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?”
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 have market?

3. Organization feasibility
   Does the organization have 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)
<table>
<thead>
<tr>
<th>Product class:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Product name:</td>
<td>To be completed once product approaches phase 2b</td>
</tr>
<tr>
<td>Date of TPP endorsement</td>
<td></td>
</tr>
<tr>
<td>Dates of TPP revisions</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Desired</th>
<th>Minimally acceptable</th>
<th>“Insert Product Name” profile (Completed as product approaches phase 2b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target</td>
<td>Rationale</td>
<td>Target</td>
</tr>
</tbody>
</table>

- **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
Market feasibility: Is there a market for the product?

- Customer segments on business model canvas
  - **TAM** = Total Available Market
  - **SAM** = Segment 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?

![Supply & Demand Graph](image)
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

Facility construction
Research and Development
Registration
Operational costs & COGs

Cost

Benefit

Productivity gain
Export to the region

Cost-benefit analysis

Biosimilar investment

Do nothing

Cost

Benefit

Productivity gain

Importation value cost

Cost - benefit analysis
Timeline of the Biosimilar investment project

Time horizon 30 years

**Do nothing**

**Biosimilar investment**

**R&D phase**

- Facility construction (5 years)
- Scale up
  - Laboratory Synthesis (2 years)
  - Clinical trial phase (7 years)
  - Approval phase (155-365 days)

**Manufacturing phase**

- Biosimilar market entry

**Cost**

- Facility construction cost
- R & D cost
- Approval cost
- Importation value cost

**Benefit**

- Productivity gain
- Progression free survival time
- Export $
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

*Indication in E2 program of NLEM
ครอบคลุมยาอย่างน้อยตามบัญชียาหลักแห่งชาติ หากมีความจำเป็นต้องใช้ยา
นอกบัญชีต้องมีคณะกรรมการแพทย์รับรอง
มีการบริหารจัดการยาราคาแพง เช่นยาในเรื่อง บางรายการ โดยเปิดให้ตาม
เงื่อนไขที่กำหนด

<table>
<thead>
<tr>
<th>ประกันสังคม</th>
<th>ครอบคลุมยาตามบัญชียาหลักแห่งชาติ</th>
<th>30 บาท/บัตรทอง</th>
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<tr>
<td></td>
<td>มีการบริหารจัดการยาราคาแพง เช่นยาในบัญชี จ2 แยกต่างหาก</td>
<td>0 บาท/UC</td>
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ครอบคลุมยาตามบัญชียาหลักแห่งชาติ | มีการบริหารจัดการยาราคาแพง เช่นยาในบัญชี จ2 แยกต่างหาก | 0 บาท/UC |

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

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Price</th>
<th>Circumstances/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost-Based (pricing based on cost of product)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost-Plus</td>
<td>Cost + Desired Profit Margin</td>
<td>• Guarantees profit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inelastic-demand and little competition</td>
</tr>
<tr>
<td>Target-Return</td>
<td>Cost x Desired Return on Investment</td>
<td>• Guarantees profit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Inelastic demand and little competition</td>
</tr>
<tr>
<td>Geographic/Seasonal/Population</td>
<td>Different price for different locations, groups or seasons</td>
<td>• Different costs for different locations, groups or seasons</td>
</tr>
<tr>
<td><strong>Competitor-Based (pricing based on prices of competing products)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Price-Matching</td>
<td>Price = competitors</td>
<td>• Other advantages (e.g., lower cost) over competitors</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Large target population</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• May want to maintain status quo</td>
</tr>
<tr>
<td>Price-Undercutting</td>
<td>Price &lt;&lt; competitors</td>
<td>• Elastic demand</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Maximize quantity sold</td>
</tr>
</tbody>
</table>

Pricing structure and strategy

<table>
<thead>
<tr>
<th>Demand-Based (pricing based on customer demand)</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Skim Pricing</strong></td>
<td>High for customer segment that has inelastic demand</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Penetration</strong></td>
<td>Low to maximize adoption</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Premium (prestige)</strong></td>
<td>High to signal quality</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Economy</strong></td>
<td>Low to maximize quantity sold</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Captive Product</strong></td>
<td>Very High for Customers who must have the product</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Geographic/Seasonal/Population</strong></td>
<td>Different price for different locations, groups of seasons</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Portfolio-based (pricing based on other products in the manufacturer's portfolio)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Price Lining</strong></td>
<td>Similar price for all product offerings</td>
</tr>
<tr>
<td></td>
<td>Simplifies accounting</td>
</tr>
<tr>
<td></td>
<td>Less flexible</td>
</tr>
<tr>
<td><strong>Bundle</strong></td>
<td>Price for combined package of several products</td>
</tr>
<tr>
<td></td>
<td>Products naturally fit together</td>
</tr>
<tr>
<td></td>
<td>Similar customers demand similar products</td>
</tr>
<tr>
<td><strong>Product Line</strong></td>
<td>Price different products in portfolio based on their relative value</td>
</tr>
<tr>
<td></td>
<td>Easy to assess differential value of different products</td>
</tr>
<tr>
<td></td>
<td>Elastic demand</td>
</tr>
<tr>
<td><strong>Goldilocks (Framing)</strong></td>
<td>High so that lower priced products looks better by comparison</td>
</tr>
<tr>
<td></td>
<td>Lower priced similar products in portfolio</td>
</tr>
<tr>
<td></td>
<td>Elastic demand</td>
</tr>
<tr>
<td><strong>Loss Leader</strong></td>
<td>Very low to draw customers to portfolio</td>
</tr>
<tr>
<td></td>
<td>Goal is sell other products</td>
</tr>
<tr>
<td></td>
<td>Customer loyalty to portfolio</td>
</tr>
<tr>
<td><strong>Optional Product</strong></td>
<td>Offer &quot;extras&quot; for additional price</td>
</tr>
<tr>
<td></td>
<td>Product has accessories/options (e.g., vaccine administration devices)</td>
</tr>
</tbody>
</table>

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

Not reimbursable by public insurance in Thailand

Increased overall survival rate and progression free survival

Only 2% of patient access Bevacizumab
Investment costs of Bevacizumab biosimilar

<table>
<thead>
<tr>
<th>Cost</th>
<th>Worst Case (ล้านบาท)</th>
<th>Best Case (ล้านบาท)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Development</td>
<td>2,400</td>
<td>1,200</td>
</tr>
<tr>
<td>Facility Construction</td>
<td>5,877</td>
<td>5,676</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>7,560</td>
<td>3,780</td>
</tr>
<tr>
<td>Formulation Development</td>
<td>600</td>
<td>300</td>
</tr>
<tr>
<td>Registration</td>
<td>240</td>
<td>120</td>
</tr>
<tr>
<td>Total</td>
<td>16,677</td>
<td>11,076</td>
</tr>
</tbody>
</table>
Variable costs of Bevacizumab biosimilar

Variable costs

Annual sales
### Results of cost-benefit analysis: Bevacizumab

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

**Diagrams:**
- **Base case scenario**
- **Best case scenario**
- **Worst case scenario**
Sensitivity analysis

Discount rate
Percent Price increase
Percent Waste
Administration & Marketing costs
Unit price
Research and Development Cost
Ratio of Facility & Process construction cost