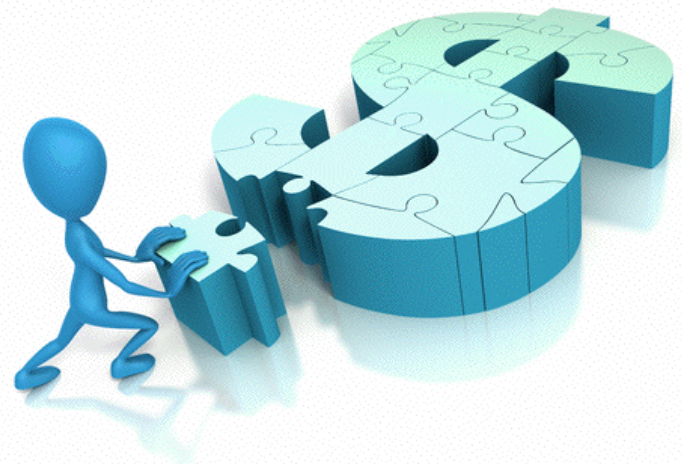


Finance In Pharmaceutical Industry



Presented by Evgenia Neff

Pfizer Research and Development Finance



Finance Workshop

Welcome to the “Shark Tank”....



Framework

- Real-Life Examples of Business Cases – Analysis
- Build your business case and present to the Shark Tank

Business cases can be classified into the following project type categories

Cross-Pollination Cases:

Product is already registered in another country/region and a base dossier is available that can be replicated/modified for the new market. Different commercial team may be “originator” of the request for filing.

A **CP/New Registration:** The country doesn't have the product in any form on the market. Full registration dossier for an asset – complete package – clinical, safety, quality + is needed. (ie. Country A sells product XYZ as 20 and 40mg tablet. Country B has no XYZ on the market. The project is to file both strengths of XYZ in country B by modifying country A's dossier.)

B **CP/Product Enhancement:** The country has the product in another formulation or strength, so the submission in the country is considered a “Product Enhancement”. (ie Country A sells product XYZ as 20 and 40mg tablet. Country B has only 20 mg tablet of XYZ. The project is to file 40mg tablet of XYZ in country B by replicating or modifying country A's dossier.)

C **CP/New Indication:** The country has the product on the market for another indication. Same dosage form/formulation but a new medical use. (ie Country A sells 20mg capsule of product XYZ for indications N & K. Country B sells 20mg product XYZ only for indication N. The project is to file in country B by modifying country A's dossier for indication K.)

D **Product Enhancement:** A new form, formulation, packaging or delivery system not registered in any other market by Pfizer will be utilized to deliver the active ingredient. For example, original registration is with capsules at 50 and 100 mg strengths in bottles. A product enhancement for this original registration may be a 200 mg strength, a tablet, etc.

E **Dual Brand:** Same active ingredient and form registered under a new “brand” name. This approach allows for second tier payers typically.

F **New Indication:** An update to registration dossier for an asset – complete package – clinical, safety, quality Same dosage form/formulation but a new medical use that can be detailed.

G **In-License:** Asset brought in via business development that requires internal technical work prior to dossier filling or alternatively Pfizer has responsibility for the regulatory submission of an in-licensed asset (originating company is technical only with no regulatory capabilities).

H **General Support:** Other growth opportunities. (ie. Preparing citizen petition)

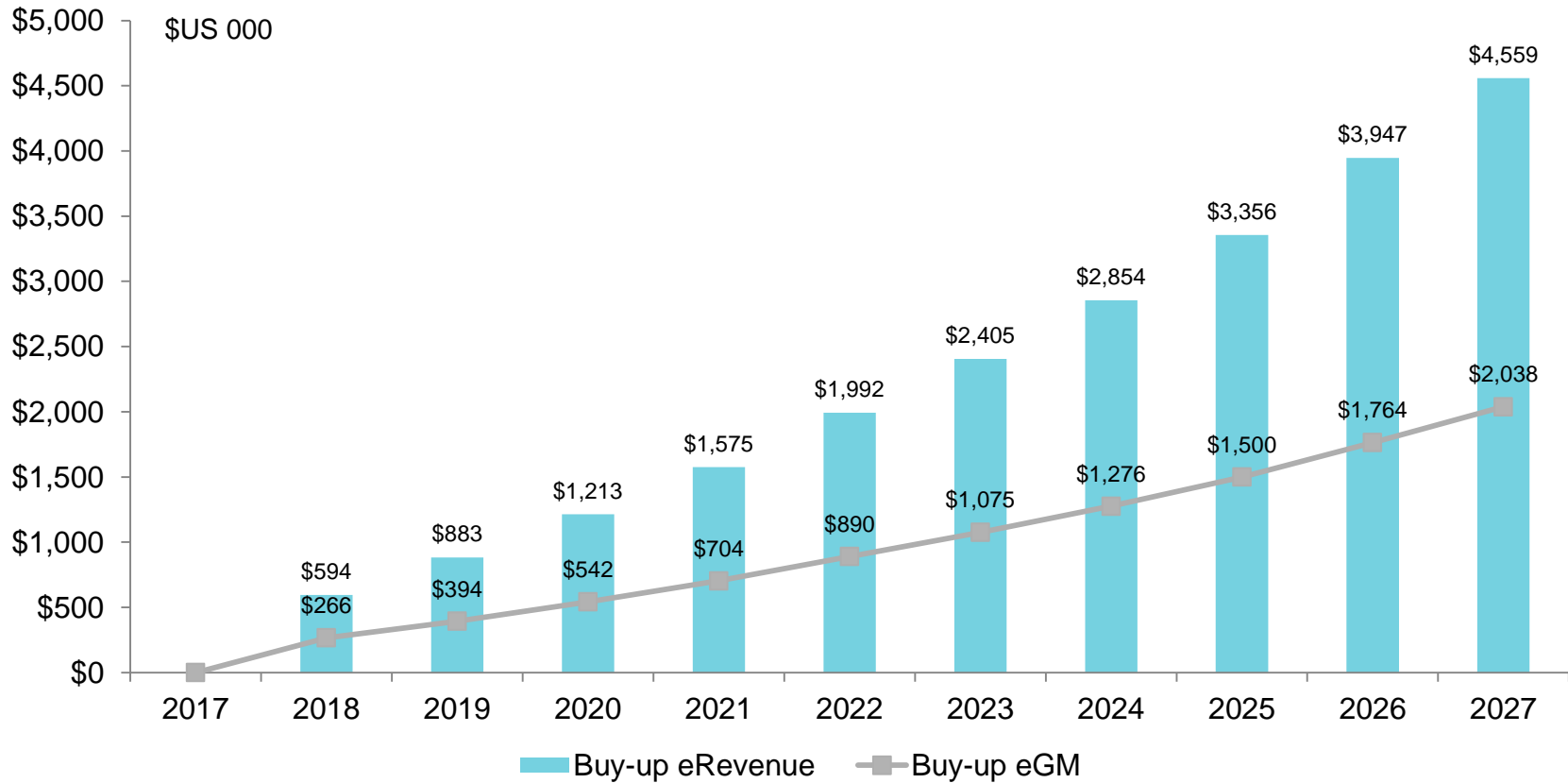
Asia Trade-off Proposal for Product A India

Therapeutic Area	Project Type	Launch Year	eNPV (\$M)	eIRR (%)	PTRS	Payback Period
Pain / Inflammation	CP / PE (B)	2018	\$4.3MM	67%	64%	2.5
Regions / Markets	Asia: India					
Value Proposition for the Investment	<ul style="list-style-type: none"> Register Product A 100 mg, 200 mg Launch Product in India leveraging the ABC trial to mitigate previous cardiovascular concerns Cumulative 5 year revenues of \$9MM. No additional resources required Price increase of 10% for first five years and 10% every alternate year thereafter Resources for this case will come from recently cancelled Project B in Japan due to: <ul style="list-style-type: none"> - The PMDA (Pharmaceuticals and Medical Devices Agency - Japan Regulator) has not accepted proposed 'no study' plan - The requirement for a BE study would be cost prohibitive - The likelihood of success of the BE study is considered to be low 					
Key Risks/ Challenges	No regulatory barrier as these strengths are currently available in India from competitors					

Incr Financial Metrics (\$M)	Endorsed	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	LRF Contribution
eRevenue (Asia)	?	\$0.0	\$0.6	\$0.9	\$1.2	\$1.6	\$2.0	\$2.4	\$2.9	\$3.4	\$3.9	\$47.6
R&D Direct												
R&D Indirect		(\$0.1)	(\$0.0)	(\$0.0)								(\$0.2)
R&D Functional												

Asia Trade-off Proposal for Product ABC India

Incremental Revenue & Gross Margin



**eRevenue (risk adjusted Revenue); eGM (risk adjusted Gross Margin)

Product CBA Colombia – Project Code#1111 (Buy Up)

Therapeutic Area	Project Type	Launch Year	eNPV (\$M)	eIRR (%)	PTRS	Payback Period
Women's Health	Cross Pollination / New Registration (A)	Potentially Feb 2020	\$3.5MM	61%	95%	3.5 Year
Regions / Markets	Latin America – Colombia					
Value Proposition for the Investment	<ul style="list-style-type: none"> • Launch Product CBA in Colombia • Leverage additional pharmacovigilance data to strengthen the submission by supporting the treatment benefits 					
Key Risks/ Challenges	<ul style="list-style-type: none"> • In 2015 submitted this product for registration in Colombia but it was rejected by the board of health 					

Incr Financial Metrics (\$M)	Endorsed	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	LRF Contribution
eRevenue (LA)	?	-	-	-	\$0.2	\$0.6	\$1.0	\$1.4	\$1.5	\$1.6	\$1.7	\$23.1
R&D Direct		(\$0.05)	(\$0.05)									(\$0.1)
R&D Indirect		(\$0.1)	(\$0.04)	(\$0.02)								(\$0.2)
R&D Functional												

Shark Tank

- Now that you became a finance expert, let's go back to our question from Day 1 and modify it slightly:

“If you won the lottery, what would you invest your money in?”

- Assuming you won \$2,000,000 USD, but after paying \$250,000 in taxes you have \$1,750,000 left.
- Review a list of the proposed buy-up cases on the next slide, and decide which ones you would invest in, and why (*refer to slides #80-83 of the Finance Module*)
- **You have 5 min to complete this exercise**

Projects for buy-up consideration... you only have \$1.7MM to invest!

Case	Title	Region	Countries	eNPV	eIRR	2017 R&D Budget	Description / Status
A	Product A Cross Pollination / New Reg.	Latin America	Colombia	\$3.5MM	61%	\$0.5MM	<ul style="list-style-type: none"> Endorsed regionally Previously submitted, but rejected by local health authorities due insufficient evidence to address health concerns New existing clinical data now available will provide evidence to support the benefits
B	Product B / New indication	North America	US	\$2.2MM	110%	\$1.0MM	<ul style="list-style-type: none"> Proposal to update the language in the label addressing breast density concerns previously rejected by the FDA during the original submission
C	Product C Cross Pollination / New Reg.	Asia	Australia and New Zealand	\$5.1MM	48%	\$0.2MM	<ul style="list-style-type: none"> Endorsed regionally Proposed as next buy up opportunity for the region There are concerns regarding the level of support needed to contemporized the dossier
D	Product D (strategic importance)	Latin America / add. Markets	Colombia, Peru, Bolivia	\$1.0MM	25%	\$0.1MM	<ul style="list-style-type: none"> Add these markets to ongoing case Sell Product D to public health systems (HS) HS will offer Product D to patients via the local hospitals, clinics, and drug shops Second access stream to social marketers who buy Product D from Pfizer and re sell to patients in local settings.
E	Product E (strategic importance)	Africa/ Middle East	Several	\$0.2MM	10%	\$0.5MM	<ul style="list-style-type: none"> Product E is currently registered and distributed in multiple markets under the global umbrella However, the markets in this business case required registration in order to be of access to the public:
F	Product B/ New Indication	North America	US	\$50MM (1 trial)	35% (1 trial)	\$1.5MM	<ul style="list-style-type: none"> Preparation for FDA (Food and Drug Administration) meeting ongoing Initiative will be revisited post FDA meeting and potentially be brought to Portfolio Board for full funding endorsement

Correct Answer:

- It is your money, you can invest as you wish 😊!
- However, you will gain a better return if you invest in the projects with highest eIRR (rate of return).
- But do not forget about strategically important projects that focus on patients with limited access to quality medical care and medicines.

Projects for buy-up consideration... you only have \$1.7MM to invest! (Jenia's choice)

Case	Title	Region	Countries	eNPV	eIRR	2017 R&D Budget	Description / Status
(2) A	Product A Cross Pollination / New Reg.	Latin America	Colombia	\$3.5MM	61%	\$0.5MM	<ul style="list-style-type: none"> Endorsed regionally Previously submitted, but rejected by local health authorities due insufficient evidence to address health concerns New existing clinical data now available will provide evidence to support the benefits
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And remaining \$100,000



больше чем
 ОБРАЗОБАНИЕ

Your Business Cases

Now it is your turn to seek an investment from the Shark Tank:

- Come up with an idea, any idea really. It does not have to be pharma related.
- Build your business case
- Project how much money you would need to invest and what will the cash flow look like
- Fill out the template
- Present your case
- If we like your idea, and financials are attractive, your project will get funded (note: with SharkTank currency)
- You have 20 min to complete this task

Online Calculator: <http://www.datadynamica.com/irr.asp>

Finance in Pharma Industry

Business Case Template

Title/Name	
Project Description	
Start Date	
End Date	
Risks	
Required Investment (Total Cost)	

- Project Revenue and expenses
 - Calculate Net Income (Cash Flow)
 - Calculate NPV and IRR assuming 5% discounted rate
- Refer to slides #70-79 (Finance Module)*

		2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
Revenue	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
Expenses	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
Net Income = Cash Flow	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$	\$
Initial Investment	\$										
NPV	\$										
IRR	%										

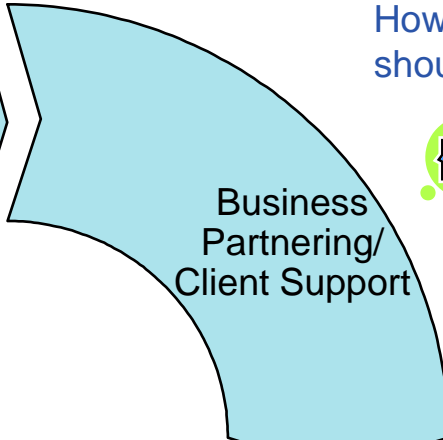
Finance Cycle and Support

How are we spending compare to budget and forecast?



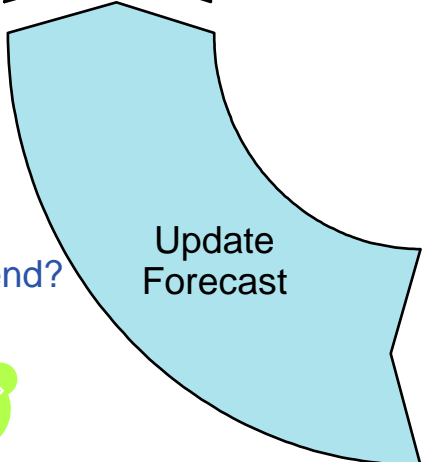
Reporting, Analysis, Compliance

How should we spend and what should we invest in?



Business Partnering/ Client Support

How much will we spend?



Update Forecast

How much are we allowed and can spend?



Develop Budget

Conclusion and what we learned...

- Importance of Finance and why it really matters
- **Finance processes** which sooner or later you will run into in your career path (more likely...)
 - Annual Plan, Budget (including Clinical Trial Budgets), Forecast, Financial Reporting and Analysis
- **Financial Statement** and what they tell us about performance and well-being of the company
 - Balance Sheet, Income Statement, Cash Flow
- **Basic accounting principles** – Matching and Accrual
- How to **evaluate a project** and **choose an investment option** with highest return and value
- What are these 'fancy' terms finance is using : ***NPV, IRR, Pay-Back and Break-Even Point***? And how to use these when **making an investment decision**?

Спасибо!!!