. McGlone. "Pricing of new vaccines." *Human vaccines* 6.8 (2010): 619-626.

# Pricing structure and strategy

Demand-Based (pricing based on customer demand)		
<b>Skim Pricing</b>	<i>High for customer segment that has inelastic demand</i>	<ul style="list-style-type: none"> <li>• Customer segment with inelastic Demand</li> <li>• Maximize profit margin</li> </ul>
<b>Penetration</b>	<i>Low to maximize adoption</i>	<ul style="list-style-type: none"> <li>• Large Target Population with highly elastic demand</li> <li>• High production capacity</li> </ul>
<b>Premium (prestige)</b>	<i>High to signal quality</i>	<ul style="list-style-type: none"> <li>• Quality important to customers</li> <li>• Variable quality among competing products</li> </ul>
<b>Economy</b>	<i>Low to maximize quantity sold</i>	<ul style="list-style-type: none"> <li>• Highly elastic demand</li> <li>• Low costs</li> </ul>
<b>Captive Product</b>	<i>Very High for Customers who must have the product</i>	<ul style="list-style-type: none"> <li>• Essential product with few alternatives</li> <li>• Maximize profit margin</li> </ul>
<b>Geographic/ Seasonal/Population</b>	<i>Different price for different locations, groups or seasons</i>	<ul style="list-style-type: none"> <li>• Different demand for different locations, groups or seasons</li> </ul>
Portfolio-based (pricing based on other products in the manufacturer's portfolio)		
<b>Price Lining</b>	<i>Similar price for all product offerings</i>	<ul style="list-style-type: none"> <li>• Simplifies accounting</li> <li>• Less flexible</li> </ul>
<b>Bundle</b>	<i>Price for combined package of several products</i>	<ul style="list-style-type: none"> <li>• Products naturally fit together</li> <li>• Similar customers demand similar products</li> </ul>
<b>Product Line</b>	<i>Price different products in portfolio based on their relative value</i>	<ul style="list-style-type: none"> <li>• Easy to assess differential value of different products</li> <li>• Elastic demand</li> </ul>
<b>Goldilocks (Framing)</b>	<i>High so that lower priced products looks better by comparison</i>	<ul style="list-style-type: none"> <li>• Lower priced similar products in portfolio</li> <li>• Elastic demand</li> </ul>
<b>Loss Leader</b>	<i>Very low to draw customers to portfolio</i>	<ul style="list-style-type: none"> <li>• Goal is sell other products</li> <li>• Customer loyalty to portfolio</li> </ul>
<b>Optional Product</b>	<i>Offer "extras" for additional price</i>	<ul style="list-style-type: none"> <li>• Product has accessories/options (e.g., vaccine administration devices)</li> </ul>

Lee, Bruce Y., and Sarah M. McGlone. "Pricing of new vaccines." *Human vaccines* 6.8 (2010): 619-626.

# When TAM is beyond the local market

- Understanding the health care system is the key
- Regulatory requirement is the barrier to entry into other markets
- Customer segment
  - Public health insurance payer: How to be reimbursable?
  - Self-pay patient
- For vaccine
  - Mostly provided to public for free
  - understanding the global trend: WHO recommendation
  - Country's immunization program

# Other benefits

- From a societal perspective
- Benefits of having the product
  - Increasing access to medicine
    - Patient who would otherwise couldn't access because of the price
    - Life year gained & Productivity gained
  - Reduce importation of the product
    - Importation value of Avastin® (original of bevacizumab) in 2017 is about 236,155,865 baht per year

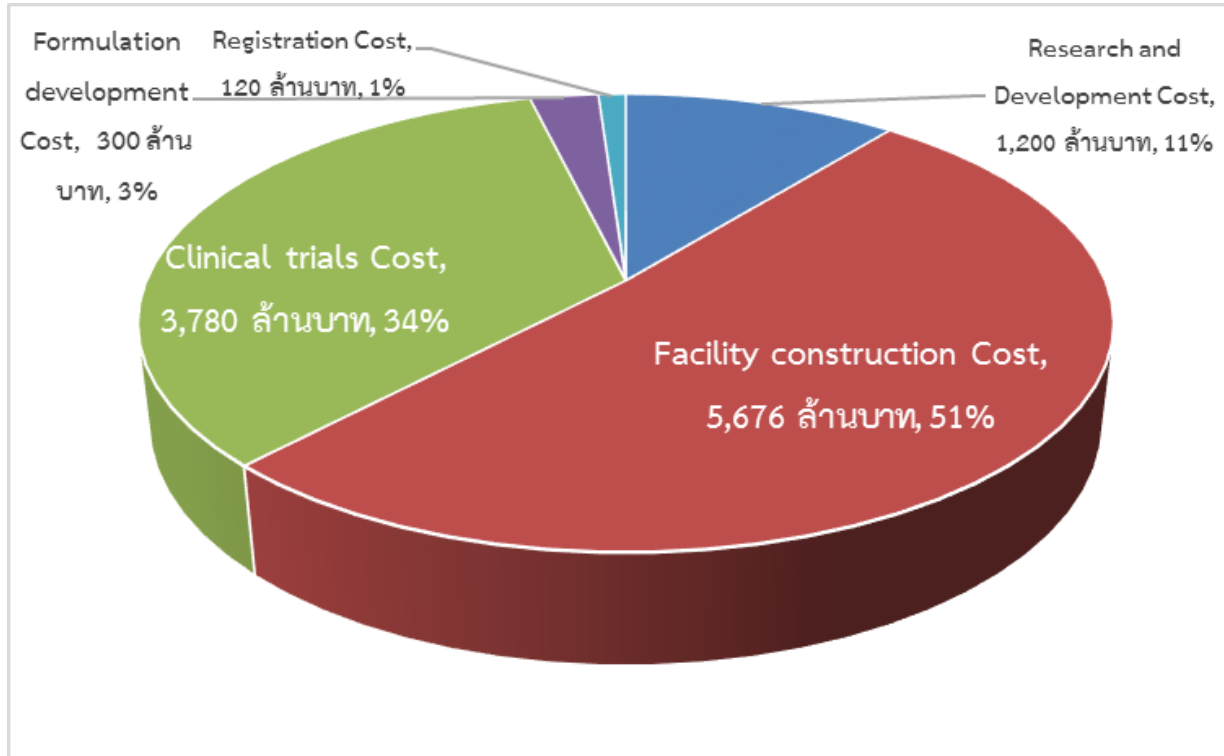
Bevacizumab

increased overall  
survival rate and  
progression free  
survival

Not reimbursable by public  
insurance in Thailand

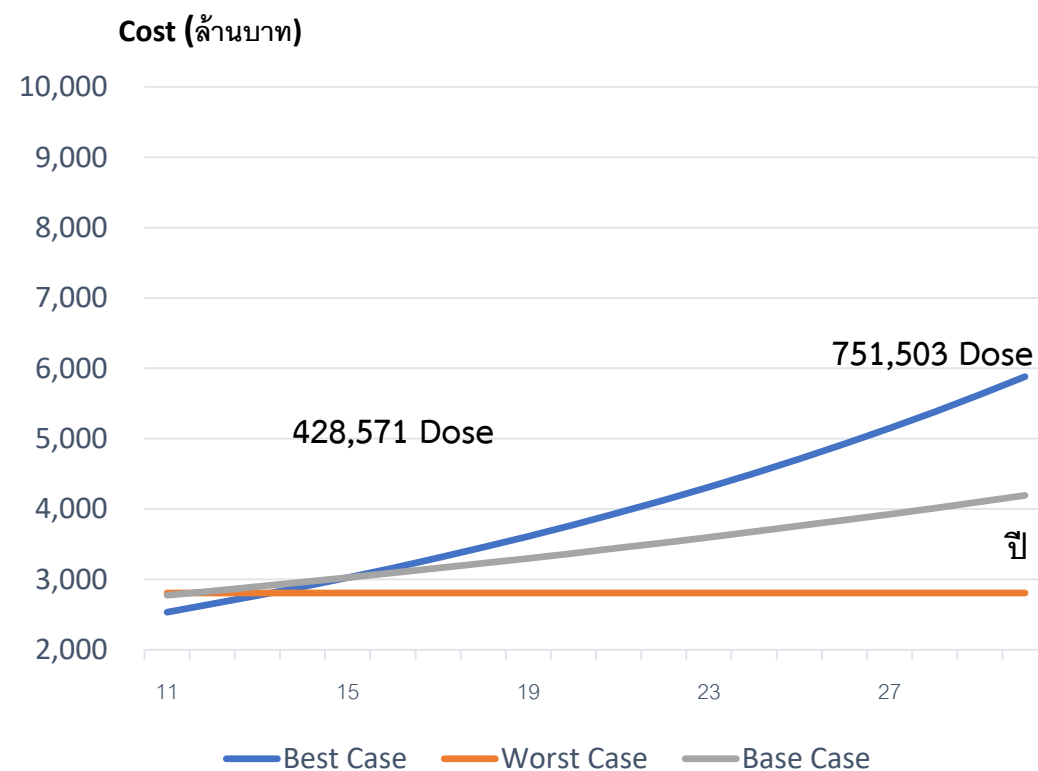
Only 2% of patient access  
Bevacizumab

# Investment costs of Bevacizumab biosimilar

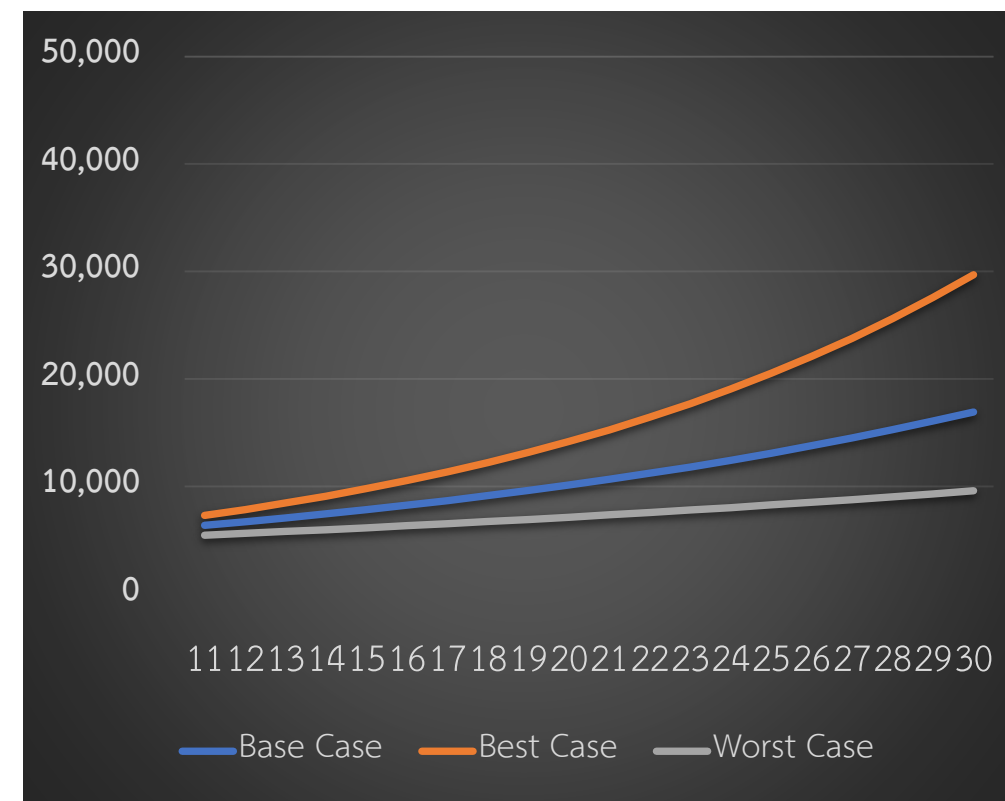


Cost	Worst Case (ล้านบาท)	Best Case (ล้านบาท)
Research and Development	2,400	1,200
Facility Construction	5,877	5,676
Clinical Trials	7,560	3,780
Formulation Development	600	300
Registration	240	120
Total	16,677	11,076

# Variable costs of Bevacizumab biosimilar



Variable costs

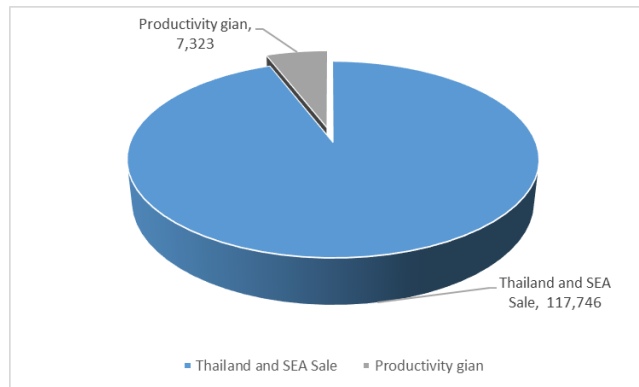


Annual sales

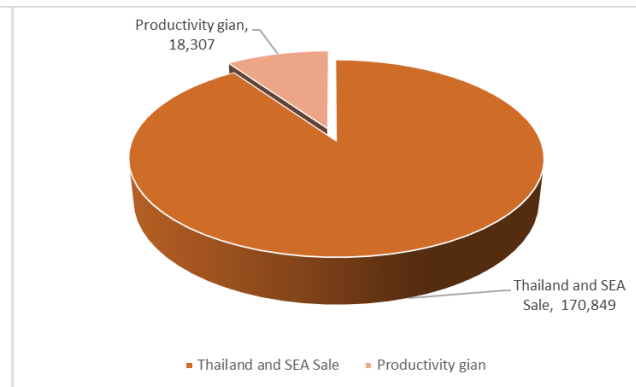


# Results of cost-benefit analysis: Bevacizumab

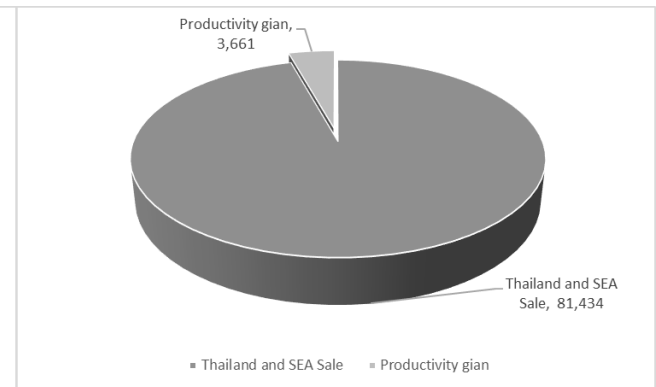
Scenario	Total cost (ล้านบาท)	Total benefit (ล้านบาท)	Net Present Value (ล้านบาท)	IRR (%)	B/C ratio	Break- even year
Base case scenario	79,042	125,069	46,027	58	1.58	14
Best case scenario	90,089	189,156	99,067	110	2.10	12
Worst case scenario	66,493	85,095	18,602	28	1.28	17



Base case scenario



Best case scenario



Worst case scenario

# Sensitivity analysis

