A New Approach to Early-Stage Portfolio Decision Making

Conventional assessment methods can't handle long-lead-time investments in life sciences
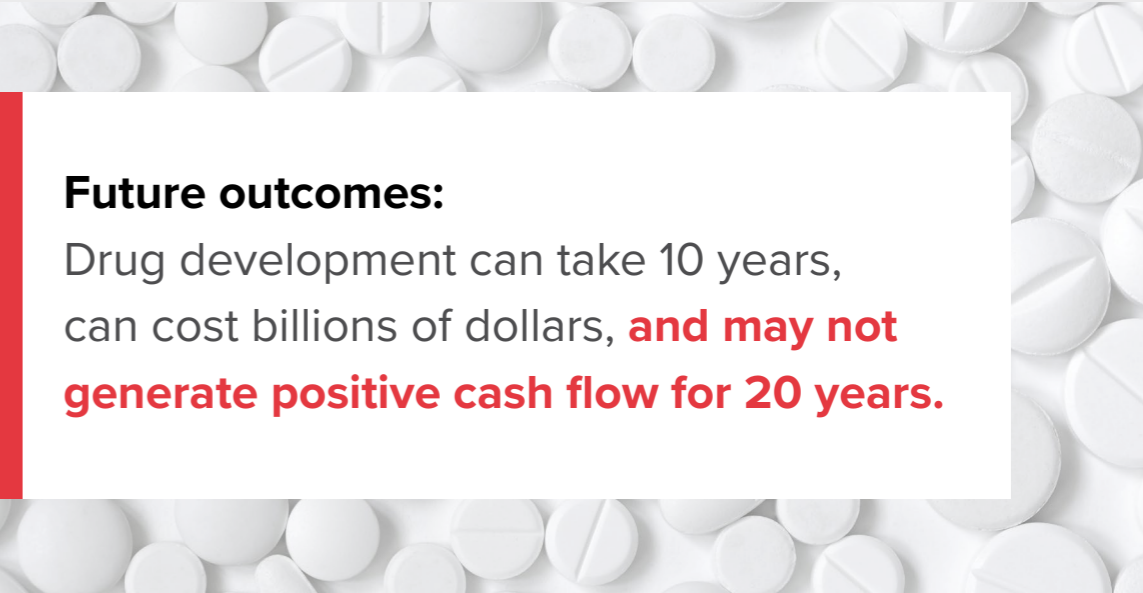
To learn more, view our recent webinar
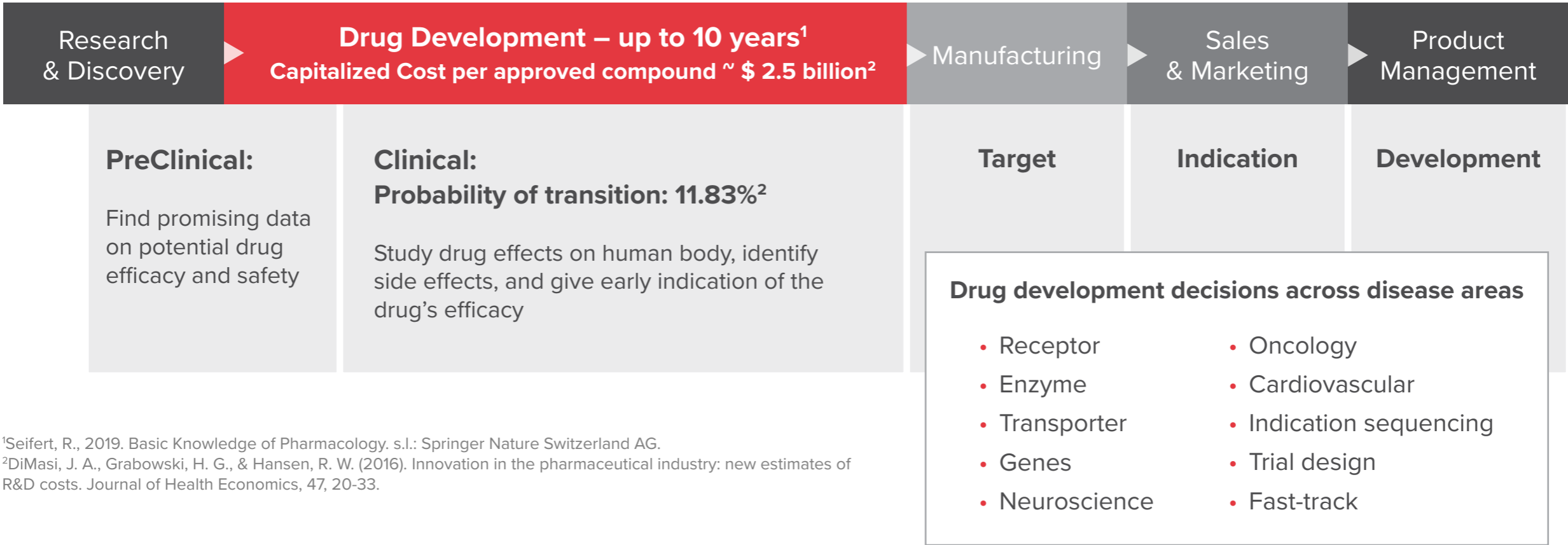on a new approach to early-stage portfolio decision making.

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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.**

Research & Discovery	Drug Development – up to 10 years[1] Capitalized 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
- Enzyme
- Transporter
- Genes
- Neuroscience

- Oncology
- Cardiovascular
- Indication sequencing
- Trial design
- Fast-track

[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.

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.

[3]Stewart, J. J., Allison, P. N. & Johnson, R. S., 2001. Putting a price on biotechnology. Nature Biotechnology.
[4]Phillips, 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.
[5]Smietana, K., Ekstrom, L., Jeffery, B. & Moller, M., 2015. Improving R&D productivity. Nature Reviews Drug Discovery.
[6]Peck, R. W. et al., 2015. Why is it hard to terminate failing R&D in pharmaceutical R&D. Nature Reviews Drug Discovery.

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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.

2 **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.

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Start with Elements of Decision Quality

03 Meaningful, Realiable Information

02 Creative Double Alternatives

04 Clear Values & Tradeoffs

Elements of Decision Quality

01 Appropriate Frame

05 Logically Correct Reasoning

06 Commitment to Action

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:**
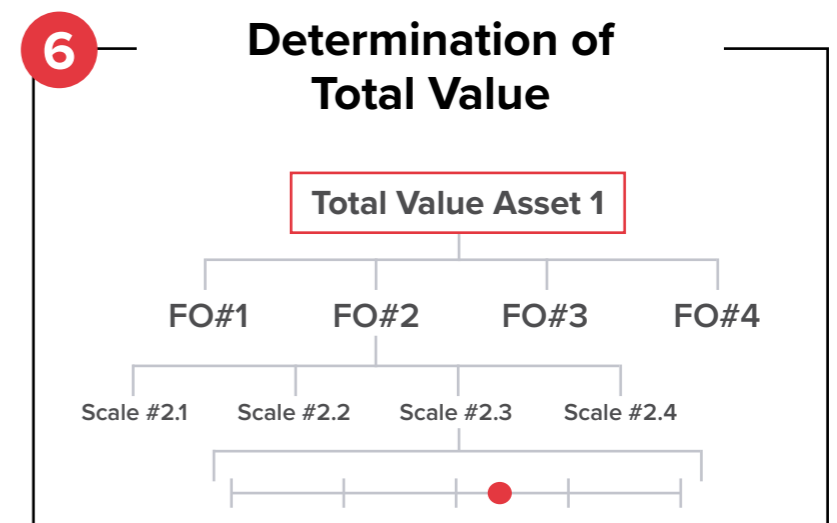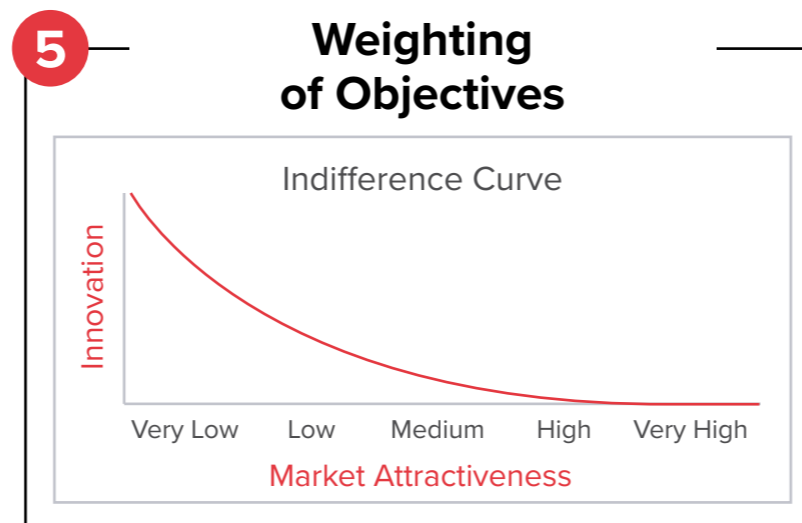
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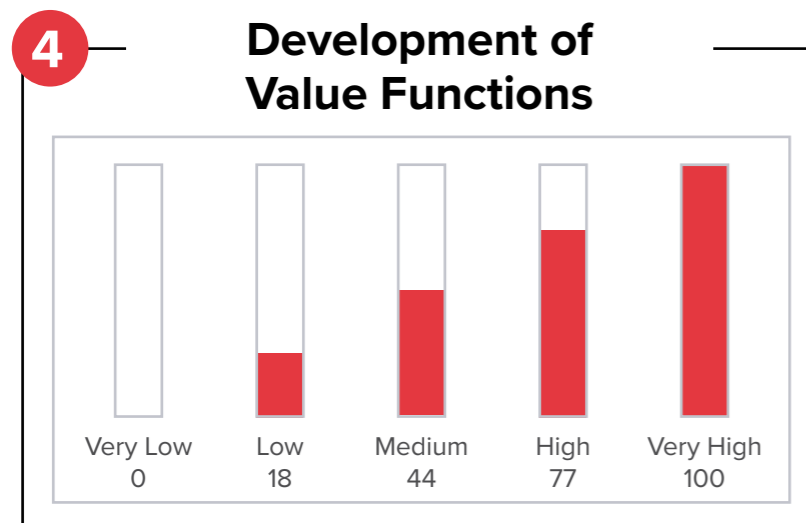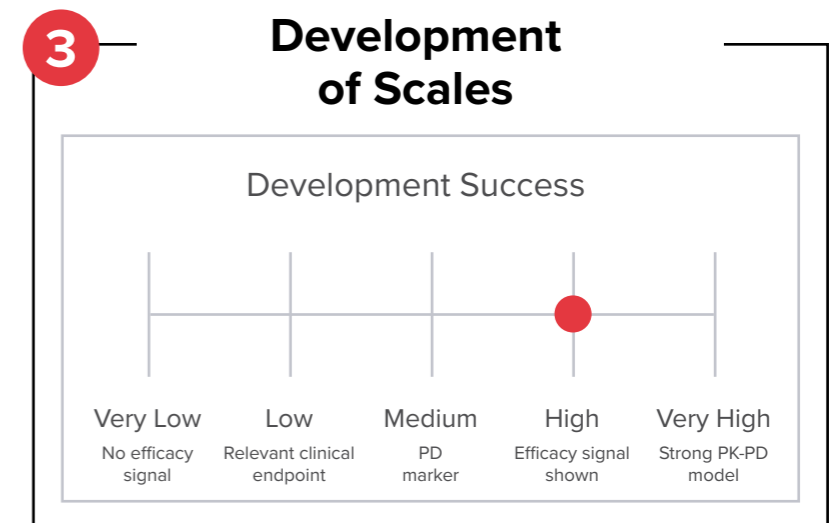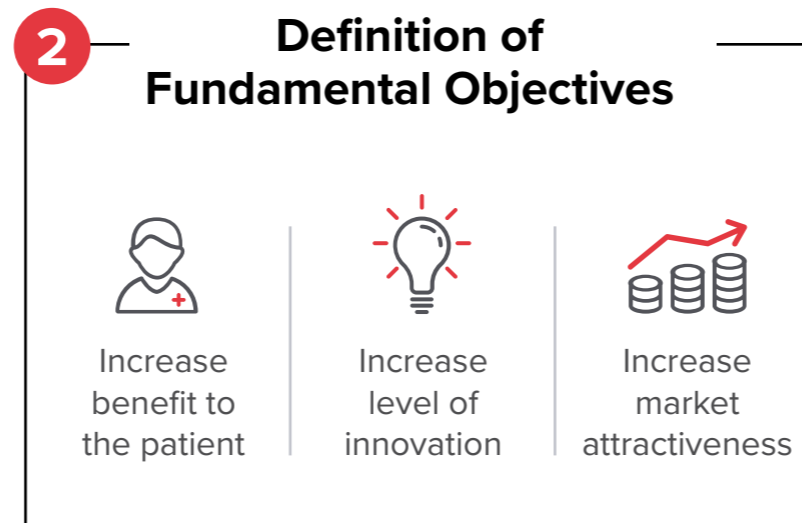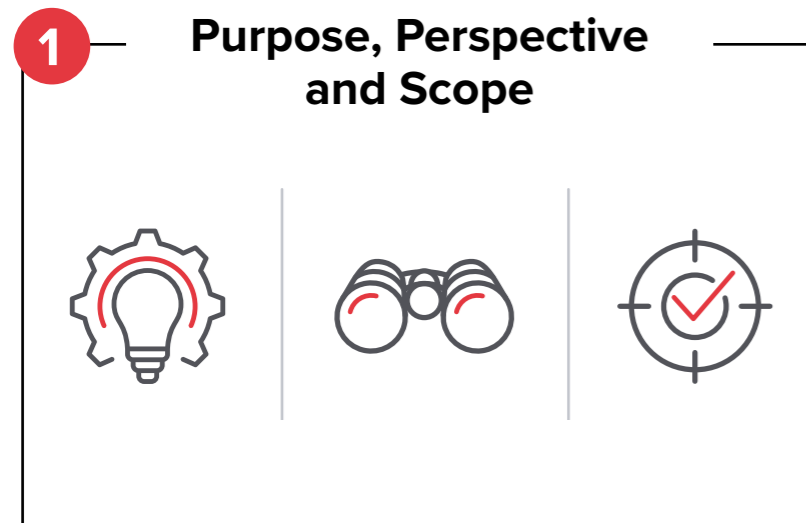
06 Commitment to Action

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.)

1 **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.

2 **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."

3 **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

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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.
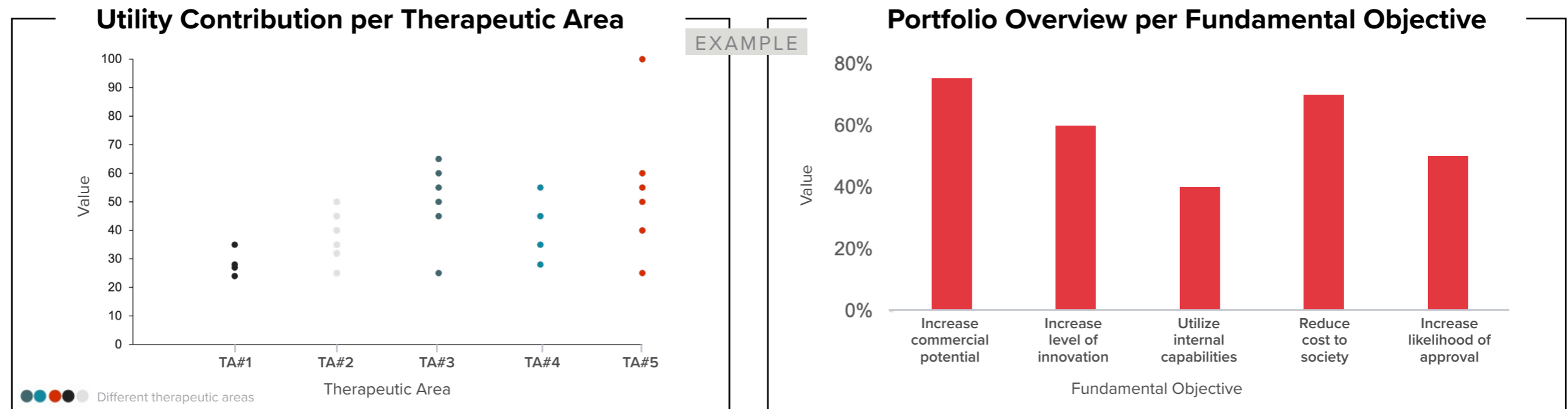
1 — **Purpose, Perspective and Scope**

2 — **Definition of Fundamental Objectives**

Increase benefit to the patient

Increase level of innovation

Increase market attractiveness

3 — **Development of Scales**

Development Success

Very Low	Low	Medium	High	Very High
No efficacy signal	Relevant clinical endpoint	PD marker	Efficacy signal shown	Strong PK-PD model

4 — **Development of Value Functions**

Very Low	Low	Medium	High	Very High
0	18	44	77	100

5 — **Weighting of Objectives**

Indifference Curve

Innovation

Very Low   Low   Medium   High   Very High

Market Attractiveness

6 — **Determination of Total Value**

Total Value Asset 1

FO#1   FO#2   FO#3   FO#4

Scale #2.1   Scale #2.2   Scale #2.3   Scale #2.4

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

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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.

Utility Contribution per Therapeutic Area

EXAMPLE

Value / Therapeutic Area / Different therapeutic areas

Portfolio Overview per Fundamental Objective

Value / Fundamental Objective: Increase commercial potential, Increase level of innovation, Utilize internal capabilities, Reduce cost to society, Increase likelihood of approval

This comprehensive overview is useful in making quicker, more agile decisions, including allocation of resources.

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This approach overcomes the key challenges common in other approaches

1 **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.

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

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