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Keys to Effective Project Prioritization in Biopharma

Guidebook

The Power of Predictability

Executive Summary

The purpose of strategic portfolio management (SPM) is to direct an organization's money and energy to the projects that matter most to achieving the company's strategic objectives. Most companies have more investment opportunities than they can execute (i.e. the portfolio is larger than the pipeline), and so choices must be made about which projects to include in the pipeline.

Once selected, the SPM process is not over because the portfolio is constantly changing — via in-licensing, out-licensing, stage-gate advancements and terminations. So strategic portfolio management must be an ongoing and adaptive effort.

Key concept: A portfolio is the set of all opportunities available to be worked on (e.g. through freedom-to-operate patent rights); whereas the pipeline is the subset of those opportunities that are funded, resourced, and actively being worked on.

An holistic SPM process for selecting the projects to be in the pipeline includes identification, evaluation, prioritization and optimization of investment opportunities. Of these activities, I've found that prioritization is often the most difficult because it involves a level of subjectivity, personal biases and business politics.

Project prioritization in the pharmaceutical industry is especially difficult because the experimental nature of drug development makes it impossible to accurately predict outcomes (and therefore the value) of investment opportunities. In this guidebook, we will explore this challenge more deeply, and then describe four key elements that should be put in place to effectively prioritize a biopharma company's projects.

The Challenge of Prioritizing Biopharma Projects

Drug development projects in the biopharmaceutical industry are costly, time consuming and risky — an environment that epitomizes the necessity for prioritization. However, biopharma projects are particularly challenging to prioritize because most of the common economic metrics for ranking projects (e.g. return on investment, net present value, internal rate of return) cannot be accurately and reliably calculated.

In industries like construction or software development, the outcome of a project is a known result. If you're building a bridge, you know that if you implement all the right pieces, the outcome will be a bridge; if you're building a software application, you know that if you create all the right code, the outcome will be the software application.

However, with biopharma projects, where the desired outcome is a safe and effective drug, you're dealing with unpredictable biological systems that may or may not result in the desired outcome. When you administer a medication to treat a patient's disease, it may not be effective in resolving the disease or it may be too toxic to give to patients. Thus, in biopharma, the successful achievement of an outcome (a marketed drug) is impossible to predict, and so we cannot calculate the exact value of a drug development investment opportunity.

Because there is no accurate methodology to calculate a return on investment for biopharma projects, prioritization is often done with assumptions, estimation, guessing and predicting. These guesses and predictions are fraught with bias. Project teams will guess the likelihood of a drug achieving the intended result through assessment of pre-clinical models and benchmarking exercises, but these guesses are usually optimistic and not grounded in hard evidence. Even the leaders of an organization have a personal bias or may want to "protect their turf" by ranking their projects higher than is appropriate, often arguing on behalf of the scientific interest, even if that scientific interest does not translate to market opportunity.

The elements listed below will help biopharma organizations of any size to prioritize their projects using a data-driven, unbiased methodology and multi-input governance framework.

4 Keys to Effective Project Prioritization

To effectively prioritize the inventory of investment opportunities, an organization must have the following elements in place:

1. A clear governance framework

2. A clear definition of the cases that will be included in the prioritization exercise

3. A robust, consistent and transparent methodology

4. Accurate, reliable and interpretable information

1. Establish a clear governance framework

The first key element for effective project prioritization in any company, not just biopharma, is to have a clear understanding of who sets the priorities. Decision-making rules should be agreed to and documented in a governance framework that describes the groups, structures, remits and processes used to prioritize projects.

Key concept: Governance is the management structure through which decisions are made on the projects that an organization should work on.

At small companies, there may only be the governing body (e.g., the executive committee) involved in making decisions on investment opportunities; whereas at larger organizations, there may be several groups involved in the decision-making process. These groups may be responsible for reviewing certain aspects of the business case, such as the development strategy, the scientific or technical feasibility, or the commercial potential. Though there may be many groups involved in the process, there should be only one governing body with the authority to decide on priorities. That single, accountable decision-making body should have appropriate purview and control over the projects it is prioritizing.
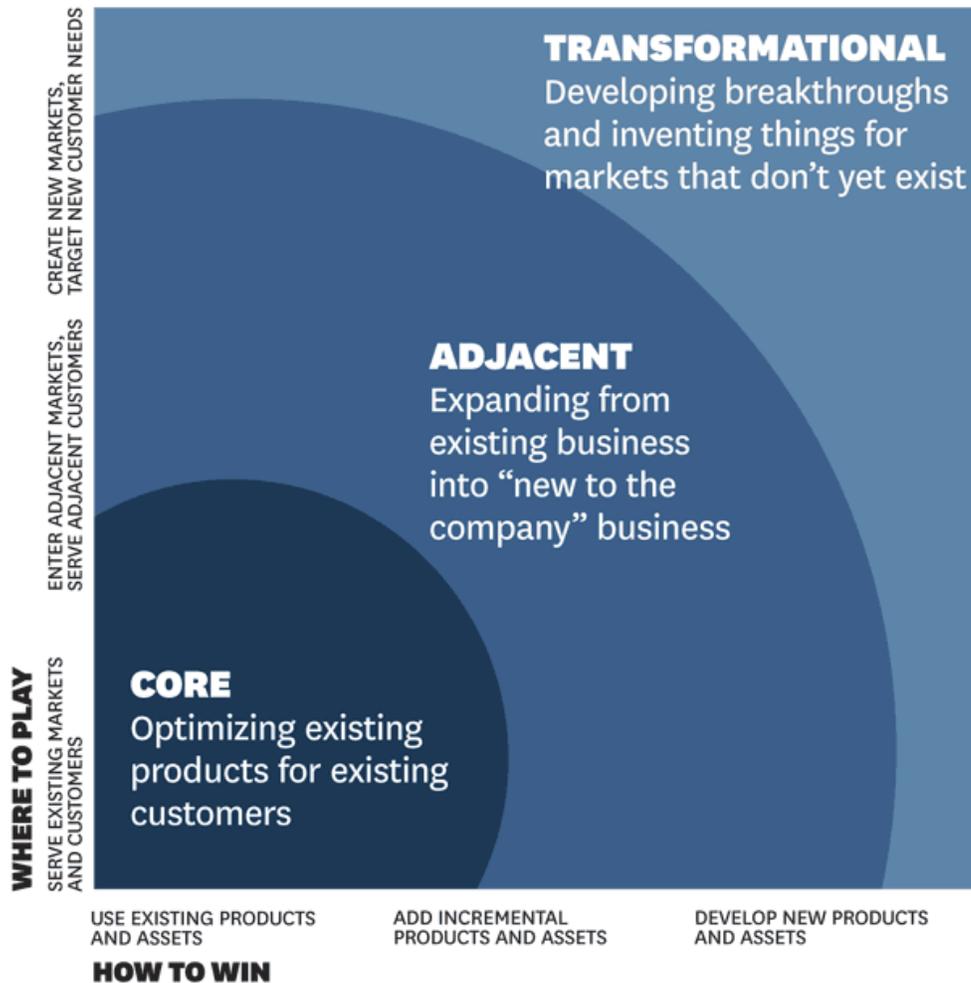
Figure 1: Harvard Business Review's The Innovation Ambition Matrix.

When defining the remits of each group involved in the prioritization process, it is helpful to have a predefined decision-making framework. There are many out there (see Table 1), so it is important to pick one and be consistent with its usage throughout the organization. These decision-making frameworks will clarify the roles and responsibilities of each group involved in the process, and it is important to establish this model at the beginning of the process so that all the stakeholders are aware of their participation in the process. Companies with the strongest innovation track records can articulate a clear innovation ambition. See Figure 1.

My favorite approach is [Bain & Co.'s RAPID framework](#) because it outlines all the key roles in the decision-making process.

An example of how to apply the RAPID framework to a portfolio prioritization process is given in Table 2.

DAI	Decision Maker, Advice Giver, Informed Stakeholder
DACI	Driver, Approver, Contributor, Informed
DARE	Decider, Advisor, Recommender, Execution Stakeholders
RAPID	Recommend, Agree, Perform, Input, Decide

Table 1: Common decision-making models

Recommend	Product Development Core Team
Input	New Product Planning, Commercial Planning, FP&A, Portfolio Management
Agree	Development Review Forum, Commercial Review Forum
Decide	Oncology Business Unit Portfolio Committee
Perform	Portfolio Management

Table 2: Example of applying RAPID framework to an oncology business unit portfolio prioritization workflow

An appropriately setup governance framework with broadly understood decision-making rules and roles will help not only expedite the prioritization process, but also to eliminate bias. The governance structure should provide a venue for "healthy debate" between parties to ensure biases and emotions are not driving the prioritization conversation.

In addition, having a single, accountable decision-making body should eliminate the swirl after a decision is made. In effect, the accountable decision-making body is the "final word" that the rest of the organization will then adopt and implement.

4 Pitfalls in Decision-Making

Making and executing decisions is the lifeblood of organizations. The faster a company can enact high-quality choices, the more value it delivers. Yet, a recent study by **McKinsey & Company** found 80% of organizations report struggles with decision making. Below four major pitfalls are outlined.

1. No clear decider

If told that you were responsible or accountable for a decision, would you get to make that decision? What if you were to be consulted? Too many stakeholders end up with a vote or veto. While it is often helpful to involve people in decisions, this only works when fewer people have a vote. Narrow down the list of decision-makers.

2. Poor orchestration of stakeholders

When making a decision, when was the last time that you planned who would have what kind of input and when? Too often, there's confusion around who decides, what kind of input is required and when it is required. Bring stakeholders together to provide the right input at the right time, without breeding bureaucracy that diminishes decision quality. Consider key points of collaboration and coordination, then plan from there.

3. Poor delegation practices

When decisions are delegated to less senior colleagues (a great practice), they often do not feel empowered to make the final decision—let alone a recommendation—without the insurance of being backed by all consulted parties and having their superiors' support. In the end, the delegated decision is often escalated to the more senior party, wasting time and leaving many feeling disempowered. Assign clear, accountable decision-makers, then collectively agree on escalation protocols.

4. Ineffective meeting management

Despite the number of "critical" meetings leaders attend, most executives are nonplussed at best when describing their experiences. Ineffective meeting management begets ineffective meetings—many agenda items fail to call out whether they require a decision, are up for discussion, or are simply to provide information. This lack of clarity associated with RACI often results in more meetings, more information and more presentations. Decision meetings should have decisions on the agenda. Also, remember that not every decision needs a meeting.

The limits of RACI--and a better way to make decisions | McKinsey & Company

2. Define the scope

When considering a prioritization exercise, one must first define the cases (i.e., projects) that will be assessed. Biopharma projects are commonly grouped at 3 levels: asset, indication, or clinical trial. I prefer to prioritize projects at the indication level for several reasons:

- Indications are the drivers of value through label language and, hence, market share

- Target product profiles, development plans, and valuations are all commonly set at the indication level

- Some assets are used to treat multiple indications (so-called "portfolio-in-a-pill" assets), therefore making it challenging to evaluate them against other assets that only treat a single indication

- Several clinical trials may be needed to obtain a single indication statement, and some clinical trials may be dependent on others, making it difficult to prioritize one clinical trial over another

Key concept: Biopharma project prioritization is best done at the indication level, and all clinical trials that enable the indication are assumed to inherit the same priority.

Thus, the project team should prepare a business case for each indication it is interested in pursuing, and these cases will be included in the prioritization exercise. A further delineation must also be made around the scope of the projects that are under review. For example:

- New opportunities, ongoing projects, or both?

- The company's full portfolio or a subset (e.g. oncology only)?

- What planning horizon is being considered (e.g. a certain milestone must be achieved in the next 3 years)?

For large companies, the portfolio of opportunities is often grouped by therapeutic area. For example, the Oncology business unit will have its own budget, and therefore will need to make its own priorities that are distinct from, say, the Internal Medicine business unit. At a smaller company, the portfolio of opportunities may include all the assets across the company. Some organizations may separate the early development pipeline from the late development pipeline, each with its own governing body, and therefore each with its own portfolio to prioritize.

3. Use a robust, consistent, and transparent methodology

The method by which projects will be prioritized needs to be clearly defined and understood by both the governing bodies and the project teams. For example:

> • What criteria will be used to assess projects?
>
> • Will projects be force-ranked or categorized into tiers?
>
> • What are the implications of the prioritization results?

A systematic and transparent portfolio prioritization process will drive alignment on the resulting priority schema. To ensure consistent inputs are received, it is helpful to provide project teams with a template that includes the criteria that will be used to score the projects. Some examples of criteria include the following:

> • **Costs**, including research, development, manufacturing, and commercial costs
>
> • **Revenues**, such as peak year sales, peak revenue
>
> • **Risk profile**, such as the probability of technical and regulatory success (PTRS) or probability of launch (POL)
>
> • **Valuation**, such as expected net present value (eNPV), return on investment (ROI), or internal rate of return (IRR)

I'd like to acknowledge that, while the above criteria provide numerical metrics that can be compared across projects, there are intangible aspects of each project that also need to be considered. For example, the reward of being a first-in-class innovator can generate value to an organization beyond just the value of the project itself.

Therefore, scientific potential must also be considered. In addition, market dynamics, including competitive landscape analysis, market access barriers, market share assumptions, intellectual property protection (i.e., patent expiry), and marketing exclusivity opportunities (e.g. orphan drug, pediatric exclusivity), must also be considered when evaluating a project against its competitors.

The method and implications of the resulting priority schema must also be agreed across the organization. Two methods I commonly see include a force-ranked listing approach and the tiered approach. A forced-ranking approach results in a list of projects in order of importance to the organization.

For companies with a large portfolio, this is often a more arduous task than is necessary. My preferred approach is to group projects into tiers, with each tier having a clear set of implications. For example:

> • **High:** high value projects that are granted special privileges (e.g., access to a project sponsor from senior leadership, staffed with the most experienced team members, increased spend threshold, faster access to governance)

> • **Standard:** projects that are part of the company's core strategy

> • **Low:** projects that may be cancelled or postponed in order to allocate resources to higher-tier projects

> • **For future consideration:** projects that do not currently meet a strategic objective, but are worth considering in the future should the objectives change; these projects should not be resourced or funded

> • **Discontinued:** projects that should be removed from the pipeline and not considered again in the future; these projects should not be resourced or funded

I sometimes hear of project prioritization being referred to by its resourcing, where top projects are fully resourced and lower projects are minimally resourced. To me, this is a mistake. If a project is worth doing, it is worth doing right. So any project in the pipeline should be adequately resourced. The point of prioritizing them is that when tradeoff decisions are needed, the resources from the lower-tiered projects will be reallocated to higher-tiered projects, knowing that the de-resourced project is then removed from the pipeline.

Having a consistent methodology should ensure the results of the prioritization process are considered fair and agreeable. Transparency to the process encourages buy-in to the output. A simple slide deck that describes the methodology, with reinforcing training to the organization on a regular basis, is usually sufficient to keep the process running smoothly. I have seen companies invest in training videos that describe the methodology in detail so that new employees become aware of the process at the time of onboarding.

4. Have accurate, reliable, and interpretable information

Despite the previously mentioned flaws in calculating economic metrics for biopharma projects, analytics still has a place in biopharma project prioritization. Governing bodies need access to accurate, reliable information to make informed decisions. But having accurate information by itself is not enough, it needs to be presented in a way that allows decision makers to understand the differences between projects. Thus, accurate information and an interpretable presentation format are needed.

The plethora of inputs and potential prioritization schemas is often too complex for anyone to keep straight in their head, so some sort of computerized assistance is usually needed. These systems not only serve as a database for the inputs received from project teams, but also as a decision support tool that provides interpretable visualizations of options for a prioritized book of work.

Most companies I work with use a comprehensive, centralized portfolio management system to house all the relevant project information to support the prioritization process. These systems allow for data-driven decisions about the portfolio, capacity optimization, scenarios analyses, benefits tracking, and integration with the company's project management solution to ensure appropriate controls are in place.

With respect to project prioritization, these systems serve as the central database for the business case information mentioned above that are used as scoring criteria as well as proposed project schedules and time-phased cost and resource requirements. Schedules, cost, and resource estimates then become the baseline for managing the project throughout its lifecycle.

As mentioned previously, biopharma projects cannot be prioritized by analytics alone, and so the system needs to allow for subjective preferences to influence the final priority schema. Such projects can be "forced in" to the prioritization schema, leaving the remaining projects to be variables in the prioritization exercise.

As you can see, the portfolio management system needs to be structured and objective, and at the same time flexible and adaptive. It also needs to be customizable to biopharma project inputs, which will differ from other industries like construction or software development. It helps to have the governance framework, scope definitions, and methodology all in place before selecting and implementing the portfolio management system so that the most seamless and robust process is delivered.

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Conclusion

Despite the importance of project prioritization for biopharma companies, I've found that some do not do it at all, and many do not do it well. This is usually because these organizations are missing one or more key elements of effective project prioritization.

Companies need robust governance to ensure the right projects are being carried out and the best value for money is being achieved in meeting the company's objectives. They need a clearly defined scope of the projects that are under consideration in the prioritization exercise. They need a consistent and transparent methodology. And they need accurate, reliable, and interpretable information, often supported by a supportive portfolio management system.

As SPM continues to evolve and mature in biopharma, companies of all sizes can benefit from establishing and fine-tuning their portfolio management process. The above key elements can serve as a useful blueprint for creating and optimizing the SPM capability in your organization.

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Author Bio

Joe Stalder is a project management professional working in the biopharmaceutical industry. With over 10 years of experience managing drug development projects in a variety of company sizes and cultures, including Pfizer, Roche, and AstraZeneca, Joe has developed a knack for finding the best project management tools, techniques, and methodologies to meet every situation. This has led him to develop the GRIDALL Project Management Framework, a comprehensive tool for assessing PMO capabilities, managing project information, and improving project communication.

Joe is passionate about improving the state of the project management discipline within the biopharmaceutical industry. He is a regular speaker at biopharma project and portfolio management conferences, including the Healthcare PPM Toolbox and the American Pharma and Medtech PPM Conference series. He is the author of an upcoming book on managing drug development projects. He is co-chair of the SSF Chapter of BioPharma Project Management (BPPM) and founder of the USA Chapter of the Pharmaceutical Industry Project Management Group (PIPMG).

Joe currently lives in San Diego, California, where he enjoys the beaches and tacos of southern California. In his nonworking time, he shuttles around two young boys to various energy-burning activities and gets in the ocean for surfing whenever possible.
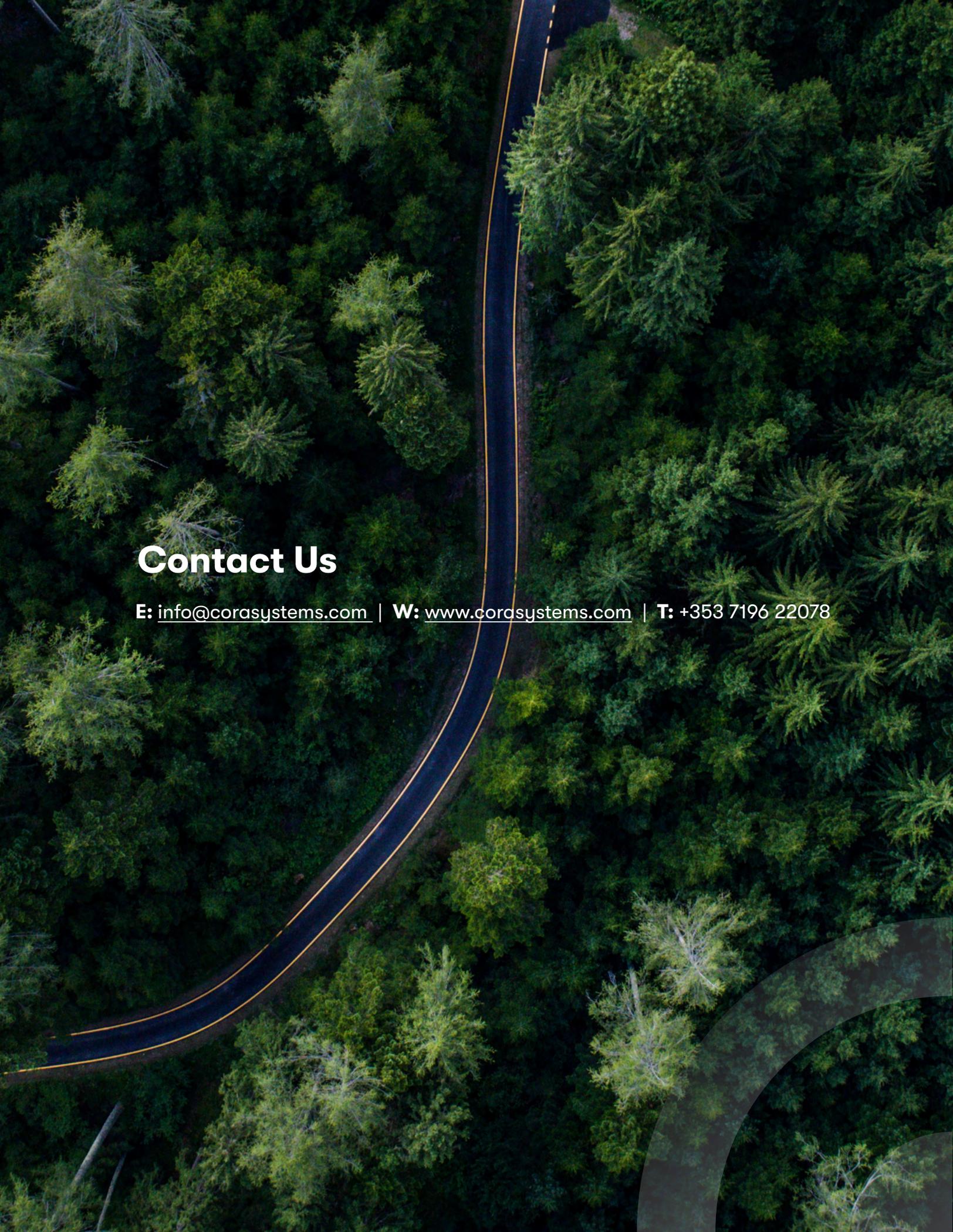
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