Thank you for your interest and participation in the Strategy Toolkits workshop.

The goal of the group discussion is to give the participants a chance to apply the principles they learned from the lecture. The task they will perform is describing the operating environment of a scientific enterprise from browsing the company's website, and discussing possible next moves for the enterprise. The group members can choose to perform a SWOT, PEST or Four Corners analysis for a company of interest or an academic lab.

A sample lesson plan for a 2 hr session:

6-6:15pm, Review key concepts. talk about each assessment from video 1 & talk about the strategy process from video 2

6:15-6:25pm, Introduce the activity. Break into small groups and describe the operating environment of a scientific enterprise. The group members can choose to perform a SWOT, PEST or Four Corners analysis for a company of interest or an academic lab. They may continue this activity with a company of interest from last week. I'll be explicit about one academic group. *Assign roles in the group, like note takers and presenter.*

6:25-7:15p, Facilitated activity. Make sure they answer:

- Why did you choose the SWOT / PEST / Four Corners to assess your company?
- What is the external landscape for that specific company
- Based on the analysis, what is a possible next move for the company?

7:15-7:45p, Group presentations. 3 minutes each, with 2 minutes of Q&A.

7:50-8p, Review and questions, evaluations.

Direct the conversation from the start.

Each group will need to select a company and an analysis. Remind them that they will present on the reason they selected that assessment and the next steps they would take based on the assessment. This will help focus the group discussion.

Questions to answer in today's discussion:

- What is the external landscape for that specific company? (external assessment)
- Why did you choose the SWOT / PEST / Four Corners to assess your company? (tools)
- Based on the analysis, what is a possible next move for the company?



As a reminder, the Strategy Toolkits module comprises two major topics. Today's discussion will cover part 1:

Part 1. Environmental Assessment - frameworks to evaluate an operating environment including competitors, stakeholders, supplies, and economic, regulatory or technology trends; SWOT, Four Corners and PEST analyses. By the end of part 1, participants will be able to:

- Describe commonly used tools for environmental assessments
- Explain the benefits of doing the analyses
- Identify which tool applies best in a given setting
- Use one or more tools to describe the operating environment of a scientific enterprise

Part 2. Developing Strategy - tools to help set, generate, and prioritize an enterprise's goals. By the end of part 2, participants will be able to:

- Describe the key elements of an enterprise's strategy
- Identify common tools used to facilitate strategy development
- Draft SMART objectives
- Explain the value of monitoring progress towards goals

As a reminder, we have defined the concepts below -

SWOT (strengths, weaknesses, opportunities, threats) analysis - a study undertaken by an organization to identify its internal strengths and weaknesses, as well as its external opportunities and threats; a tool when used in a business context can help to carve a sustainable niche in a market

Four corners analysis (drivers, strategy, assumptions, capabilities)- A model designed to help strategists assess a competitor's intent and objectives, and likely future actions; used in developing a strategy and performing competitive intelligence; can be a useful analysis in the absence of data

PEST analysis (political, economic, socio-cultural and technological) - A strategic tool for understanding market growth or decline, business position, potential and direction for operations; helps determine how macro-environmental factors can affect the performance and activities of a business in the long-term

SMART (Specific, Measurable, Actionable, Realistic, and Time-based) goals - Goals that help you achieve your strategy

What if conversation stalls?

Below, you will find a list of questions to prompt the participants.

After asking a question, steel yourself to wait through the silence, responses will come. If you notice the same 2-3 people speaking, and want broader participation you might say: "Let's hear from someone we haven't heard from yet" or "How about someone from this side of the group?" etc. You can also move around the group—you will boost participation from whatever direction you face.



Questions to prompt conversation:

- Push students to think about strategy how could they go about engaging in the opportunities they have and solving their threats?
 - o What are competitors doing?
 - What is the market? (Esp important for smaller market) some companies will look to get acquired if they want to get somewhere.
 - o Internally: What products do we have? Do they make sense given the environment?
 - What are the holes or gaps we have/ what can we do to fill this out?
 - o Who are our customers?
- Students may ask, if not, ask about prioritizing (the next step beyond brainstorming)- with so many ideas and strategies how would a company like Juno prioritize?
 - Actionability is it realistic? What is the market competition?
 - o Feasibility of clinical trial? Is the outcome easy to detect?
 - o Size of the market? How much do you take at the end of the day?
 - o If have extra time, ask them to plot this on a 2-way matrix
- When we think of SWOT, does it always have to do with analyzing a competitor? SWOT can be used for internal assessment. Strength and weakness are for their own company, and to understand O&T need to understand both the surrounding environment and your own.
- Is there something novel or new about the company or do they want to take a new direction? May consider PEST over SWOT

What types of questions might the participants ask me during the discussion?

When we previously administered this course, we recorded the most common questions. Below you will find this list of questions followed by possible responses in the gray text.

Facilitator tip – The facilitator's role is to prompt the group discussion. When a student or postdoc asks a question, consider giving a broad answer to get them started, but then point them in the direction of the website where they can find it themselves. You may also ask the question back to the group to see if anyone else has a response.

Questions participants may ask

For SWOT analysis

- How do you determine (S)trengths? Possible response: what do they do best? [if no response] go back to value proposition, why/what.
- (W)eaknesses? Ask: what was the biggest problem?
- (0)pportunities? Ask: what else could they improve to win in the market?
 - o [If students get stuck thinking about science/technology] Think outside the box beyond the pipeline to what they can improve?
 - What other opportunities do they have? Think about the stakeholders
 - o So who are the customers? Aside from the patients?
- (T)hreats? Ask: who are their competitors out there?
 - o What types of companies are they?
 - o How are they competitive?

[SWOT example from JUNO conversation]:

• If companies are targeting the same molecule, how would your company differentiate itself?



This is another trick for pharma, you either file for adults or kids. For example, what did Novartis do recently? They just got FDA approval, but what did they file for? What indication? Important to find out what they filed for and what indication?

- What is the lead indication for the company most advanced in clinical trials? Check the pipeline section of the website.
- **Is it first or second generation?** They won't get as big of a share of the market. They will need to prove efficacy and overcome the biggest problem safety.
- What else are they targeting in the pipeline? Look in the pipeline for other targets like types of cancer or tumors. Ex for Juno: The problem of hematologic cancer is that it's kind of small target population. So by going to solid tumor they would be expanding their market.
- What else could they improve to win in the market to get a lot of patients to take their drug? This goes beyond the pipeline. Think outside the box to what they can improve? Types of patients (how ill), drug delivery, or manufacturing issues. For ex: what do you think about the health status of relapse, refractory patients? It takes 4 weeks to manufacture CAR-T? It's going to take so long for them to get their CAR-T back, they could just die during that time. If the delivery process is not streamlined, it may delay when the patients can access the drug.
- What can a company do if they have a bad reputation, like Kite was known as a bad CAR-T company? Improve safety and efficacy; target specificity.

For Four Corners analysis

- What are the Four Corners? Drivers, strategy, assumptions, capabilities
- **Drivers?** Ask: What are their goals? What are their values? What do they find important? Who are their customers?
- **Strategy?** Ask: Where have they been focusing? Where is their growth? What are they presenting to investors? What are their relationships? Investments? Can look at quarterly earning reports or find interviews with the CEO/Executive Q&As.
- Assumptions? Ask: What do you think they think are their strengths and weaknesses? How
 would they describe their markets? How do companies see themselves (ex: same
 technology, but identity as a sequencing company like Illumina vs. diagnostic like Grail), and
 do they see themselves as being the same market or not? Do they have the same potential
 customers?
- Capabilities? Ask: What are their assets? What confidence do they have? What kind of ability
 to adapt to changes do they have? Financial (ex: do they have capital to acquire a company?)
 Technology having internal resources to do their work (ex: send their sequencing for their
 diagnostics). Known/established brand?
- Why would you use Four Corners? Possible response: you can get inside competitors heads; to consider what it would be like to partner with them. How are they going to approach this technology? How are they going to make decisions? Will their culture fit us, will their philosophy of business fit us? Also, you do this assessment because you can't often get public info on their technology or strengths and weaknesses. Then when you are ready for the next stage (ex: commercial launch of diagnostic like Grail), will they be a good partner?
- For Four Corners, do you start with your company's point of view or the competitors? You first want to understand your company then get into the head of the competitor. But for the limited time, define basics for your company (ex: Grail is young and developing a new technology), so understand Illumina (the competitor)
- What types of info can you look at? Sales for example. And precedence and how they have handled partners in the past. Do they like making deals or give partners revenue to keep doing their thing. For example: do they partner with people and then as soon as the technology is successful do they just buy it out right and is that okay?



• Do companies do Four Corners analysis on themselves? No, because a company would know it's own culture. A company would do a SWOT for internal assessment.

[Example from Illumina's Four Corners analysis]:

- In 2017, 2.4B in sales and their shares fell 23%. How do you find out why their stocks fell? Go on Illumina website and look at their news or Google, because an analyst likely wrote about what happened for a drop that big.
- What might it say if their presentations only talk about sales? The company may not be pushing innovation with their investors. Not talking about growth potential. Focusing on the short view. Their strategy may be cashing in on what they have
- What might cause a drop in stocks? Lower revenue than expected. Product didn't launch. No new innovations
- Why spin off? Regulatory requirements (ex: Diagnostics require a lot, while sequencing doesn't have a lot of regulatory constraints). Different marketing skill. Financial costs associated with development and/or running a clinical trial. Expertise for those drivers.

PEST Analysis [academic example]

- Political? Regulations and ethical concerns? Who might advocate for you? What does the
 university care about? What is the NIH NSF focusing on? Right time for clinical translational
 studies?
- **Economic?** What division? What is the university/gov't funding? New endowments? Does the PI just do research (also see patients)? New funding mechanisms?
- **Social?** Do other labs at the university do this? Will a postdoc spin out the research? How do colleagues regard the PI? Who might be reviewing the work?
- **Technology?** How executing experiments (ex: balance animal models and human studies)? How acquire equipment (ex: run a core)? Collaborate? New and better technologies to use?
- Why would you use PEST? If innovating and staring a new direction, could be useful to look at the current environment. What is the landscape?
- What type of info do you look for? Lab websites. Research overview. Grant portfolio. Partnerships. Runs a core.

General

- What about the strategy of partnering? Some of the other companies are doing that, they
 could go with other partnerships, but Juno has some of this going. Ex: Kite is kind of small,
 but Novartis has a lot of partnerships, collaborations, and funds. And Juno is small
 comparatively, so they'll need to engage in partnerships to be able to compete with the
 larger companies.
- What makes a market "huge"? Where the opportunity/indication has a biggest market: # products already there (competitors), number of patients, efficacy/disease severity
- What if a company wants to try something new that they don't have expertise in? If they
 don't have the in house resources or expertise, partnering might be a good option to figure
 out durability.
- Who are the customers besides the patients? Doctors. Help the doctors understand the process as well. One appeal could be providing lower cost for a contract (e.g. Costco). Also hospitals and insurers
- What does regulatory look like? Most pharmas have a regulatory team. They would need to talk to the FDA.
- With so many strategies, how does a company prioritize? A company usually proposes a workshop with the key stakeholders from each major part of the company and formally



works out what's important to the company and score it. Based on that you have a score/weighing system depending on their priorities, may look at long-term vs short-term. And that's how they decide what to execute first.

- Actionability is it realistic? What is the market competition?
- o Feasibility of clinical trial? Is the outcome easy to detect?
- Size of the market? How much do you take at the end of the day?
- How do companies move on from big failures? If they are small, then they may position itself to be an acquisition target just so the name can change. IT may be a good idea to get acquired. For bigger companies, depends who that potential partner may be; are they poised and ready to take up this program? What direction do they want to take the company?
- Is there a quick way for companies to look at what the competitors are in the space? Can look at competitors in the clinical trials; public and private databases are available.

Helpful questions from the Business Development module

- How do we define a gap? Possible response What is the company's strategy? How does it want to make money or grow in the future? Have them determine the company's value proposition and define what the company is focusing on to help them determine what gaps need to be filled in terms of therapeutic area, technology or stakeholders. Platform companies could look to expand to other therapeutic areas. Disease-focused companies could look to expand their products or technologies. Example value proposition for Five Prime Therapeutics Platform technology bringing genomics in a novel way to mouse models, to help validate the potential viability of potential clinical targets.
- What is an example of a financial gap? An example would be to grow revenue. A company's target may not yet be on the market, and they are focusing on only one therapeutic area, they need revenue if they want to grow.
- What is an example of an expertise gap? If they are focusing on one area and they want to expand to other areas, they probably don't have people in this new area. Probably need to hire in this new area or collaborate with academic labs.
- What is an example of a market gap? A company could have a drug in neuro and now want to get into oncology. Oncology is lucrative right now.
- How do you determine gaps for a technology-based company? Look at current pipeline candidates. Gaps could span multiple potential therapeutic targets and different areas. Scenario Let's assume they are a mature, platform company. Maybe they chose early on to focus in one clinical area, and have some drugs in the pipeline already. Check news articles to see if they've done a licensing deal or partnered for those products. In this case, they could have active collaborations in one clinical area buttoned up, and could look to fill a market gap, or a different therapeutic area altogether. Alternatively, if there are no licenses, there could be a technology or product gap. Ex: Five Prime Therapeutics they are using mice as their platform to identify novel targets that can be further developed.
- How do you know what deals a company has already done? Companies publish their pipeline. To find this information, look if they have to put the partner logo companies they have worked with. Press releases are another place to find what types of deals they're doing. Are they selling the asset, or are they co-developing and want to do some of the work

- themselves? A company may not want to sell the whole company, but it's difficult to develop everything on your own.
- Can you get information from clinical trials? Clinical trials may give you information about unmet medical need, and hint at subsets of patients that a company hasn't identified yet.
 Could look at clinical trial failures in certain markets.
- Where can I find information about competitors? Information about competitors may not be found on the website, but the 10K (financial document) will talk about competitors.
 Additional sources for identifying competitors are clinicaltrials.gov and google searches.
- Is it better for a company to develop products for multiple diseases areas or explore just one? There's no right answer. Think about the variations. If it's a platform company, may want the ability to spin off multiple drug targets and may not be limited to therapeutic area or clinical indication. One possibility Start with one target and see how that develops; build a collaboration with academia. Depends on how supportive your investors are and how mature the company is regarding size or success with current products.

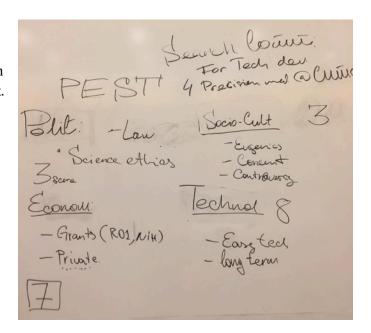
Career-related questions

- How many BD professionals are in a company? Depends on the company. Usually when the business reaches over 15-20 people and the senior folks are doing too much, they'll hire on someone for business development. And if you're 50-100 people, they'll have two BD professionals. More and more companies are hiring with a PhD or MD pre-requisite.
- Why do some companies want business vs science people in BD roles? Depends what they're looking for. If they want someone who is tech savvy and can communicate with bigger companies. Other companies may want someone with business background. Usually it's the former, someone who has a deep understanding of the technology or biology.

Group reporting from 2018, Columbia

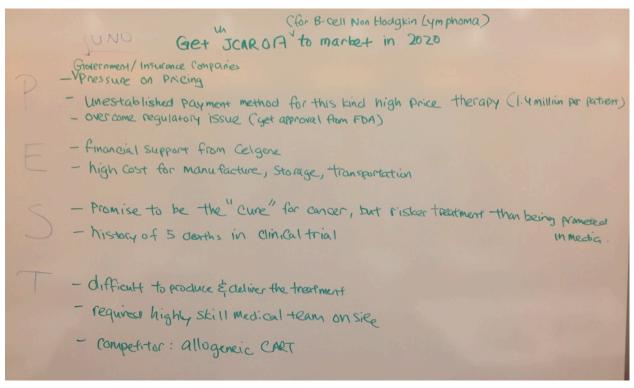
Academic group – their prompt was an analysis of a potential faculty candidate. They selected the PEST analysis rather than a SWOT analysis to have a more global look. If they were assessing the candidate's research program, they would have done a SWOT, but wanted to see fit for the department, university, and US.

They choose to give ratings on a 10pt scale where 10 was the highest. Overall, they decided not to hire the candidate.



Juno - PEST analysis

Juno was just acquired by Celgene and they wanted to assess how this might affect getting to market in 2020. They noted the history of deaths and being 2^{nd} to market, so they might focus on efficacy of the drug. They also noted cost of the drug.



InterSECT - SWOT

Selected because InterSECT is a stable market. The company is first to market, but has only captured a limited, or small portion, of the market. The group noticed increase cost for sales and marketing team, which offset revenue; and why InterSECT does not have positive profit. Their next steps would be new markets and targeting other stakeholders like doctors and insurers to capture more of the market.

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Intersect

Strength

-Established products, Unique

1FDA app. Product

-First to market

-Alread distribution network

-Alread distribution network

-Still no positive profit

Threats

-Competitor Entry

-Expanding sales globally

-Getting more products (+FDA approx)

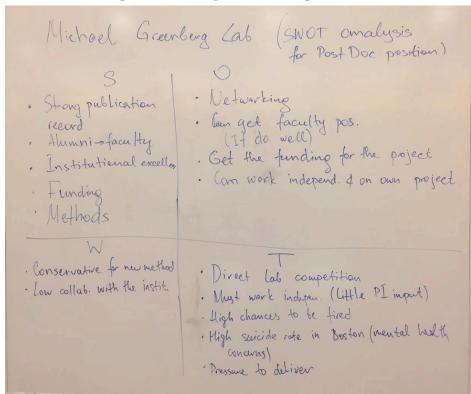
-Become primary beatment

Not Steps: Enter new markets, Become first-to-twarket.

Develop new products

Find partner to access markets of interest
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Academic example: assessing as a future postdoc advisor



They approached the assessment as a future postdoc. They looked at the S/W as assessing the lab and O/T as their opportunities and threats should they decide to join the lab. Note: they set their own metrics for an employment decision. Not typical of the external categorization for 0/T.

They decided not to join the lab.

Group reporting from 2017, UCSF

Academic group (no poster picture) Lab they assessed - Mark Looney lab

PEST - there wasn't a competitor to look at; SWOT would be hard because we didn't know a lot of information about the lab. Plate biogenesis of the lung

PEST to look at whether or not this new project should stay in the lab or go out?

- P NIH budget, human studies (ethics etc..), core facilities (they have access to this, but it could take up a lot of time in the lab)
- E economically good to spin the work into institutional funding vs. getting other NIH grants.
- S postdoc that developed this is leaving (is there enough space for 2 labs pursuing this?), position in department (would the department support this?), public attention (could help to leverage additional resources for funding and garner social support).
- T (technology) core facility (could help to push work), disadvantage is that this development relies in imaging, not a unique technology. May be a good thing to do industry collaborations

JUNO (no picture of poster)

L - 2 presenters

Used SWOT to see where they are and the environment

Competitors - looked at Novartis and Kite who are doing CAR-T as well. Novartis targets ALL and DLBCL. Kite looking at DLBCL

Juno is looking at DLBCL so thought: improved target specificity and safety and efficacy. Outside of improving the particular cancer, moving out of blood cancers into solid tumors there would be a bigger market

these competitors are looking at blood cancers, so even though they are looking at a smaller market, they do a better job addressing the side effects. For Juno, we saw that they are not as 'fast' at making the product, because Juno is relying on making CAR-T from patients as opposed to looking at a cell-line option that works for everyone.

assessing delivery process (can we be faster than 4-weeks) or maybe collaborate with offthe shelf so patients have a treatment starting while they're waiting for specialized CAR-T. Another strategy is that they could make themselves an acquisition target if they can't recover from the negative press.

A lot of opportunities. We felt they would need to rank what they could do via: Actionability/market size/feasibility.

START-UP - Care anytime

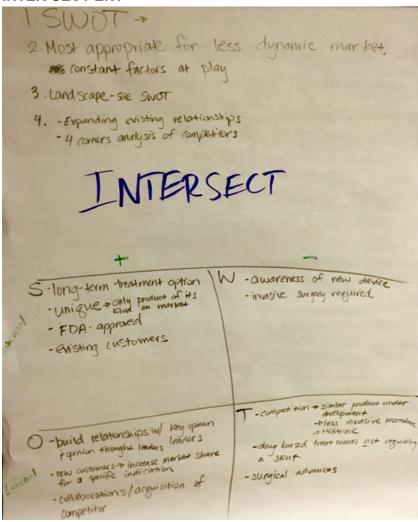
S - push in medicine towards prevention as opposed to treatments.

W - the startup is funded by owner, no big companies and need to start a new market. Not enough funds and penetrate to a new market. Also still in the process of developing new protocols to prevent chronic diseases, still have to work on diagnoses and treatments. More research needed to convince physicians that adiponectin is a good marker.

T - other physicians in the country could be competition in the future.



INTER-SECT ENT



L - 2 presenters
L: We felt SWOT would
be best, it's not a nondynamic market, but we
felt that there weren't
many factors that would
make it totally novel.
Because it's doing
something that was done
before just in another part
of the body.
L: internal SWOT:
Strength: long-term
treatment option, to our
knowledge is the only of

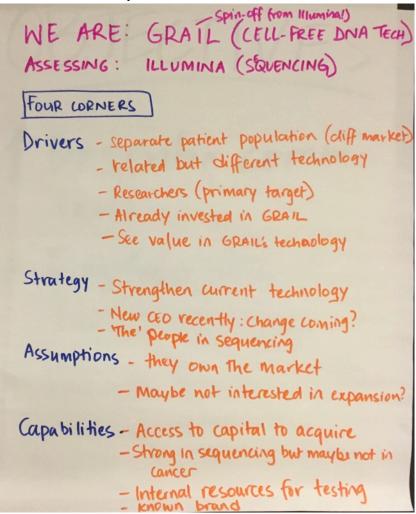
Strength: long-term treatment option, to our knowledge is the only of its kind, but there are a couple comparable but not totally directly competitive (not FDA approved) vs this product IS FDA approved and they're working with patients already. Weakness: they don't really have the 'word out'

not really have

industry/pharma adopting. Invasive approach which would be hard to adapt. External OT

- O build relationships with KOL/ Opinion Thought leaders to help get the word out contact them by going to conference. Build relationships with new customers, increasing the market share for a new indication In looking into the product we looked at other products that are similar.
- O If we looked at other products they could be intimidated so they could consider acquiring these other companies.
- T Similar products out there, not as invasive, so could pull people away. Drug-based treatments that don't require surgery. Also if someone comes out with a better surgical advancement. Another drug that is better than your drug that's another device. Next steps KOL, 4 corners analysis on your competitors. Long term: acquiring another company or be acquired.

GRAIL/Illumina - spin off



Four corners Grail is a cell-free DNA technology, detect cancer antigens Used: 4 corners because they wanted to see if they would be good at collaborating. Looked at perspective from grail analyzing illumina. Grail targets patients, but Illumina is looking at researchers and companies, but they are already invested in Grail (own 20%). But potential value there because

Strategy - illumina is trying to control the whole market in sequencing. And things might change since illumina just got a CEO. Illumina might not want to expand because they decided to spin out Grail.

Illumina has good access to capital and good technology in market. Maintain partnership or collaborate? Collaborate yes, voted.