

A New Approach to Early-Stage Portfolio Decision Making

Conventional assessment methods can't handle long-lead-time investments in life sciences



To learn more, <u>view our recent webinar</u> on a new approach to early-stage portfolio decision making.

Long-lead-time decisions often involve a great deal of uncertainty

Decisions today:

Early-development pharmaceutical decisions often require significant investment and are made with limited or uncertain information. In the drug development stage of the pharma value chain, companies often have a diversity of projects that require decisions now and have uncertain preclinical and clinical data.

Future outcomes:

Drug development can take 10 years, can cost billions of dollars, and may not generate positive cash flow for 20 years.

		Drug Development – up to 10 years ¹ ized Cost per approved compound " \$ 2.5 billion ²	► Manufacturing	Sales & Marketing	Product Management
	PreClinical: Find promising data on potential drug efficacy and safety	Clinical: Probability of transition: 11.83% ² Study drug effects on human body, identify side effects, and give early indication of the drug's efficacy	Target	Indication	Development
			Drug development decisions across disease areas Receptor Oncology		
² DiMasi, J. A	¹ Seifert, R., 2019. Basic Knowledge of Pharmacology. s.l.: Springer Nature Switzerland AG. ² DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. Journal of Health Economics, 47, 20-33.			CardiovaIndicatioTrial desFast-trac	tion sequencing esign



Current approaches to making decisions in uncertain environments have shortcomings in early-stage, long-lead-time decisions

There are several well-established approaches to making decisions in uncertain environments—categorized as **qualitative** and **quantitative**. But these approaches have shortcomings when applied in early-stage, long-lead-time decisions.

Commonly Used Approaches



Qualitative approaches:

Describe projects according to several independent attributes, e.g., stage, disease area, risk, price range. Portfolio discussions are facilitated by heat maps.



Quantitative approaches:

Discounted cash-flow models determine the net present value of assets. Based on net present value distributions, decisions are made that are trading off value per associated risk.

Shortcomings



Estimating the approximate value of an early asset and its technology often leads to unrealistic expectations.³



The high degree of uncertainty leads to little confidence in the NPV so that low-risk assets with shorter time horizons are preferred.⁴



In the absence of clear guidelines, early-drug development decisions are prone to distortions.^{5,6}

Mitigation Strategy



Develop an improved **portfolio management** process.



Agree on **decision criteria** to consistently evaluate all projects and to communicate decisions to the company.



Define **scales and structures** that meaningfully differentiate projects.



Define preferences based on agreed decision criteria that describe portfolio strategy.

Conventional approaches might work well for short-term investments where a company has experience and expertise. However, for long-lead-time projects with more innovation, less experience, and more uncertainties, these qualitative and quantitative approaches don't work well.

⁶Peck, R. W. et al., 2015. Why is it hard to terminate failing R&D in pharmaceutical R&D. Nature Reviews Drug Discovery.



³Stewart, J. J., Allison, P. N. & Johnson, R. S., 2001. Putting a price on biotechnology. Nature Biotechnology.

⁴Phillips, L. D. & Bana e Costa, C. A., 2007. Transparent prioritisation, budgeting and resource allocation with multi-criteria decision analysis and decision conferencing. Annals of Operations Research, 154(1), pp. 51-68. ⁵Smietana, K., Ekstrom, L., Jeffery, B. & Moller, M., 2015. Improving R&D productivity. Nature Reviews Drug Discovery.

To make robust, consistent decisions, three key challenges must be overcome

1 Differing objectives

Decision makers often have their own decision criteria and own objectives. Without agreement on objectives, decision makers are unable to make decisions in a company's long-term interest.

Diverging preferences

Lack of understanding of objectives leads to different preferences among decision makers. An absence of a clear structure and process for making decisions leads to non-reproducible and understandable tradeoffs across multiple decisions.

3 Systematic biases

Biases are distortions that can mislead decision makers. Common biases are motivational and cognitive biases.

Biases can impair decision making; they can result in risk avoidance and preference for lower-risk projects with shorter time horizons, and avoidance of investments in longer-term innovation. Biases can lead to selecting suboptimal strategies that are not in a company's best interests.





An approach to overcoming challenges in making early-stage, long-lead-time decisions—

Start with Elements of Decision Quality



SDG has developed the 'Elements of Decision Quality' approach for making long-lead-time decisions in the face of high uncertainty that is better than current approaches and overcomes the major decision-making challenges.

This approach uses a combination of decision analytic concepts and tools that support decision making. The framework describes the essential demands of a systematic decision methodology.

Other methodologies used for early-stage development decisions do not fulfill all of these requirements. Early-stage decisions are different due to the high degree of ambiguity and uncertainty.

For example, in making pharmaceutical decisions, other methodologies focus on the technical determinants of a drug candidate, like pharmacokinetics, leaving objectives outside of consideration. But without clarity on objectives and a process for dealing with conflicting objectives, decision makers are not able to decide in the interest of the company. In risky situations, companies tend to shy away from more risky innovation, which leads to bias against innovation and low R&D productivity.



A combination of decision analytics concepts and tools



After starting with the framework of decision quality, SDG uses additional frameworks, analytic concepts, and tools to support decision making. **Three analytic concepts and tools are:**



SDG uses these concepts in assisting clients with early-stage pharmaceutical decisions where there is a high degree of uncertainty. (The concepts and tools also apply to other industries.) Value-Focused Thinking (VFT). VFT supports the development of a set of fundamental objectives and is used to identify the fundamental value drivers in a portfolio; this goes far beyond defining value merely as discounted cash flows.

Multi-Criteria Decision Making (MCDM). MCDM is a decision-making tool that involves the analysis of various available choices; it provides the basis for evaluation and comparison. Due to its clarity and transparency when assessing multiple criteria, MCDM is very helpful in reducing the ambiguity that leads to low innovation bias. Simplicity allows for easily distinguishing among alternatives. Transparency ensures acceptance and understanding of decision makers.

"With MCDM, we aggregate the value of an alternative from its individual performance against the fundamental objectives."

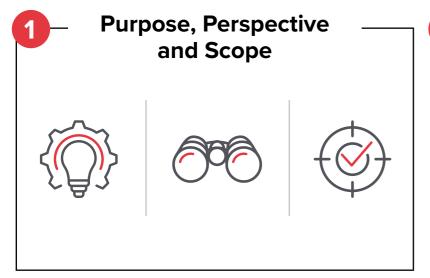
Entscheidungsnavi. This is a free online decision support tool—which translates as "decision navigator"—that can facilitate challenging discussions on preferences and tradeoffs. It can also improve transparency for decision makers by displaying impacts of different preferences. Access the tool at entscheidungsnavi.com

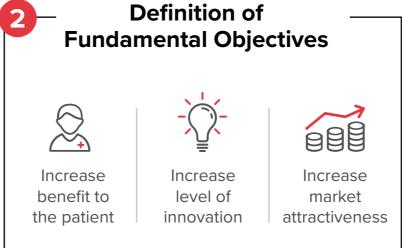


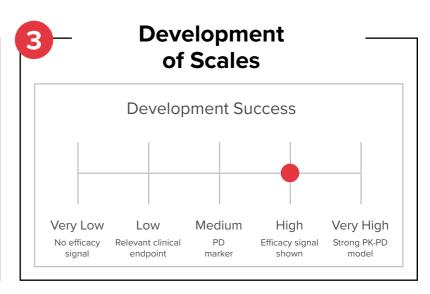
SDG implements this methodology by involving decision makers and decision support teams

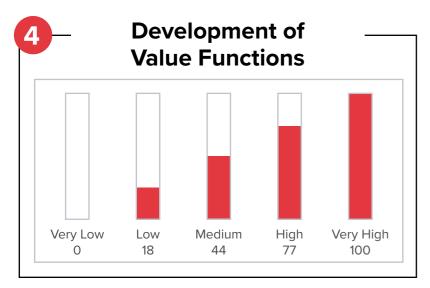


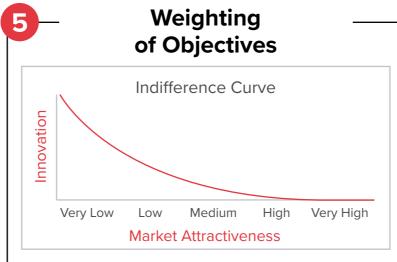
In six steps, shown below, SDG's decision process is defined with responsibilities for key decision makers and for organizational decision support teams.

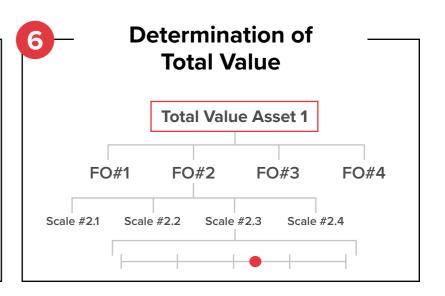












Throughout this entire process, clarity around roles and responsibilities is critical.

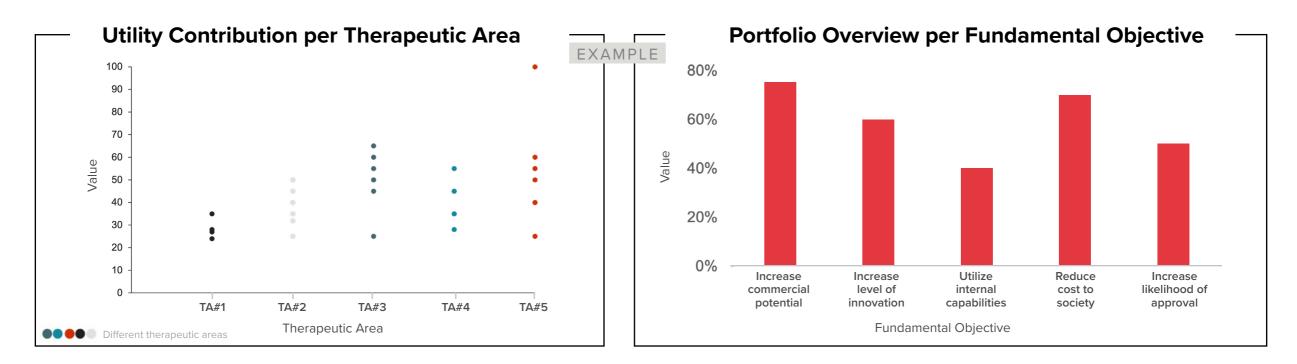


This approach enables agile decision making

In leveraging the combined VFT and MCDM frameworks with a pharmaceutical company, SDG used an approach similar to the illustrative example shown below.

On the left are how different drug candidates rank against each other in various therapeutic areas. The comparison shows those areas more in line with strategy given the company's fundamental objectives.

On the right is an overview of how the company's portfolio looks based on the company's fundamental objectives. This provides a first insight into the portfolio's relative strengths and weaknesses. Further insights can be derived by comparing different portfolios. This kind of comparison illuminates the tradeoffs the organization is facing. It further challenges the objectives as executives strive to address how much of one objective they are willing to sacrifice in order to get more of another.



 $oldsymbol{oldsymbol{\bot}}$ This comprehensive overview is useful in making quicker, more agile decisions, including allocation of resources. $oldsymbol{oldsymbol{\bot}}$



This approach overcomes the key challenges common in other approaches

How to overcome differing objectives

Clarify objectives by distinguishing between strategic and operational. Engage in strategic discussions about preferences and objectives.

RESULTS: Increased efficiency of decision-making process and greater transparency and visibility.

2 How to overcome diverging preferences

Create transparency through sharing objective weights of decision makers with the company to enable open discussions.

RESULTS: A common understanding in the company of the strategy and the weights. By understanding how portfolio decisions are made, project teams can work to make their project a better fit in the overall portfolio. This increases the chance of success of projects.

3 How to overcome systematic biases

Put in place debiasing measures along with clear roles and responsibilities to ensure consistent quality checks across projects.

RESULTS: Decreased biases leads to improved decision making and increased innovation.





This methodology contributes dramatically to the portfolio decision making for various kinds of projects



Benefits of this methodology include unearthing strengths and weaknesses of projects, increasing transparency and visibility for the organization, improving the efficiency of decision making, and enhancing the quality of assessments.



Strengths and weaknesses of projects in the portfolio are unearthed

Looking at how each project performs across the different fundamental objectives in a deconstructed way leads to a prioritization of projects with corresponding reallocations of investments.



Transparency and visibility are established for the organization

Communicating criteria and how portfolio decisions are made enables each project team to work toward making their project a better fit within the overall portfolio.



Efficiency of the decision-making process is increased

By separating discussions about scientific expectations from strategic discussions about preference and objectives, all activities become very focused.



Quality of assessments is continuously improved

Debiasing measures are put into place and clear roles and responsibilities ensure consistent quality checks across the projects.

About SDG

Founded in 1981, Strategic Decisions Group is a strategy consulting firm renowned for its expertise in strategic decision making, risk management, stakeholder alignment, and value creation. Through a collaborative, team-based approach, SDG helps its clients in life sciences and investment-intensive industries find innovative, creative strategies to thrive today, while also helping them build internal competencies to meet future competitive challenges.

Visit sdg.com/life-sciences



Deepak Veeraraghavan
Partner & Head of Global Life Sciences
Strategic Decisions Group
Düsseldorf
vdeepak@sdg.com
+49 211 54 23 00-14



William Leaf-Herrmann
Partner & Head of Life Sciences, North America
Strategic Decisions Group
Boston
wleaf@sdg.com
+1 617 233 0217

To learn more, view our recent webinar on a new approach to early-stage portfolio decision making.

Strategic Decisions Group