Bio Professional Development Program

The QUICK SCREEN, the 3 Ps, and the QST

Presented by:

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IGE- JACOBS AND RADY, UCSD

EMSOP- RUTGERS

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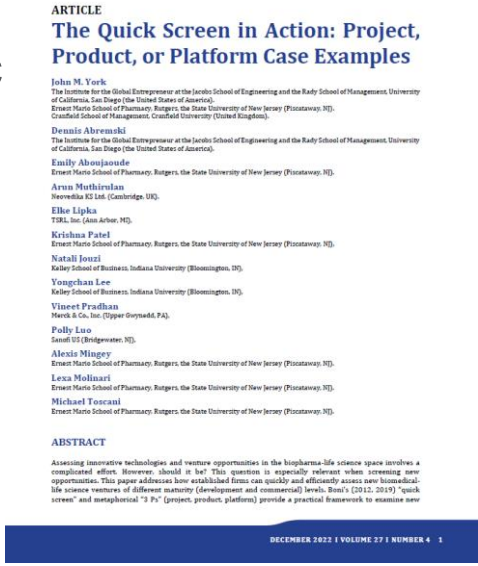

ARTICLE

The Quick Screen in Action: Project, Product, or Platform Case Examples

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ABSTRACT

Assessing innovative technologies and venture opportunities in the biopharma-life science space involves a complicated effort. However, should it be? This question is especially relevant when screening new opportunities. This paper addresses how established firms can quickly and efficiently assess new biomedical-life science ventures of different maturity (development and commercial) levels. Boni's (2012, 2019) "quick screen" and metaphorical "3 Ps" (project, product, platform) provide a practical framework to examine new

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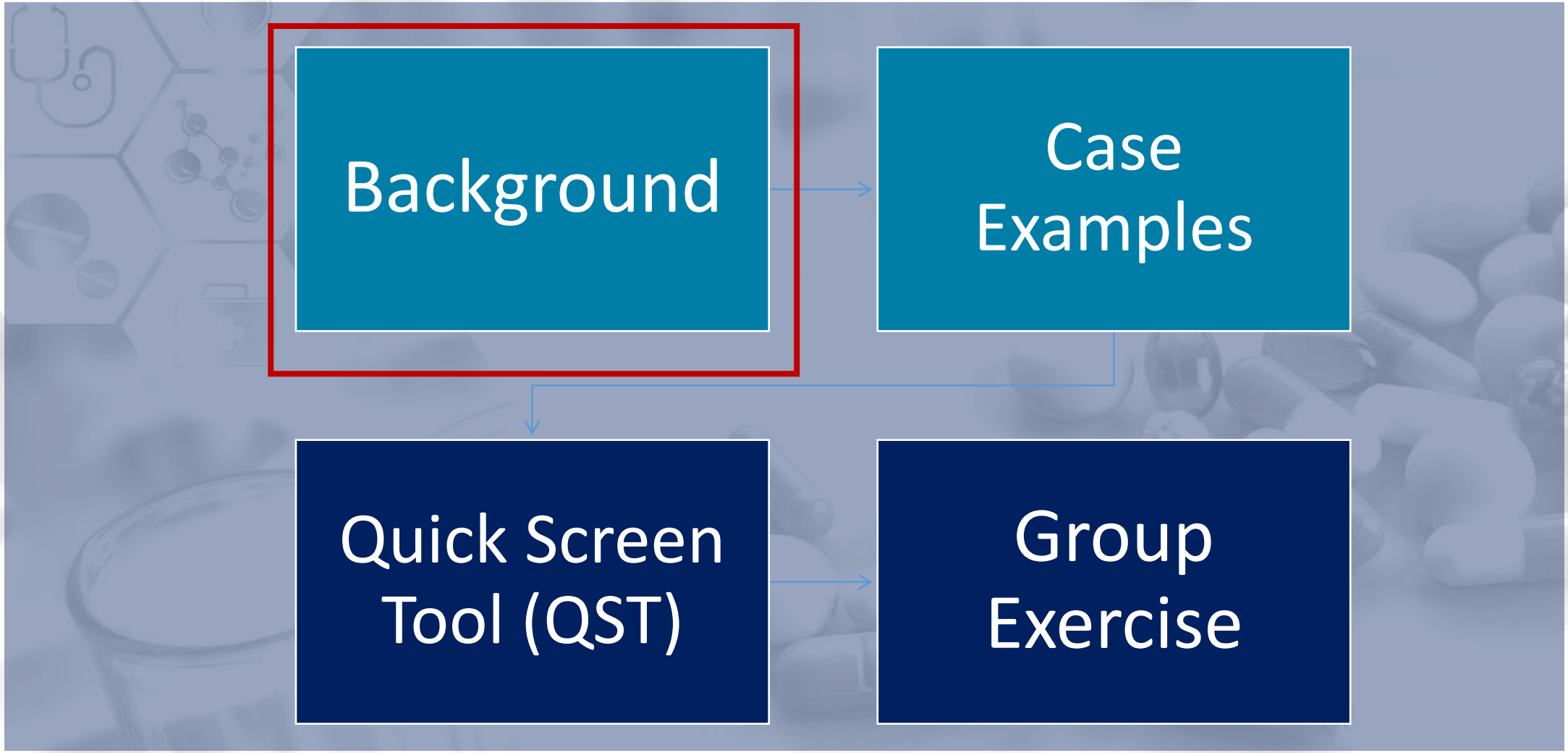
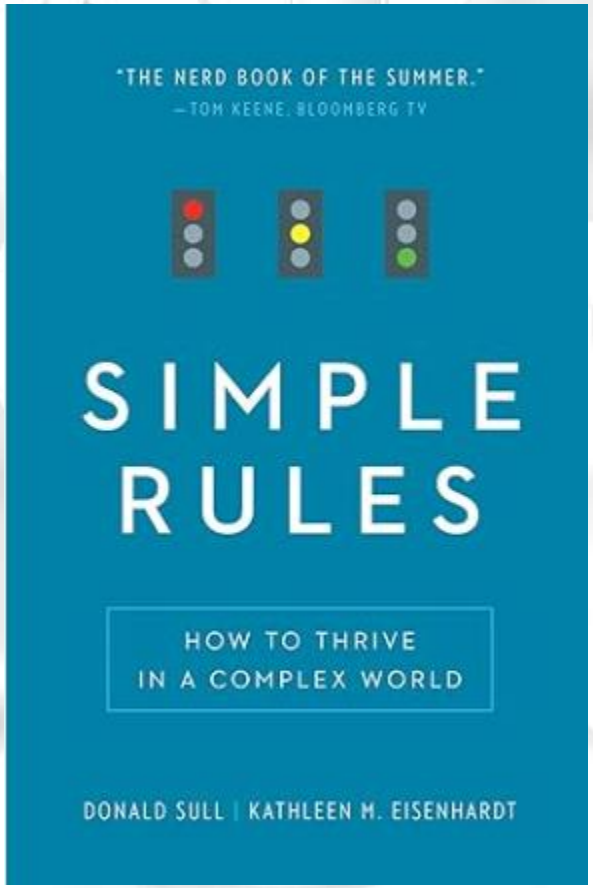
Quick Screen Session Roadmap



OVERARCHING QUESTION

How can biopharmas quickly assess biomedical startups of different maturity (development & commercial) levels?

LET'S START WITH THE CONCEPT OF "SIMPLE RULES"



Donald Sull, PhD
Sloan, MIT

Kathleen Eisenhardt, PhD
Stanford Technologies Venture Program
School of Engineering

Simple rules: a handful of guidelines tailored to the user and the task at hand, balancing concrete guidance with the freedom to exercise judgment.

Usually involve three-to-five points.

Help people thrive in complex situations by providing a flexible and effective framework for decision-making.

Useful from business to sports to personal life.

Types: How to, Boundary, Priority, Timing, and Exit.

Boni Introduced the Quick Screen as a Useful Set of Rules

Art Boni, PhD
Professor Emeritus,
Carnegie Mellon University
Editor Emeritus,
Journal of Commercial Biotechnology

Article

Evolution of the Screening Metaphor: Project, Product, or Platform?

Arthur A. Boni
John R. Thorne Distinguished Career Professor of Entrepreneurship, Emeritus, Tepper School of Business at Carnegie Mellon, Editor-in-Chief, Journal of Commercial Biotechnology

ABSTRACT

There are multiple options or paths to the market to be considered when developing the commercialization strategy for translating a technology or invention into an innovation. We present a very simple screening methodology that may be applied to facilitate a quick, but structured approach for the entrepreneur to identify which option or options may be most viable to create, deliver and capture value in potential markets. We construct the metaphors "project, product, or platform" to categorize three potential commercialization pathways to reach the market. Projects are best pursued with commercial partners via licensing arrangements. Products may be pursued using a research and development company business model. Platform is intended to signify creation and growth of a lasting, scalable organization intended to develop and bring multiple disruptive or transformative innovations to market. Which path to the marketplace is appropriate, or even possible will depend on a number of factors. These include: the magnitude of value being created for the market; the competitive set; and, the uniqueness of the solution and its sustainable, competitive advantage that can be created. It is also necessary to determine whether the value captured by the business model that may be constructed could generate sufficient profitability to balance the commercialization risks, while meeting the goals and objectives of the founders, investors and partners over an appropriate time line.

Journal of Commercial Biotechnology (2019) 24(4), 7–13. doi: 10.5912/jcb909

INTRODUCTION

This article focuses on articulating a simple, structured screening methodology for identifying and evaluating ideas as potential opportunities for commercialization. The methodology is structured around 5 pillars that are needed to build and grow profitable, sustainable businesses. A key component of the methodology is to identify appropriate business models that create, deliver, and capture value consistent with the strength and viability of the opportunity being pursued and the risks associated with commercialization.

This methodology was developed to kick off the first session of the annual Biotechnology Entrepreneurship Bootcamp held at the international BIO convention each year. An article was then published as part of our first special edition in J. Commercial Biotechnology, c. f. Boni (2012)[1]. Since that time, we have also published a much more comprehensive, and in-depth overview of the entire commercialization and innovation methodology that deals with the development and implementation of commercialization and innovation strategies, c. f. Special Edition of JCB, titled "The Business of Commercialization and Innovation, Boni et al (2018)[2]. This more recent, cross-industry perspective also includes case studies pertinent to biopharma, MedTech and Digital Medicine. Given this more recent work, our original article is now being updated herein, and includes some new perspectives.

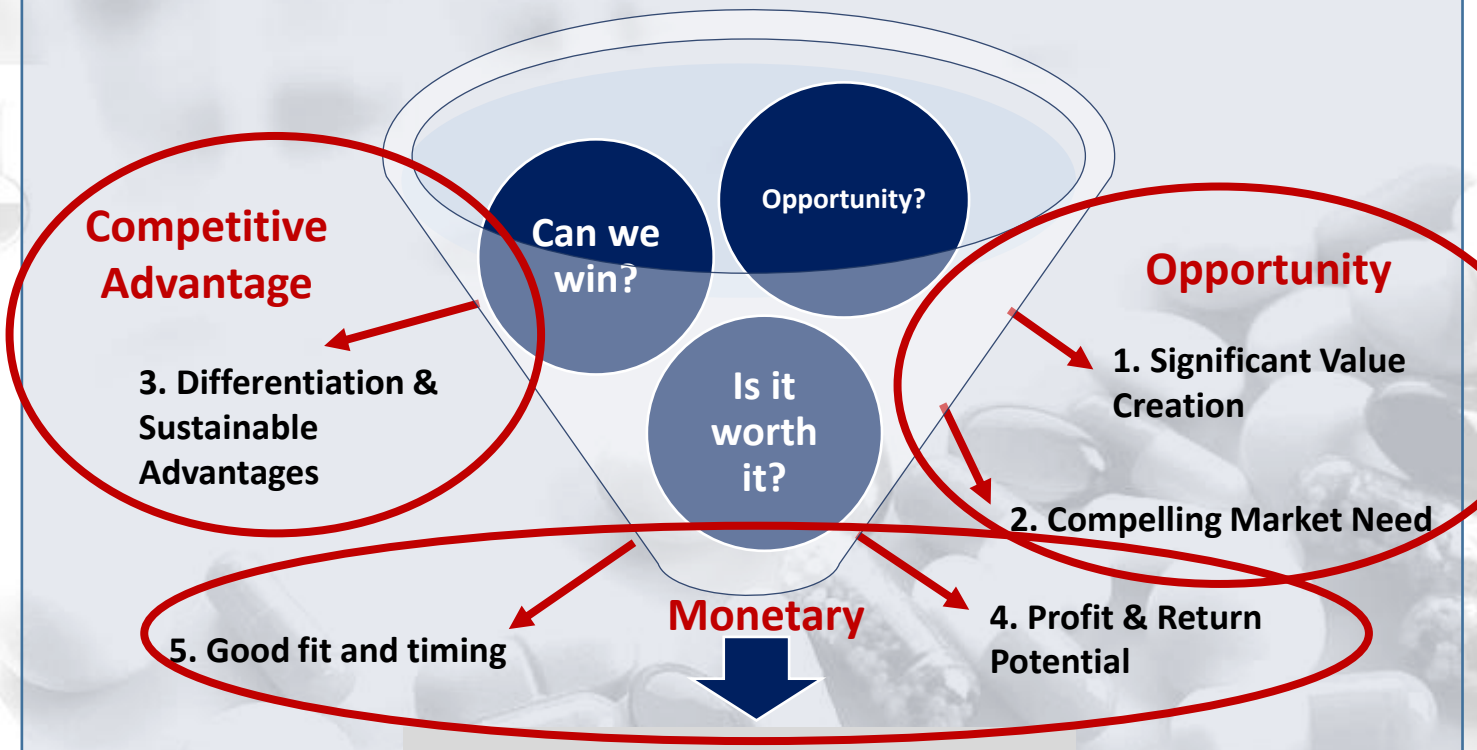
The original article was titled, "Project, Product, or Company" since we focused on a development of categories of business model variations for potential opportunities in the broad biopharma and MedTech industries. With emphasis on simplicity, we took a *metaphorical approach* and suggested a framework that describes three potential pathways "from the laboratory to the market". All of these characterize and highlight the commercialization challenges, and identify an "appropriate" path to the market consistent with the risks, rewards, investment required, and with the extant or expected competitive landscape.

We first presented a very simple screening methodology that may be applied to facilitate a quick, but structured approach for the entrepreneur to understand which options may be most viable and lowest risk to create, deliver and capture value through the business model that is to be created and validated.

Boni, JCB 2019

At the Core of the Quick Screen….

Addresses
Three Questions
and Considers the
Five Anchors
of a Good Opportunity

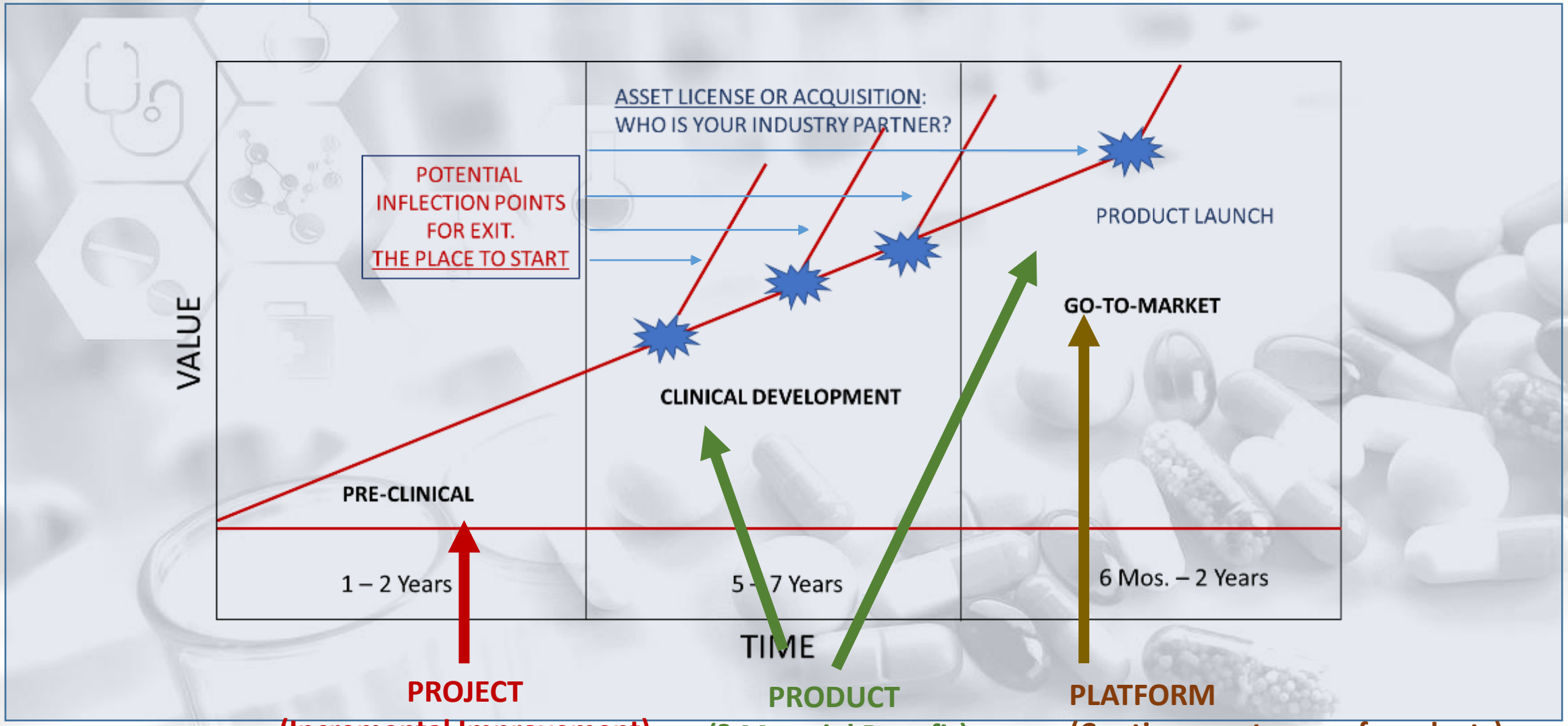


Boni, JCB 2019

The Quick Screen Is an Incredibly, Practical and Straightforward Framework for BioPharma Executives to Evaluate Assets, Products, and Programs. Its Beauty Is in Its Simplicity. It Covers the Most Meaningful Considerations That Executives Should Consider When Making Strategic Decisions.

Santos Torres, Jr.
Past Vice President of Marketing
Santen USA

The Three "Ps" Reflect Maturity Levels and Value Inflection Points



York and Abremski, 2018

Project- A Good Licensing, Grant, or Collaboration Option

Opportunity	• Early →
	  • Product not fully defined
	  • Value not yet compelling or significant

Monetary	• Low $ value in market (early stage) • Still, significant $s to ↓ tech/clinical risk
Competitive Advantage	• Other competitors • Limited IP and FTO • POD → not fully defined (early)

Boni, JCB 2019

POD= Point of differentiation; FTO= Freedom to Operate; IP= Intellectual Property

Product- A Development Stage Set to Commercialize

Opportunity

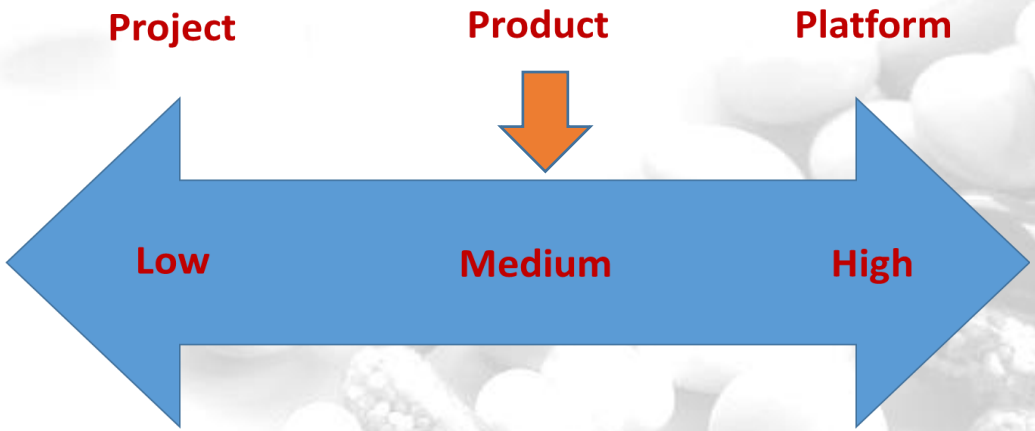
- Value
  - Interest
  - May not be compelling/significant yet

Monetary

- Investment is in
- Further development and $'s → prove significant "value"

Competitive Advantage

- In the clinic and maybe POC
- IP → more well defined
- Barriers → regulatory path and GTM



Boni, JCB 2019

IGTM= Go to Market; P= Intellectual Property; POC= Proof of Concept

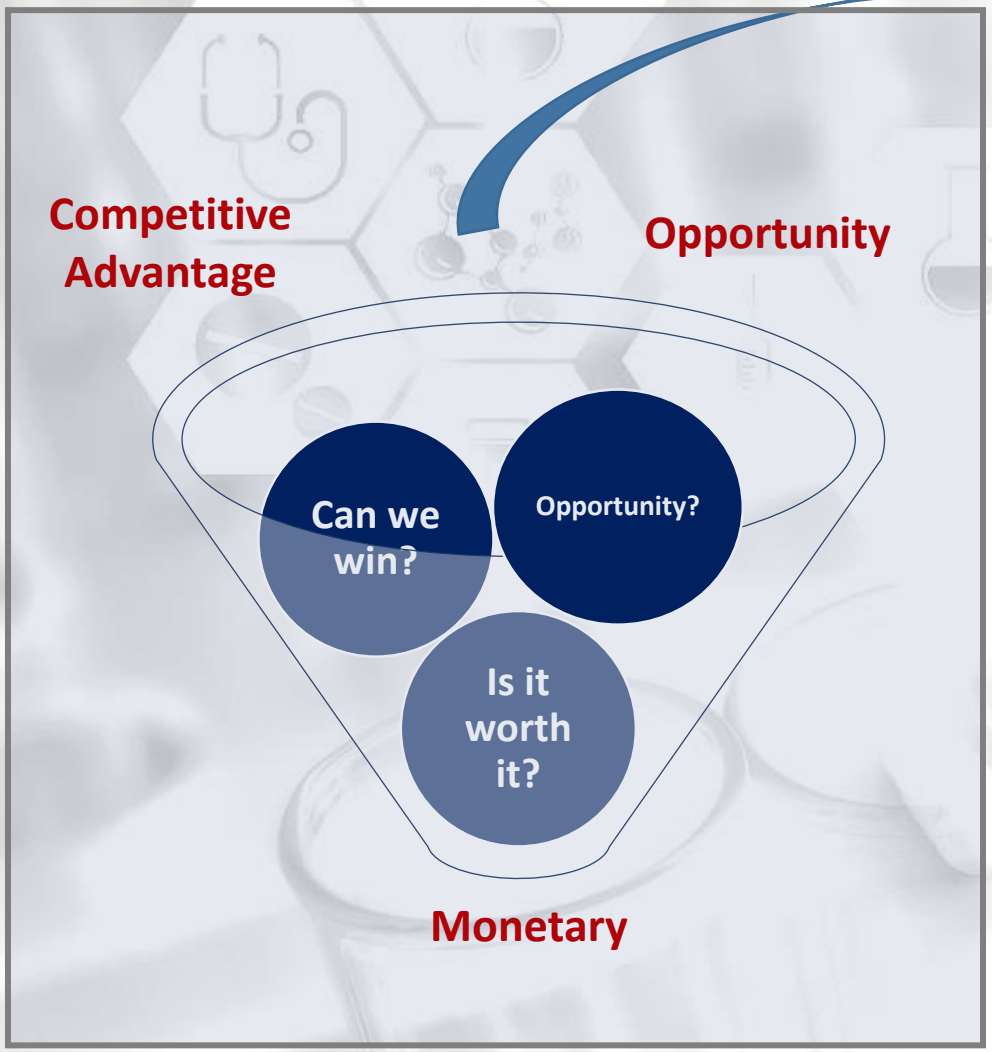
Platform- Built to Last with Multiple Products and Management Team to Carry Products Further

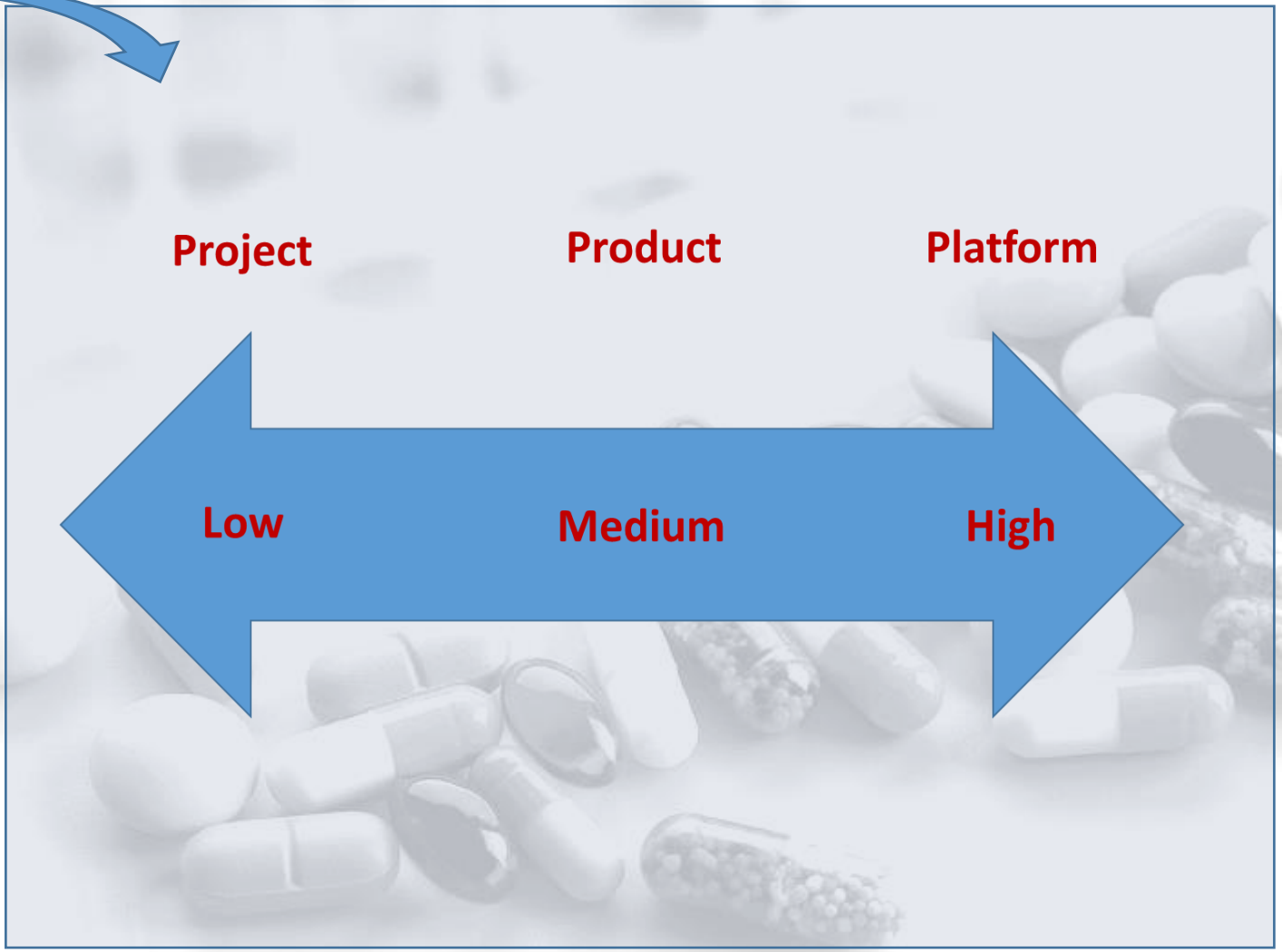
Opportunity	• Large market • Significant need • Compelling solution
Monetary	• Passed the clin/reg inflection points • ↑ profits and margins possible • ↑ROI potential for investors
Competitive Advantage	• Unique, differentiable solution • Strong IP (or can be established) • ↑ with a partnership

Boni, JCB 2019

Clin: Clinical; IP= Intellectual Property; Reg= Regulatory; ROI= Return on Investment

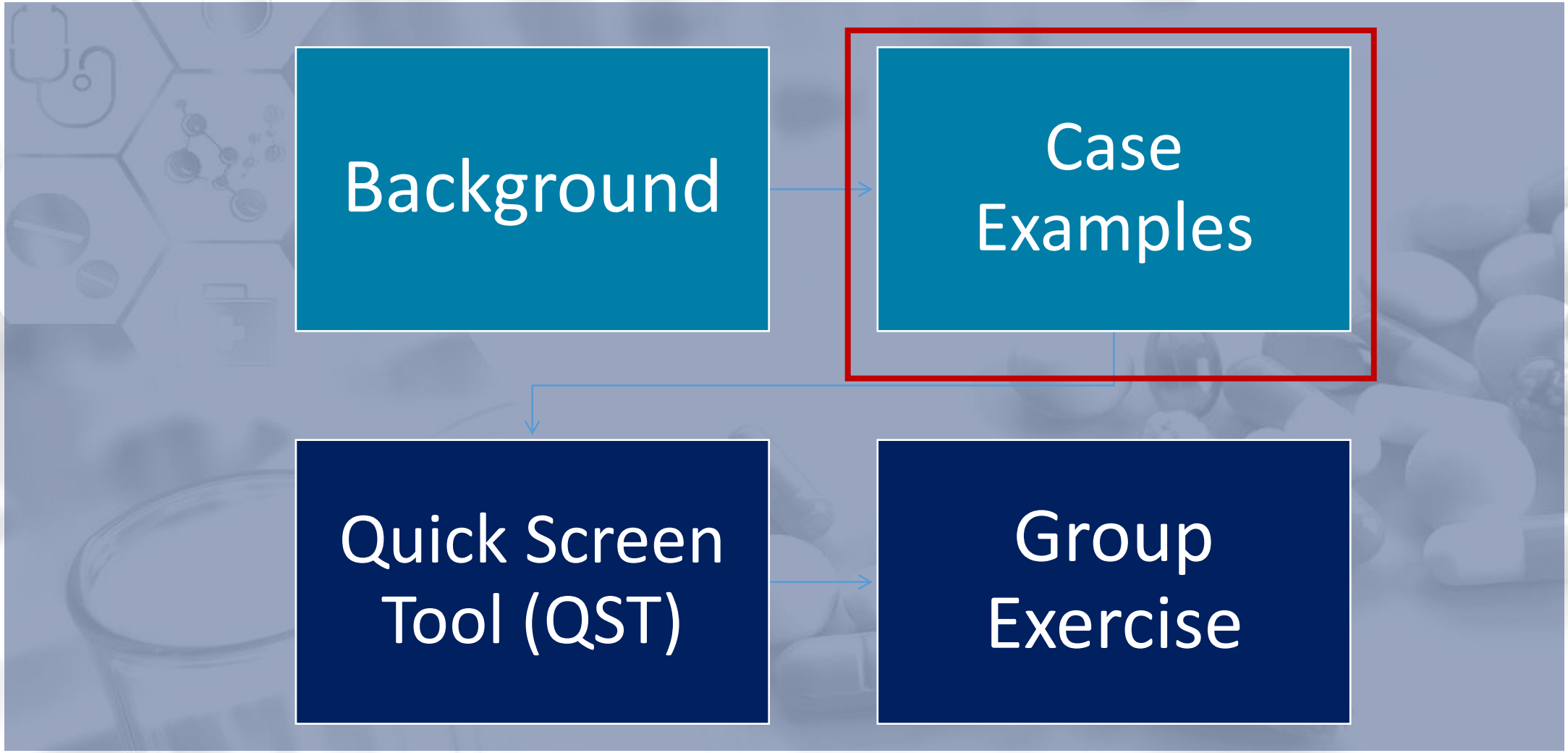
And the Quick Screen Can Sort Out How the 3 “Ps” Fit





Boni, JCB 2019

Quick Screen Session Roadmap



Case 1: Veneno Technologies- Early & Can Benefit from R&D Collaborations

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN"→ ALL LOW

	Positives	Negatives
Opportunity	• Markets: Peptide→$28.5B (2020, Global), 9.66% CAGR[1] Drug discovery→ $58.3B (2021, Global), 8.21% CAGR[2] • UMNs→ Rapid, productive screening, faster developed, expanded library, and ↑stable, novel targets	• ↑ competition, especially in the drug discovery service space • Suite→ early →service vs. product→ lower value (incomplete)
Monetary	• Raised $2M seed (2021)	• Significant capital to mature to a product and a significant inflection
Competitive Advantage	• Throughput, productivity, and efficiency • Multiple patents (Japan, US) • Scientific expertise • Projects, alliances, and licensing of technology or outputs will enhance	• Tool/service business may be questionable for a durable POD

KEY POINTS FROM THE MAP

1. Attractive markets
2. UMNs for screening/library production and sustainable oral peptides
3. Suite → Advantages, but still early
4. $ raised → Need more
5. Recent Astellas Pharma collaboration (proto-customer).
6. Other corporate collaborations.
7. Drug discovery competitive→? the tool/service business durability
8. Projects or alliances $s → lead peptide

   →Animal POC → Clinical testing

CAGR= Compounded Annual Growth Rate; POD= Point of Differentiation; ?=Questionable

JD Bioscience: Early-Stage Clinical Can Benefit from Alliances

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN"→ ALL MID

	Positives	Negatives
Opportunity	• Moving into Ph 1 a/b • Market: $144.4M→$27.2B (2019-29), 68.8% CAGR (Global)[1] • UMN→ lipid, inflammation, and fibrosis management[2,3] • Trend→ Movement to combo therapy[2] (Pfizer fast track)	• Uncomfortable investors/BD regarding NASH
Monetary	• Series A and B Funding (~$20M, Lead, Mirae Asset Capital)	• Funding needed for Ph 2 and 3
Competitive Advantage	• 1st-in-class peripheral 5HT2A antagonist • Defined IP (Korea, US) • ↓ fibrosis, inflammation, and lipids (4 animal models) • No BBB crossing • Alliance/licensing → enhance development position	• No real H/H with other assets through development

KEY POINTS FROM THE MAP

1. Large market.
2. Madrigal Pharmaceuticals, Inc. 1st FDA approval and strong demand expectations for a potential $B product- Defines a regulatory and $ path.
3. Combo therapy (Gilead/Novo Nordisk)
4. Unique MOA (fibrosis, inflammation, and lipid reduction) with POC (7 animal models).
5. JDB Completes FIH with no safety issues.
6. Complicated disease. Issues with clinical studies and approvals (Intercept).
7. Has funding; Needs more for Ph 2 and 3→ Alliance/licensing→ Move asset along.

BBB= Blood Brain Barrier; BD= Business Development; CAGR= Compounded Annual Growth Rate; FIH= First in Human; H/H= Head to Head; NASH=Non-Alcoholic SteatoHepatitis; Ph= Phase; UMN= Unmet Need

1. Global Data, NASH, 2020
2. Loomba and Shulman, 2021
3. Albhaisi and Sanyal, *Liver* Intl, 2021

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Moderna: Many Positives with Room for Growth in Alliances or May Engage in M&A

MAPPING KEY CONSIDERATIONS USING THE "QUICK SCREEN"→ ALL HIGH

	Positives
Opportunity	• **Market: Vaccines:** $67B→149B (2001-27), CAGR 10.2%[1] • **COVID-19:** $65B→$157B (2020 -25) CAGR 19.29%[2] • **mRNA:** $47B → $101B (2021-26)[3] • **UMN**→ HIV, RSV, CMV, Zika and cancer in the pipeline
Monetary	• **Revenue**→ $803.4M→$18.5B (2020-21)[4] • **Market cap**→$54.19 B (May 2022)[5] • Room for growth
Competitive Advantage	• Unique platform, strong COVID-19 experience, Strong IP • Ph 1→ HIV vaccine (mRNA-1644 & mRNA-1574) and Immuno-oncology (IL-12, MEDI 1191) • Seasoned mgmt.; large talented organization • Multiple alliances (e.g., AZ, Merck, Vertex). • Maybe M&A

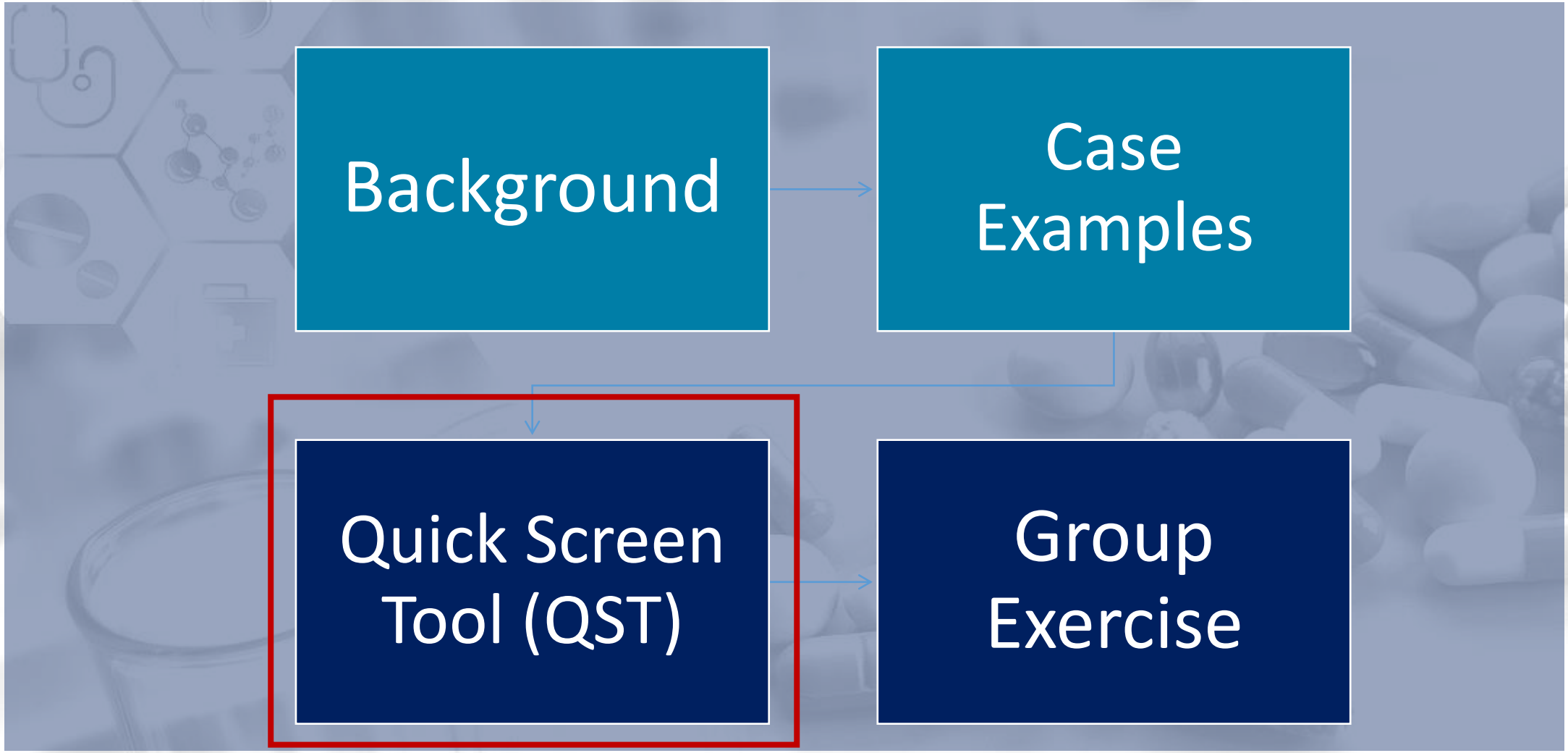
KEY POINTS FROM THE MAP

1. Defined, effective platform with commercial success
2. Pipeline ID and IO applications
3. Seasoned mgmt.; Talented organization
4. Attractive opportunities with UMNs
5. Strong revenue, but declining due to the control of COVID.
6. $ left on the table?
7. Benefit from alliance. Maybe M&A (BioNTech-Pfizer → $37B vs. Moderna → $18.5 B in 2021)

AZ= AstraZeneca; B= Billion; CAGR= Compounded Annual Growth Rate; CMV= Cytomegalovirus; COVID= Coronavirus; HIV= Human Immunodeficiency Virus; IL= Interleukin; ID= Infectious Disease; IO= Immuno-Oncology' M&A= Mergers & Acquisitions; mRNA= Messenger RNA; RSV= Respiratory Syncytial Virus.

1.Research and Markets 2022
2.Williams S. The Motley Fool, 2021
3.BCC Research, 2022
4.Marketline 2022 5. Companies Market Cap

Quick Screen Session Roadmap



A Score Card Tool to Explore

Opportunity	Weight	Low		Med		High	Super High	Weighted Score	Benchmark
		1		2		3	4		
Market Size	17%						4	0.67	0.67
Market Growth	17%			2				0.33	0.67
Application (Indication)	17%	1						0.17	0.67
Stage (Maturity)	17%					3		0.5	0.67
Competition	17%	1						0.17	0.67
Timing	17%	1						0.17	0.67
Composite Score								2.01	

Monetary	Weight	Low		Med		High	Super High	Weighted Score	Benchmark
		1		2		3	4		
Funds in	20%						4	0.8	0.8
Funds Needed	20%					3		0.6	0.8
Funding Sources	20%			2				0.4	0.8
Returns	20%			2				0.4	0.8
Stage	20%	1						0.2	0.8
Composite Score								2.4	

Competitive Advantage	Weight	Low		Med		High	Super High	Weighted Score	Benchmark
		1		2		3	4		
IP	20%						4	0.8	0.8
POD	20%			2				0.4	0.8
Unique MOA	20%					3		0.6	0.8
Organizational	20%			2				0.4	0.8
Enduring	20%			2				0.4	0.8
Composite Score								2.6	

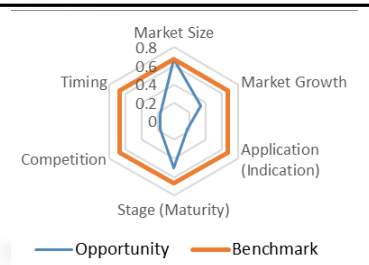
Quick Screen	Weight	Score	Weighten Score	Benchmark	Net
Opportunity	33%	2.01	0.67	1.33	
Monetary	33%	2.4	0.8	1.33	
Competitive Advantage	33%	2.6	0.87	1.33	
Total QS Compsite Score			2.34		Project

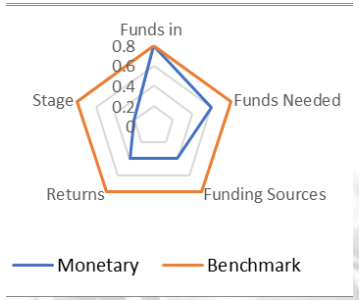
	Score Range
Project	0-4
Product	4.1-8
Platform	8.1-12

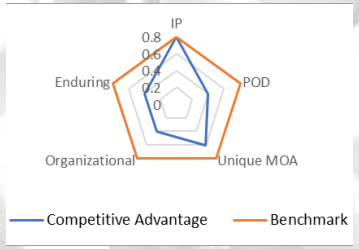
Input

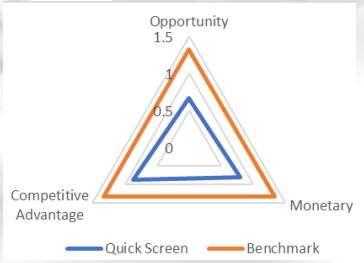
Output

Profiles vs. Benchmarks









Quantitative Evaluation

Weighted Evidenced

Signatures Within Each Screen vs. Standard

Areas to Work on

Score Case Example: Opportunity

Applying the quick screen tool to JD Biosciences produces a weighted opportunity score of 3

Opportunity		Weight	Low		Med	High	Super High	Weighted Score	Benchmark
			1		2	3	4		
Low to High	Market Size	17%					4	0.67	0.67
	Market Growth	17%					4	0.67	0.67
	Application (Indication)	17%				3		0.5	0.67
	Stage (Maturity)	17%			2			0.33	0.67
High to low	Competition	17%				3		0.5	0.67
Long to short	Timing	17%			2			0.33	0.67
Composite Score								3	

Opportunity score is composed of six different qualitative factors. Each factor is scored independently, then all six are averaged together to quantitatively characterize the opportunity.

Market Size

Market Growth

Applicati on

Stage

Competiti on

Timing

Scoring Ranges

Project: 1-2
Product: 2.01-3
Platform: 3..01-4

Score Case Example: Monetary

Applying the quick screen tool to JD Biosciences produced a weighted monetary score of 2.6

Monetary		Weight	Low		Med		High		Super High	Weighted Score	Benchmark
			1		2		3		4		
Low to High	Funds in	20%					3			0.60	0.80
High to Low	Funds Needed	20%					3			0.60	0.80
Low to High	Funding Sources	20%					3			0.60	0.80
	Returns	20%	1							0.20	0.80
Early to Late	Stage	20%					3			0.60	0.80
Composite Score										**2.60**	4.00

Monetary score is composed of five different qualitative factors. Each factor is scored independently, then all six are averaged together to quantitatively characterize the opportunity.

Funds In

Funding Sources

Stage

Funds Needed

Returns

Scoring Ranges

Project: 1-2
Product: 2.01-3
Platform: 3..01-4

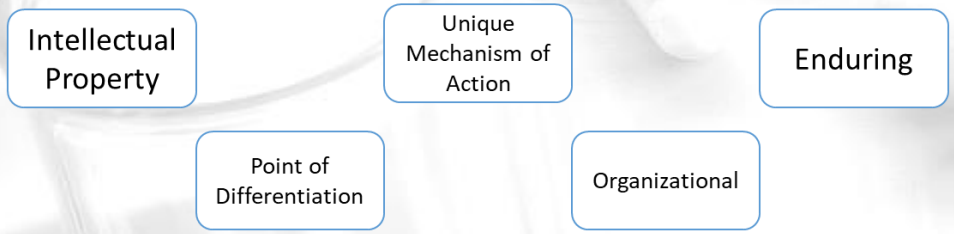
Score Case Example: Competitive Advantage

Applying the quick screen tool to JD Biosciences produced a weighted competitive advantage score of 3.0

Competitive Advantage	Weight	Low		Med		High	Super High	Weighted Score	Benchmark
		1		2		3	4		
IP	20%					3		0.60	0.80
POD	20%					3		0.60	0.80
Unique MOA	20%						4	0.80	0.80
Organizational	20%					3		0.60	0.80
Enduring	20%			2				0.40	0.80
Composite Score								**3.00**	4.00

Low to High

Competitive Advantage score is composed of five different qualitative factors. Each factor is scored independently, then all six are averaged together to quantitatively characterize the opportunity.



Scoring Ranges

Project: 1-2
Product: 2.01-3
Platform: 3..01-4

A Score Card Tool to Explore: Weighted Scoring

Applying the quick screen tool to JD Biosciences produced a final weighted score of 2.87

Quick Screen	Weight	Score	Weighted Score	Benchmark	Net
Opportunity	33%	3.00	**1.00**	1.33	
Monetary	33%	2.60	**0.87**	1.33	
Competitive Advantage	33%	3.00	**1.00**	1.33	
Total QS Compsite Score		8.60	**2.87**	4.00	**Product**

JD Biosciences receives a total quick screen composite score of 3.13 / 3.99

- The quick screen composite score represents the consolidated quantitative score for JD Biosciences
- Competitive advantage and opportunity are the strongest components, each with a weighted score of 1/1.33
- The monetary characteristics component reflects more of a weakness for JD Bioscience, garnering a weighted score of 0.87/1.33.

Scoring Ranges

Project: 1-2
Product: 2.01-3
Platform: 3..01-4

Anonymous Industry BD Feedback

We are intrigued and are exploring how we could use the tool.

We look to adapt with some of our own needs and experience.

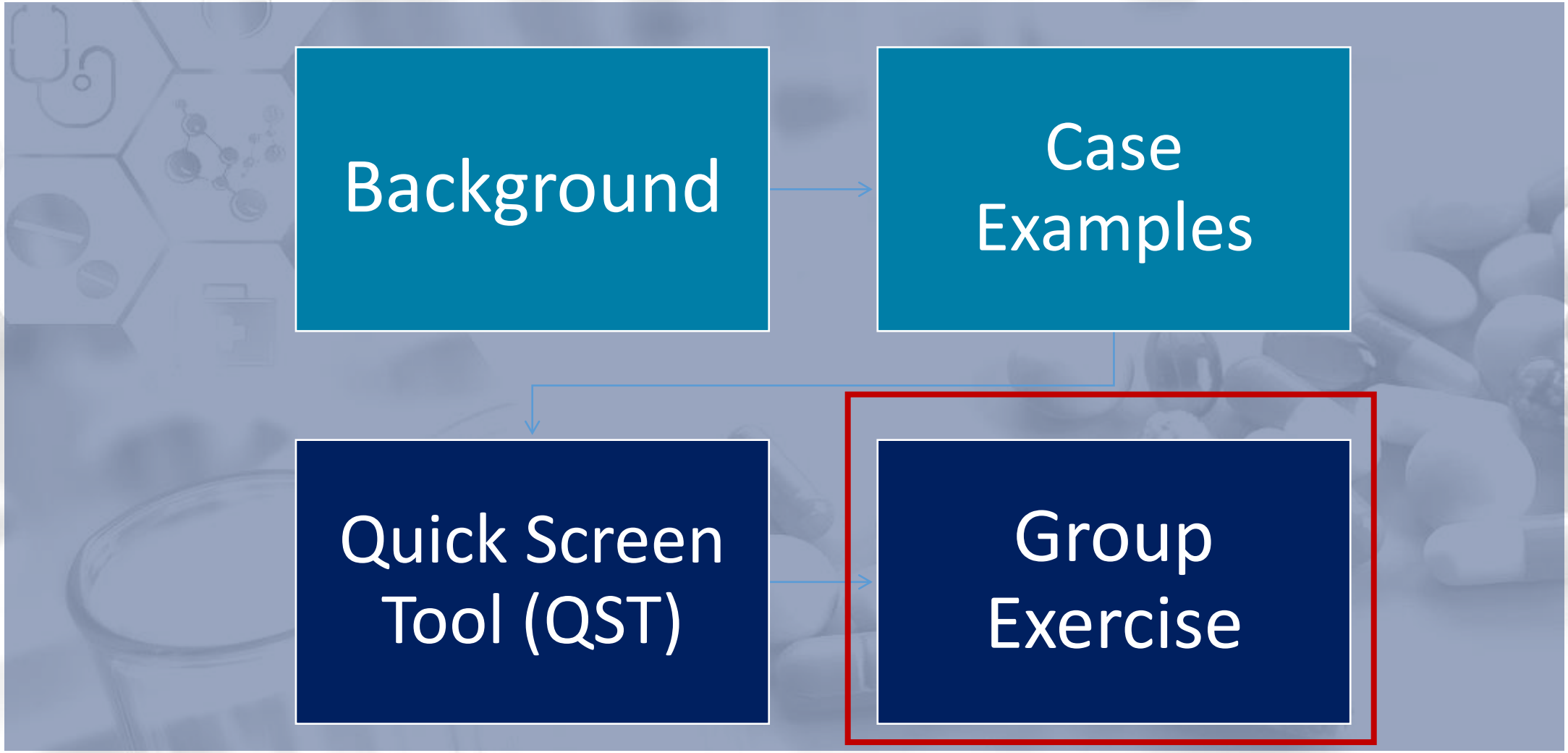
It can be helpful in screening out the many different opportunities that cross our desk.

Closing Thought….

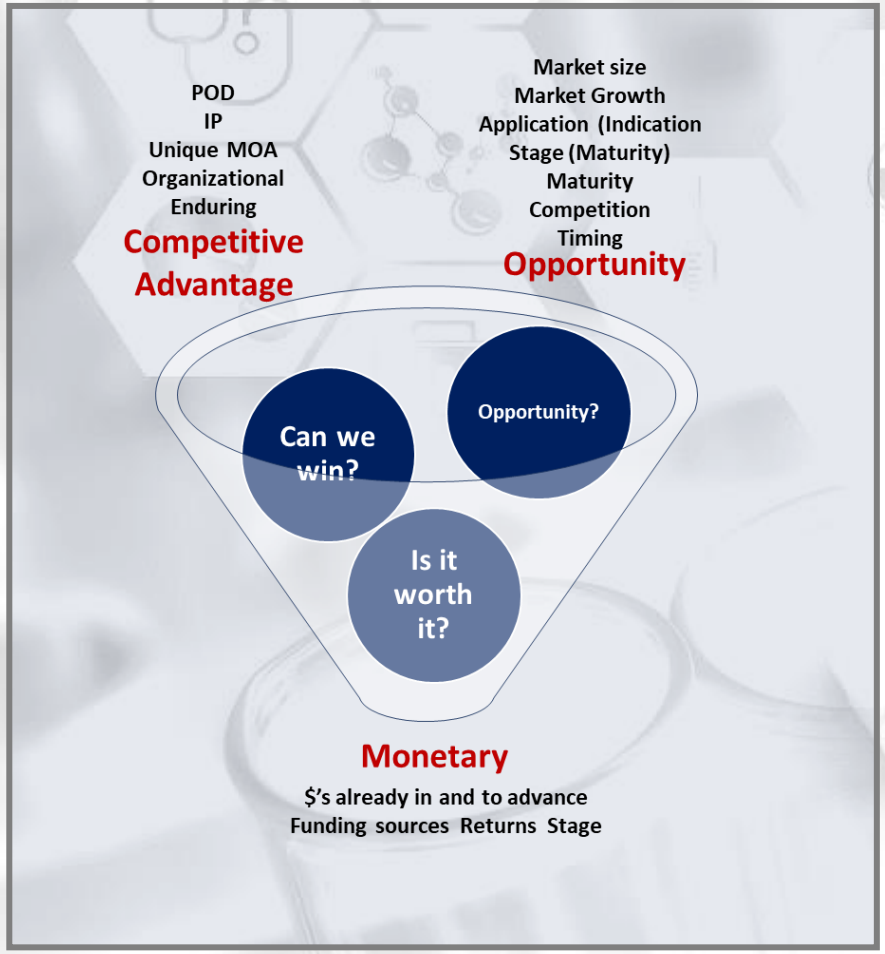
“Simplicity is the ultimate sophistication.”

- Leonardo da Vinci -

Quick Screen Session Roadmap



Case Activity: Let's Take and Map Your Case Example?



Boni, JCB 2019 IP= Intellectual Property; MOA= Mechanism of Action; POD= Point of Differentiation

Project Product Platform

Low Medium High

Map Out Your Company

https://bit.ly/YorkBioBootCamp2024

Discuss Findings in Session or 1:1 in Breaks