University of St.Gallen
Institute of Supply Chain Management

Excellence in Management of Contract Manufacturing Relationships

Consortium Study

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CSL Vifor
FRESENIUS KABI
Ivers-Lee
Kwizda Pharma

Excellence in Management of Contract Manufacturing Relationships

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List of Abbreviations

CMO	Contract Manufacturing Organization
CMR	Contract Manufacturing Relationship
D-A-CH	Germany, Austria, Switzerland
DSR	Design Science Research
ISCM-HSG	Institute of Supply Chain Management at the University of St. Gallen
KPI	Key Performance Indicator
RQ	Research Question

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Foreword ISCM-HSG

The Institute of Supply Chain Management (ISCM-HSG) at the University of St. Gallen views itself as an international platform for dialogue between science and practice in supply chain management, purchasing, and transportation. Following the motto «science-based, practice-driven,» a link is formed between cutting-edge research and applied practice solutions.

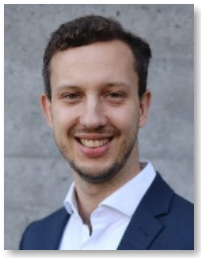
The ISCM-HSG studies complex problems of global value creation networks in concepts, methods, and instruments, thus furthering the continuous development of supply chain management in industry, trade, service, and the public sector. Furthermore, knowledge development and transfer within an international network of renowned universities and institutes are encouraged. Following its mission, the ISCM-HSG has established itself as a professional starting and return point for lifelong learning for students and executives.

The consortium study «Excellence in Management of Contract Manufacturing Relationships» deals with current challenges and opportunities of contract manufacturing in the pharmaceutical industry.

The increasing competition between supply chains instead of individual companies promotes the formation of partnerships amongst specialized companies to supply society with vital products. Leading brand companies increasingly rely on contract manufacturers to produce their products to gain access to capacity, technology, and manufacturing expertise. While such a deep level of integration can offer great potential for both sides, it also poses challenges for the companies involved. The challenge, therefore, is how the partner companies can create value together and balance their own business objectives with those of the partner under dynamic environmental conditions. The pharmaceutical industry is a pioneer in contract manufacturing, combining strong regulation with cost- and technology-intensive manufacturing that requires excellent CMR management.

The five consortium partners, consisting of brand-owning companies and contract manufacturers, are continuously confronted with these considerations in their daily business. The study integrates the joint perspective of clients and contract manufacturers on practical challenges in relationship management. It offers impulses and solutions for the excellent management of contract manufacturing relationships.

Authors



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Management Summary

Contract manufacturing relationships have become an integral part of pharmaceutical supply chains. Pharmaceutical supply chains are characterized by solid regulation, technological complexity, and high investment pressure, which encourages collaboration between client companies and CMOs. However, due to the high relevance for clients and the high complexity of pharmaceutical value creation, contract manufacturing relationships always move in a field of tension between client control and trust-based self-control. In addition, the relationship dynamics, the collaboration scope, and the multitude of different partners require companies to target their management approach with an eye on risk and value creation, as comprehensive control is unfeasible.

Against this background, the study addresses the question of excellent relationship management in pharmaceutical contract manufacturing. To this aim, the study first paints a broad picture of particular challenges. It then focuses on selected practices for developing contract manufacturing relationships, tailoring relationship management, and aligning partners. A consortium of five pharmaceutical companies from the D-A-CH (Germany, Austria, Switzerland) region, representing both the client and the CMO side, is involved in the study to ensure the practicality of the results.

First, the study findings give insights into the progression of contract manufacturing relationships amid internal and external dynamics. The Relationship Strategy Cycle concept suggest temporal segmentation of contract manufacturing relationships to focus management activities on achieving cycle-dependent objectives.

Second, regarding tailoring management approaches to unique collaborations, the study discusses current tailoring practices and provides a method-supported process for conducting meaningful partner differentiation.

Third, the study highlights the need for strategic and social alignment of the client company and CMO to achieve effective partnerships. In support of trust-based collaborations, the authors introduce the concept of the Relationship Gap to systematically include perceptions, business, and partner behavior expectations in relationship management.

All findings are presented with easy-to-use templates to adopt the proposed ideas to support practitioners on the path to excellence in the management of CMRs.

"Science-based, practice-driven"

Preface CSL Vifor

About us

CSL Vifor is a global partner of choice for pharmaceuticals and innovative, leading therapies in iron deficiency, dialysis, and nephrology. We specialize in strategic global partnering, in-licensing and developing, manufacturing, and marketing pharmaceutical products for precision healthcare, aiming to help patients around the world lead better healthier lives. Headquartered in St. Gallen, Switzerland, CSL Vifor also includes the joint company Vifor Fresenius Medical Care Renal Pharma (with Fresenius Medical Care). The parent company, CSL (ASX:CSL; USOT:CSLLY), headquartered in Melbourne, Australia, employs 30,000 people and delivers its lifesaving therapies to people in more than 100 countries.

Research interests

As CSL Vifor moves to an outsourced supply chain partnership model based on more CDMO/CMO collaboration, we are leveraging several focus area opportunities for process improvement with CMR, including:

Integrated matrix organizational model with clear leadership accountability aligning CMO interactions, communication activities, priority setting, and process performance improvement focus

- Leveraging our ERP integrated planning system and processes to support operational and strategic planning excellence
- Strengthened Sales and Operations Execution and Sales & Operational Planning cycles for process integration
- Governance, sponsorship, engagement, and support for CMO priorities and interfaces from senior management
- Implementing a Supplier Relationship Management program to improve relationships and working model with strategic CMOs covering performance, innovation/improvements, relationship management, and risk

Engaging with the Consortium Study "Excellence in Management of Contract Manufacturing Relationships" with the ISCM-HSG allows us to understand and contribute to best practices in this space and strengthen our process improvement and integration plans with strategic CMOs.

Further information

www.cslvifor.com

CSL Vifor

Preface Fresenius Kabi

About us

Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion, and clinical nutrition. Our products and services are used to help care for critically and chronically ill patients.

In 2021, the company reported sales of more than €7.1 billion. Fresenius Kabi AG is a wholly-owned subsidiary of the Fresenius SE & Co. KGaA healthcare group.

Research interests

Intravenously Administered Drugs

Fresenius Kabi offers a broad range of intravenously administered generic drugs across a wide array of therapeutic categories: oncology drugs, anesthetics & analgesics, anti-infectives, and critical care drugs. For the administration of these products, the company provides the related devices.

Infusion Therapy

For infusion therapy, Fresenius Kabi offers products for fluid and blood volume replacement. Moreover, Fresenius Kabi's product portfolio includes a broad range of infusion technologies as well as disposables for the delivery of medication for all pharmaceuticals administered via the vein.

Clinical Nutrition

Within clinical nutrition, Fresenius Kabi is one of the few companies worldwide to offer parenteral nutrition (administered intravenously) and enteral nutrition (administered as sip or tube feed via the gastrointestinal tract), as well as nutrition pumps and infusion disposables.

Both serve to help patients who cannot eat any, or sufficient, normal food. This is especially the case for patients in intensive care units, for patients who are seriously ill and with malnutrition. When the patient leaves the hospital the ambulatory services of Fresenius Kabi can care for the patient and provide him with the necessary products.

Biosimilars

In the field of biosimilars, we focus on autoimmune diseases and oncology. In 2019, the first biosimilar product by Fresenius Kabi was launched.

Devices

We offer devices used to administer I.V. generic drugs, infusion therapies, and clinical nutrition products.

Transfusion Medicine and Cell Therapies

Within transfusion medicine and cell therapies, Fresenius Kabi offers products for the collection of blood components and extracorporeal therapies.

Further information

Fresenius Kabi Global (fresenius-kabi.com)

FRESENIUS KABI
caring for life

Preface Ivers-Lee

About us

The Ivers-Lee Group is known to the pharmaceutical industry as a long-standing partner of 75 years. Over the time, the Ivers-Lee Group has gained a reputation as a reliable, quality-conscious, and flexible contract packager. At the certified manufacturing site in Burgdorf, various products are packaged for small, medium, and multinational companies in accordance with the current good manufacturing practices (cGMP). With IL-CSM Clinical Supplies Management GmbH in Lörrach, Germany, the group has a site in the EU through which imports and market releases can be handled. The unit also manages the entire project management for clinical trials. The focus is on development and market launch. The Ivers-Lee Group supports its customers in the introduction of new technologies. These include medical device assembly, small-volume stick packs, and novel blister projects. The serialization and aggregation system meets standard market requirements. The group's success story is based on a solid network of customers, partners, and suppliers.

Research interests

Strategic partnerships are an important success factor for a medium-sized company like Ivers-Lee. When building and maintaining partnerships, it is essential to better understand the client's perspective. Our experience shows that there usually is a great strategic commitment when starting a relationship. However, this initial engagement often fades away and is not sustained in the ongoing collaboration.

One of our guiding principles is:

« Ivers-Lee generates trust toward customers and employees through commitment, stability, and a culture of continuous improvement. »

In the context of continuous improvement, it was important for us to participate in this study by the University of St. Gallen to exchange ideas with other companies and the scientific community.

Further information

www.iverslee.com

Preface Kwizda Pharma

About us

Kwizda is a family-owned Austrian company that covers the entire field of expertise of drug development and supply with its divisions Pharma, Pharmaceutical Distribution, Pharmaceutical Trade, and Pharmacy Service.

As part of this group of companies, Kwizda Pharma is an internationally active company that develops, produces, and distributes branded non-prescription products. It also in-licenses and distributes prescription drugs.

Kwizda Pharma considers its mission to be providing the best possible support for market requirements with a comprehensive range of products in line with current therapeutic trends. Therefore, the wide product range includes pharmaceuticals, medical devices, and nutritional supplements for therapy and prevention in the areas of cough, cold, pain, UTI, hypertonia, diabetes, osteoporosis, and gynaecology.

Research interests

In addition to in-house production, cooperation with contract manufacturers forms an important basis for supplying the market with both prescription and over-the-counter drugs as well as medical products and dietary supplements. The respective contract manufacturers work either directly on behalf of Kwizda Pharma or indirectly via licensors of in-licensed products. This results in a variety of quality-relevant and supply-related obligations and challenges in all phases of the collaboration. As part of the study conducted with the University of St. Gallen, these aspects were examined with representatives of contract manufacturers and clients from the pharmaceutical industry, and best practice scenarios were developed.

Further information

www.kwizda-pharma.at

Introduction

Since contract manufacturing gained popularity in the second half of the 20th century, the cooperation between pharmaceutical companies and contract manufacturing organizations (CMOs) has developed significantly. Initially characterized by an arms-length mentality, contract manufacturing relationships (CMRs) have become integral to pharmaceutical companies' supply chains. Thus, pharmaceutical companies and CMOs, move toward a more substantial alignment of business strategies and expectations to achieve mutual benefit. This study takes a two-sided approach, including the client company and CMO perspective, to identify relevant issues, success factors, and appropriate practices for excellent CMR management.

Relevance and Motivation

When contract manufacturing was introduced in the pharmaceutical industry about three decades ago, CMOs primarily operated as extended workbenches, producing clients' products invisible to the end consumer. Fittingly, the Los Angeles Times called this type of production «stealth manufacturing» in 1999 (Peltz, 1999). CMOs had little strategic relevance to pharmaceutical companies at the time, and the relationships were typically opportunistic.

The industry has proliferated, and the CMOs have become more specialized and professional. At the same time, the costs for pharmaceutical research and development have increased significantly. By cooperating with CMOs, pharmaceutical companies can expand their production capacities flexibly and cost-efficiently, allowing them to utilize their resources for research and development. Furthermore, they can benefit from the contract manufacturer's production-related knowledge and access to new technologies and geographies. Due to the advantages of contract manufacturing for pharmaceutical companies, the share of subcontracted production has risen sharply in recent years. According to the European Pharmaceutical Review (2021), the global market value of pharmaceutical CMOs was estimated at USD 89.91 billion in 2020. It is expected to increase at a growth rate of 1.33 to USD 120.00 billion by 2027.

Moreover, pharmaceutical companies plan to collaborate further with CMOs and subcontract significant business activities and volumes. Likewise, CMOs continue to extend capacities, invest in manufacturing technologies, and offer further value-added services. Thus, CMRs have become increasingly crucial for the success of pharmaceutical companies. Therefore, excellence in CMR management is becoming a competitive factor for pharmaceutical companies to balance the need for cost efficiency, quality, flexibility, and innovative technologies in the supply chain.

However, previous studies, and the dialogue with practitioners, reveal room for improvement in the targeted identification and exploitation of joint business opportunities through more effective relationship management.

Study Focus and Objectives

The pharmaceutical industry is characterized by demanding quality, technical and legal requirements that restrict and hamper business relationships. Therefore, relationship managers must establish a delicate balance between control and trusted self-governance to enable flexible, compliant, efficient, and effective CMRs. In this context, three primary fields of action can be identified:

Developing CMRs: CMRs are complex relationships constantly affected by internal and external dynamics. Partnering companies must be aware of those dynamics despite the difficulty of accurately predicting and quantifying them. Whether the effects are disruptive or gradual, partners must constantly adapt management to guide the relationship in following the business objectives. Thus, a solid trust basis and open exchange on future paths and business opportunities must be embedded in CMR management.

Tailoring CMRs: As each relationship differs, management approaches must be tailored individually to the partnership and its development path. Therefore, a thorough understanding and systematic analysis of relationship criteria and differentiators affecting the management requirements of the CMR is paramount.

Aligning CMRs: Relationship alignment enables flexible and trusted cooperation outside contractual agreements. Since the partners' unspoken expectations and perceptions can differ significantly, engaging with the other side's perspective is essential to foster commitment. Therefore, active and systematic alignment represents a recurring task along the CMR's lifespan.

Against this background, the study examines the fundamental aspects of excellent relationship management of pharmaceutical CMRs. Excellent CMR management is based on systematically addressing the underlying success factors and challenges to meet the expectations of both partners. By integrating client companies' and CMOs' perspectives, the study reveals levers for excellence in CMR management. In this capacity, the study covers the management challenges of dynamic CMRs and shares insights into how to approach challenges in daily operations. Finally, it identifies tangible concepts and management practices for pharmaceutical CMRs.

All in all, the study addresses the following research question:

RQ 1)

How can pharmaceutical companies achieve excellence in the management of CMRs?

More precisely, the three following topics are considered to address the previously mentioned challenges in more detail:

RQ 1a)

How can pharmaceutical companies purposefully develop CMRs and react to changes?

RQ 1b)

How can pharmaceutical companies differentiate CMRs to tailor management?

RQ 1c)

How can pharmaceutical companies align the partner expectations in CMRs?

This study aims to promote discussion about excellent CMR management in the business community by answering the presented questions. In addition, the study's results are intended to inspire client companies and CMOs to design their relationship management activities.

Study Structure and Design

The study contains the following chapters to answer the previously stated research questions:

- Chapter 2 outlines the methodical approach of the study and explains the applied research methods.
- Chapter 3 gives an overview of the current state of knowledge on CMR management. It briefly introduces CMRs in the pharmaceutical context and focuses on industry-specific challenges.
- Chapter 4 addresses practices for the purposeful development of CMRs. It examines CMR trajectories and dynamics and presents approaches for the systematic progression of CMRs.
- Chapter 5 focuses on practices for tailoring management to CMRs. It critically discusses prevalent partner differentiation approaches and provides tools for enhancing the tailoring of CMR management.
- Chapter 6 features practices for aligning partners beyond contracts. Therefore, the relevance of expectation management in CMRs is highlighted, and the «Relationship Gap» concept is introduced.
- Chapter 7 integrates the presented findings and practices into a framework to provide impulses for excellent CMR management.
- Chapter 8 finally summarises the managerial implications. In addition, limitations and further needs for research are presented.

Figure 1 visualizes the connection between the study structure and the before-mentioned research questions, which are addressed in Chapters 4 to 7.

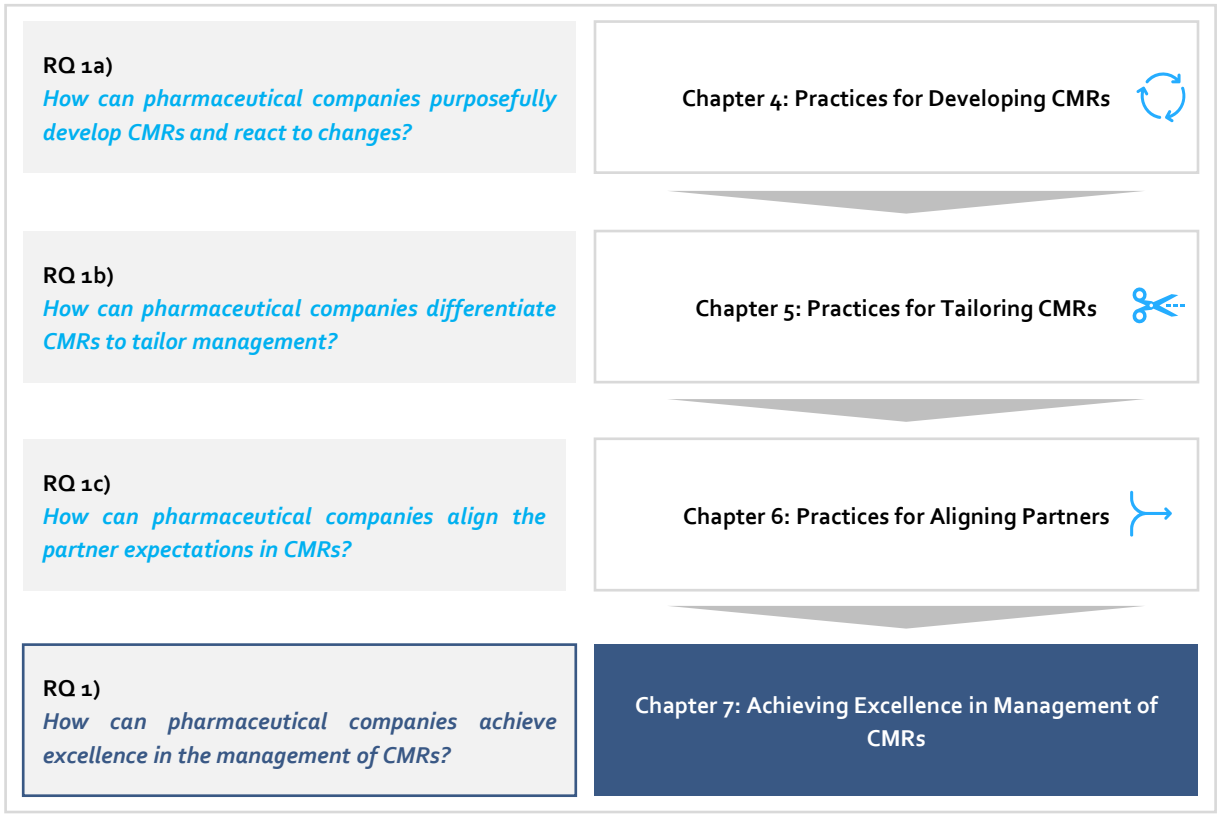

Figure 1: Study structure

Methodical Approach

The study applies a Design Science Research (DSR) approach to identify appropriate practices to support CMR management. DSR is a research methodology that enables close collaboration with practitioners to develop real-world solutions. To this aim, literature reviews, expert interviews, and focus groups were conducted to gain insights from practice and literature. The approach and methods for data collection are described in this chapter.

Overview

The DSR methodology has been developed in information science to generate valuable scientific results in a fast-paced practical environment. For this purpose, the research process continuously compares the research objective against changing practice requirements and existing knowledge to design solutions as outcomes, which DSR calls «artifacts». The designed artifacts can be either frameworks or tangible methods and physical objects. Considering the complex and dynamic environment of pharmaceutical CMRs, the DSR methodology supports the identification of substantial success factors, guidelines, and practices to enable excellent CMR management.

Hevner (2007) presents DSR as an iterative process composed of three intertwined cycles, illustrated in Figure 2. The relevance, rigor, and design cycles connect practice and theory to deliver valuable, tangible solutions.

Relevance Cycle: The relevance cycle represents the research process' interface with practice. It captures the problem situation and identifies possible opportunities for solving it. Therefore, five pharmaceutical client companies and CMOs are iteratively consulted in the relevance cycle to derive requirements for the artifact design. Lastly, the artifact developed to solve the problem can be evaluated and tested with the users to ensure its validity and value in the business environment.

Rigor Cycle: Simultaneously, the researcher analyses the knowledge base of established literature, frameworks, and methods to identify insight and impulses that can be incorporated into CMR management to address the defined challenges. Finally, the validated solutions to CMR management are added to the scientific knowledge base through the rigor cycle to serve as an orientation for future researchers and practitioners.

Design Cycle: The design cycle integrates the relevance and rigor cycle results to develop solutions based on the business needs and the available knowledge. The design process goes through several iterations in which the artifact is repeatedly evaluated by practice experts, compared with existing knowledge, and improved. The design cycle ends when the user has confirmed the artifact's usefulness and applicability.

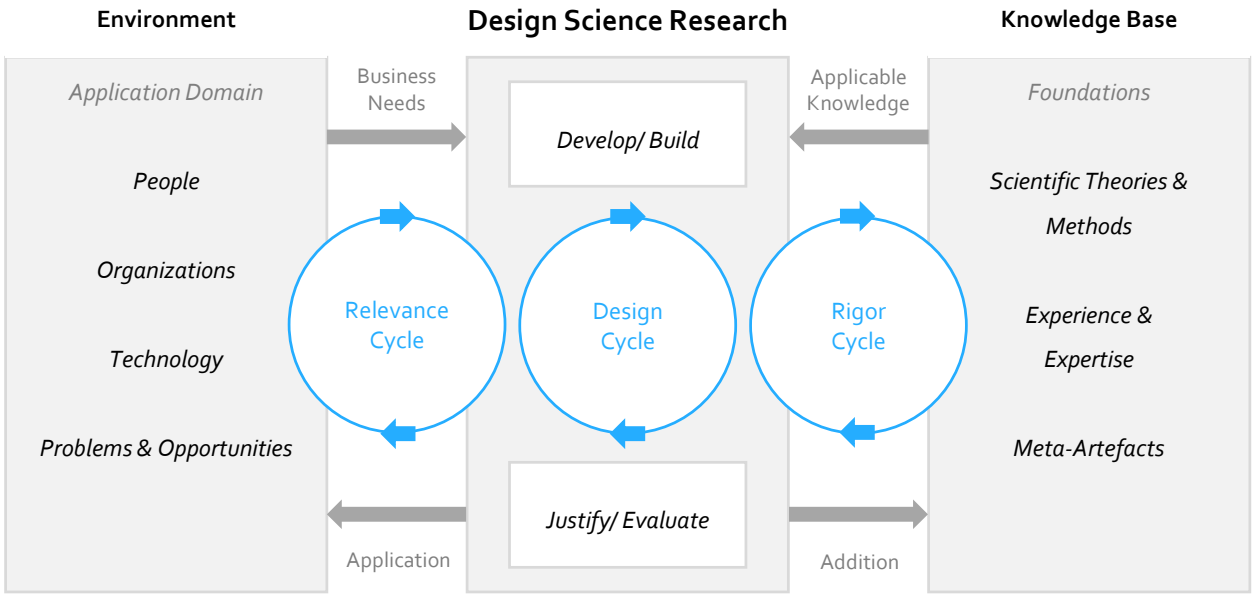

Figure 2: The Design Science Research framework

The DSR process is repeated until a finished, helpful artifact is obtained to contribute to CMR management excellence. Such an artifact can then be applied in the environment and, at the same time, represents a generation of new knowledge contributing to science.

In this study, the DSR methodology guides the research process and is supported by empirical research methods to gain insights from practice and theory. The study employs expert interviews and focus groups as part of the relevance cycle to understand the problem and evaluate the developed solutions. In the rigor cycle, literature reviews are conducted to identify existing concepts and impulses from other research fields. Finally, DSR integrates the practitioner's expertise and knowledge base insights through a continuous exchange to develop concrete solutions in the design cycle.

Expert Interviews

Expert interviews are a research method used to collect knowledge, experience, and opinions from experts who deeply understand the research topic. Along the guidelines by Saunders, Lewis & Thornhill (2020), expert interviews with representatives from pharmaceutical client companies and CMOs were conducted in the study. The interviews followed a semi-structured agenda to allow experts to present a holistic picture of the challenges of joint value creation in CMRs.

In the context of CMRs, the research method provided valuable insights since it allowed the client companies and CMOs to anonymously disclose their point of view and comment on those of the other parties. Furthermore, the interviews captured the industry experts' experiences and perceptions of current CMR management practices. Thus, the study could focus on the most pressing and promising fields for action in CMR management.

The expert interviews belonged to the DSR relevance cycle. They were conducted in the study's early stages to lay the groundwork for artifact development.

Exploratory Literature Review

Exploratory literature reviews provide an overview of the current state of knowledge on a research topic. They are used to compile all relevant information. Concerning the management of CMRs, exploratory literature reviews play a crucial role. The knowledge that can help achieve excellent CMR management is widely scattered. On the one hand, the study drew on the literature on supplier management, supply chain management, strategic alliances, and joint ventures. On the other hand, grey literature in the form of best practices in different industries was also studied to gather impulses.

Therefore, the literature review is applied as part of the rigor cycle to consider existing knowledge in solution development and to generate innovative insights into CMR management.

Focus Groups

Focus groups gained popularity as a research method in the 1980s. Like expert interviews, focus groups gather rich insights by questioning industry experts in the research field. Furthermore, focus groups can create additional added insights by interviewing several people together who are allowed to interact. For this purpose, the experts are invited to a group discussion, which is led by a researcher who serves as a moderator.

Unlike in an individual interview, the experts not only describe their opinion but also have to substantiate it to the other participants and are simultaneously confronted with their statements. Thus, new perspectives emerge through the encounter of different views and the exchange and discussion of them. Focus groups are, therefore, particularly suitable for research situations in which interpersonal relationships and diverging perspectives are relevant. As part of the study, focus groups were used to shed light on the challenges, demands, and success factors of excellent CMR management from the perspective of pharmaceutical clients and CMOs. Thus, conflicting views could be uncovered through mixed focus groups, and mutually relevant solutions could be developed and evaluated. In addition, because CMRs increasingly rely on strategic and social alignment among partners due to their high complexity, focus groups significantly contribute to the study findings.

Focus groups are part of the relevance cycle as they help understand the environment and stakeholder requirements and are used to test and evaluate the designed artifacts.

Empirical Sample

The empirical sample of this study consists of the consortium partners, which includes two typical pharmaceutical client companies, two CMOs, and one company that fills both roles. The partner companies with representatives from the D-A-CH region represent different company structures and sizes in the pharmaceutical industry. The focused empirical sample allowed for intensive interaction with partners to develop valuable contributions to the excellent management of CMRs that can be applied in practice. To this end, the study conducted 14 expert interviews and five focus groups iteratively in line with the DSR methodology. In addition, the Institute of Supply Chain Management (ISCM-HSG) contributed experience from comparable industries in contract manufacturing to stimulate new perspectives.

Within the framework of the DSR approach and methods presented, the study provides impulses to excellent CMR management based on practical requirements and scientific findings. Those impulses were subsequently evaluated for their usefulness by the focus groups. In this way, the research questions posed in advance are answered.

Knowledge Base

The knowledge base includes the established knowledge of pharmaceutical CMRs as the foundation on which the study develops solutions for excellent CMR management. Therefore, the chapter highlights the unique characteristics, importance, and challenges of CMR management in the pharmaceutical industry.

Principles of Contract Manufacturing in the Pharmaceutical Industry

Contract manufacturing is a supply chain management arrangement in which a company subcontracts one or more stages of manufacturing activity to external parties (Han, Porterfield, & Li, 2012, p. 159). Accordingly, the activities subcontracted in CMRs can include individual production steps or the entire manufacturing process. In addition, CMOs increasingly take on manufacturing-related activities such as product development, warehousing, and shipping, establishing themselves as comprehensive value-added partners.

In this context, CMRs differ from conventional outsourcing arrangements because the CMO offers comprehensive and specialized services. Therefore, the subcontracted activities are no longer isolated activities but significant parts of the value chain which the CMO administers to some extent autonomously.

Consequently, CMOs are embedded in the client company's supply chain due to the scope and relevance of the outsourced tasks, which are business critical. Furthermore, CMOs contribute significantly to the client's value creation through specialization by offering knowledge, technologies, and capacities that the client cannot reproduce easily. As a result, the formal relationship between clients and CMOs as customers and service providers is misleading. In practice, CMRs are characterized by very often intense co-dependency and high switching barriers to a different partner. As a result, a power balance emerges, which often resembles eye-level collaboration more than a buyer-supplier relationship. For example, clients have limited control over day-to-day manufacturing operations requiring trusted collaboration and are bound to the relationship for a significant time, especially after the start of the commercial phase.

In this context, the need for relationship management of CMRs is emphasized. Due to the interconnectivity of the supply chain and close collaboration, the CMO cannot be managed as a service provider or extended workbench. Instead, the CMR must be organized jointly, considering both parties' specific capabilities and perspectives. CMR management refers to all business and social aspects of relationships between clients and CMOs across all activities and products.

In addition, the pharmaceutical industry poses particular challenges to CMR management due to its industry specifics. On the one hand, the long development timelines for new products, the attrition of potential drug candidates, and the high investment needs for product development and production facilities favor cooperation with partners to share investment risks. On the other hand, broad innovation and technological advancement require access to specific capabilities, where CMOs in specific product fields, manufacturing steps, and technologies come into play. As a result, pharmaceutical CMRs bring together partners' complementary capabilities to deliver high-end medicines.

In this sense, pharmaceutical CMRs often entail much longer collaboration than CMRs in other industries. Food CMRs, for example, are often subject to more opportunistic targets, as recipes and technologies for staple foods have limited protection under competition law. Apparel and electronics CMRs face extremely short product life cycles enabling frequent partner changes. Due to their comparably high commitment intensity and longevity, pharmaceutical CMRs require particularly excellent relationship management.

Consequently, production phases must be optimally utilized to amortize the high investment costs on both sides, adjust to the growth trajectory of the product and assure uninterrupted supply to patients. First, after obtaining a patent, it is essential to quickly place the product on the market using established manufacturing and fulfillment networks. Later, transitioning from patent protection to generics entry requires a complete review of the manufacturing strategy for successful competition by focusing on supply chain efficiency.

Thus, pharmaceutical CMRs operate in an environment characterized by high-cost intensity, lengthy, highly regulated transition processes, and dynamically evolving production technologies and market needs

Benefits and Challenges of CMRs

Working with CMOs allows pharmaceutical companies to reduce capital expenditures for production technologies, equipment, facilities, and personnel in this environment. Contract manufacturing benefits client companies as the industry increasingly manufactures unique and personalized products that are often only in demand in small batches. Working with CMOs, client companies have no obligation to invest in equipment specifically for low production volumes or when the viability of a new product or technology is not yet proven. CMOs can better balance demand fluctuations and ensure high plant utilization by offering their capacity to different customers.

Similarly, CMOs provide development and manufacturing capacities and capabilities in the development and approval phases, allowing clients to scale production after registration rapidly. In addition, they can adjust production volumes flexibly to respond to market trends and legal regulations, access specific geographies, or provide business continuity as a second source. Thus, client companies and CMOs can effectively share the investment risk of pharmaceutical products through CMRs. With client companies focusing on research, product development, and marketing, CMOs focus on managing production systems and networks. Furthermore, CMOs hold operational expertise for various manufacturing technologies and materials through experience working with multiple clients. Therefore, CMRs are platforms for accessing new technologies and sharing manufacturing experiences.

However, close entanglement also poses challenges for operating CMRs. First, the technology transfer to a CMO site is a complex process prone to mismatches that can put start-up timelines at risk. Second, subcontracting manufacturing to CMOs naturally limits the client company's influence on scheduling, processing, and production quality control. In particular, access to capacity must be coordinated with the CMO as demand changes dynamically since the capacity is also offered to other customers. Third, both partners rely on each other to recoup their investments in innovative products and cutting-edge manufacturing sites.

Consequently, the complexity and scope of collaborative activities in CMRs pose challenges to efficient management by the client. Furthermore, pharmaceutical companies and CMOs maintain many CMRs simultaneously, all of

which must be considered and managed individually. For this reason, potential management attention is limited, and resources must be allocated efficiently. Therefore, tailoring management to individual CMRs is a significant challenge for client companies to support their relationships. Effective CMO self-governance is sought to overcome the limits of active control by the client. Trust-based self-governance is furthermore paramount to achieving flexibility outside predefined routines.

However, building a solid foundation of trust that enables self-governance is challenging due to the potentially conflicting goals of clients and CMOs in CMRs. Figure 3 illustrates the objectives of the partner groups based on statements from study participants and highlights potentially conflicting mindsets. In addition, CMRs are ultimately run by humans, which makes them vulnerable to opportunism, mistrust, and information asymmetries. Therefore, CMRs involve a social component significantly affecting relationship build-up and management.

Due to the complex nature and soft requirements of CMRs, the perception of whether the collaboration is successful plays a critical role in engagement. Therefore, achieving excellence in CMR management goes beyond fulfilling measurable contractual obligations and entails active management of personal relationships to institutionalize trust. Accordingly, for effective collaboration and self-governance, the expectations and perceptions of both parties must be considered.

In summary, the collaboration between clients and CMOs can reduce investment risks for both partners and uncover new business opportunities making CMRs increasingly strategic. However, in return, a dependency risk arises from the lock-in effect and reliance on the CMO.

Surveys show that while around 80% of executives in pharmaceutical companies strive for strategic partnerships with CMOs, only a quarter of the relationships live up to expectations (BCG, 2018, p.4). Thus, implementing CMR strategies through targeted management is a primary challenge for CMR management.

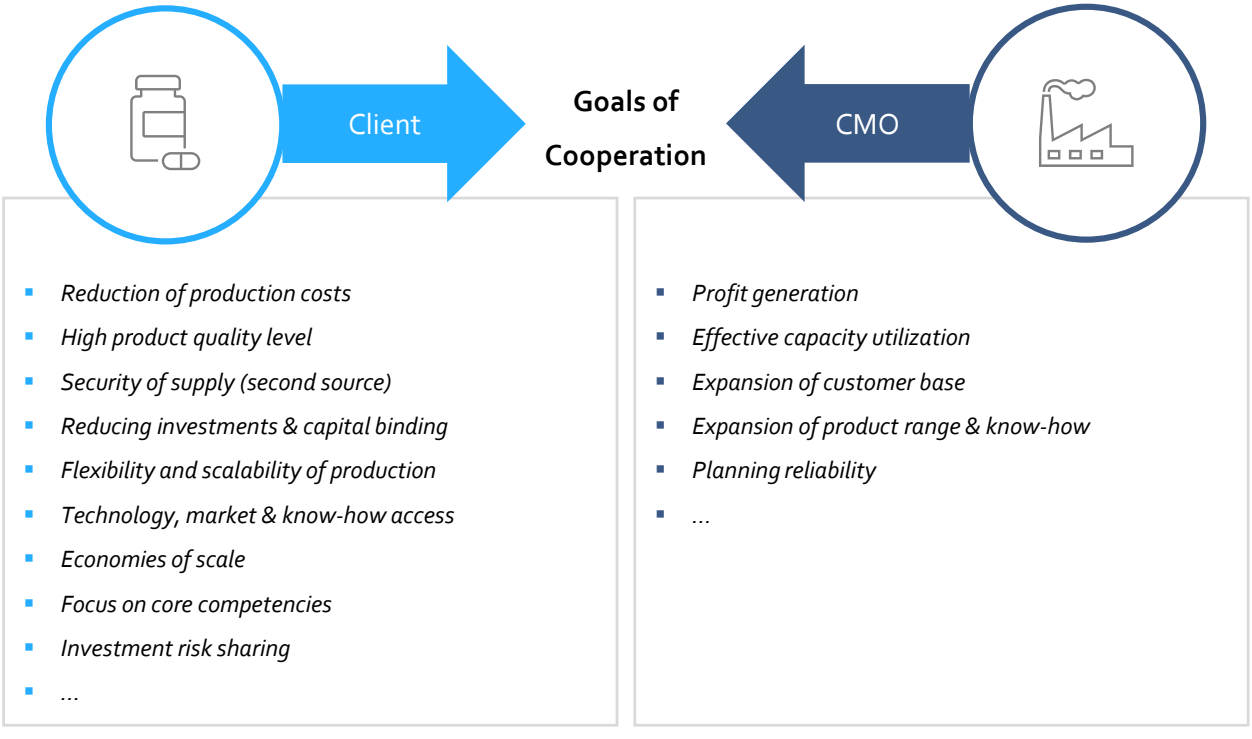

Figure 3: Goals of cooperation between client companies and CMOs

Practices for developing CMRs

Partnerships established in the context of business relationships go through various relationship cycles over the course of their lives. Each cycle possesses different characteristics and properties requiring different management approaches. At the same time, CMRs are influenced by several types of dynamics. The following chapter provides guidance for practitioners to position their CMRs in different Relationship Strategy Cycles and recognize relationship dynamics. The findings aim to promote excellence in CMR management by helping to develop CMRs and identify appropriate management solutions for the particular setting.

It seems apparent that business relationships go through various stages. Nevertheless, these stages are usually difficult to capture in practice. An obvious approach in CMRs is to differentiate relationship stages according to the entailed product's life cycles. However, during the study's course, it turned out that there is no predictable correlation between product life cycles and relationship life cycles. One reason is that CMRs can include different products, and relationship management goes far beyond product management.

In order to understand changes in relationships, it is helpful to look at the causes of those changes. It is noticeable that there are changes that the actors themselves trigger (e.g., through management decisions) and are, therefore, predictable to a certain extent. At the same time, there are dynamics caused by external influences and changes that are difficult or impossible to determine before they occur. To purposefully develop the CMR, despite its complexity and prevailing dynamics, it is necessary to understand the relationship progression and the impact of dynamics on it. Therefore, the study introduces a concept to explain CMR development paths based on Relationship Strategy Cycles and relationship dynamics.

Positioning in Strategy Cycles

The concept of the Relationship Strategy Cycles was developed to segment CMR along their lifespan and focus management resources on each cycle's particular challenges. The Relationship Strategy Cycles consist of five cycles each CMR may go through during its lifetime. Each of these cycles possesses different characteristics and properties and requires different management approaches. Consequently, positioning in these cycles allows pharmaceutical companies to tailor management to the most pressing issues of the relationship stage and plan future development. The five cycles are presented in the following paragraphs:

Onboarding Cycle:

The Onboarding Cycle is every CMR's first and only cycle with no predecessor. Initiated by the official decision to enter a CMR, the Onboarding Cycle typically lasts until all setup activities and production ramp-up are completed. Onboarding plays a crucial role in CMRs in building a stable, trustful and effective relationship. The cycle's goals entail getting to know the other party and their expectations, defining CMR's entry and exit criteria, and crafting the collaboration's legal, financial, operational, and social framework.

To set up the relationship in terms of personal and organizational matters, intensive exchange between the two parties is necessary. Coordination requirements in the Onboarding Cycle entail the establishment of personnel interfaces and governance forums, temporary project structures for support, technical transfer, validation batches, alignment of operational routines and qualifications, production planning, and quality control and production oversight. The relationship intensity, therefore, shows an increasing progression in the Onboarding Cycle. When the essential setup activities are completed, the intensity slowly decreases again.

The willingness to invest in the relationship is also comparably high initially. This is because the onboarding phase builds the foundation for successful and efficient cooperation, and the parties believe that investments in this phase will positively impact the future. However, since the partners are still familiarizing themselves, trust is built on a leap of faith, requiring open communication during this sensitive stage. The onboarding management tasks focus on aligning ways of working together, including communication and escalation pathways, on ensuring compliance for the further course of the collaboration. Therefore, performance measurement beyond joint success criteria and milestones is secondary in onboarding. CMRs must first find a productive balance regarding cost, quality, (project) plan adherence, and delivery reliability. Therefore, instead of metrics, milestone plans are used in the Onboarding Cycle. Without proper formal and informal relationship building, where partners' expectations and ways of working are understood, the future success of the relationships can easily be put at risk if misalignments affect commercial production performance.

Anchoring Cycle:

Once the setup activities of the Onboarding Cycle have been completed, the relationship enters the Anchoring Cycle. Anchoring refers to the CMR's desired, stable state in a relationship where production runs smoothly to the contractually agreed extent, and the relationship repays its investments. In this phase, both parties' needs have been internalized, management routines have been established, and production is stable. The Anchoring Cycle is typically the longest cycle in a CMR and gets revisited multiple times after strategic changes have been made. For example, the manufacturing contract may include one or various products. Adding or dismissing products from the CMRs is typically associated with changes, after which the CMR returns to the Anchoring Cycle. Production stability then involves all covered products.

Similar to production levels during the Anchoring Cycle, the intensity of the relationship also remains stable since no relevant changes occur in this phase. The cycle's stability fosters routine in processes and activities, which entail better predictability and, thus, performance. Given the proven performance, the client may consider reducing the intensity of operational and quality oversight and delegating activities to the CMO. Consequently, relationship intensity is typically lower than during Onboarding with a greater degree of trusted CMO self-governance.

However, routine is often accompanied by diminishing management attention as long as no harmful incidents occur. As a result, communication is usually streamlined, consciously and unconsciously, decreasing consensus and overlooking opportunities for improvement or new projects. Likewise, investment willingness is generally low in the Anchoring Cycle because the prerequisites for production have already been created, and recouping investments is paramount at this stage. Replacements and renewals mainly drive investments in the Anchoring Cycle.

Expansion Cycle:

The Expansion Cycle represents a transition phase among the Relationship Strategy Cycles. An increase in collaborative activity characterizes the cycle. Triggers for such an increase can be, for example, the introduction of new products, production stages, geographical expansion, the establishment of dedicated sites, or significantly increased quantities of existing products to the CMR. Once the transition is complete, and a balance is achieved, the CMR returns to the Anchoring Cycle.

The intensity of the relationship increases during an Expansion Cycle, as structures must be adapted to the expanded collaboration. The structures involved may be similar to those in onboarding regarding the organization, project management, communication, facilities, and licenses. Consequently, a high level of communication and coordination is required. At the same time, mutual dependency and, thus, strategic risk and operational risk increase in the Expansion Cycle. At the operational level, the stability and performance of established production must be maintained despite any disruptive project activities while ensuring adherence to the project plan.

Accordingly, management involvement is required, possibly through temporary project organizations, resulting in significant relationship intensity. Therefore, along with the necessity to adapt the relationship management, the focus is placed on restructuring interfaces and fostering alignment and safeguards to account for the increased dependency. In addition, the notion of performance management is changing because, despite greater additional project activities and interferences, the current production output must be kept stable. Since delivering the same performance can become more complicated, both partners must pay special attention to it and support each other during the transition. However, because business needs must be met quickly, and investments must be recouped, the transition must be completed timely. Thus it diverts attention from performance management which both partners must not neglect as a joint task.

Finally, investment willingness is usually high at this stage, as a proven business case and harmonious collaboration are considered prerequisites for CMR expansion.

Consolidation Cycle:

The Consolidation Cycle represents the counterpart of the Expansion Cycle, as product activity is not increased but reduced in this phase. Consequently, in consolidation, manufacturing quantities, the number of products, or production stages are reduced or dismissed from the CMR. The reason for such a reduction in production activity can be, for example, a drop in market demand or the realization that production is no longer worthwhile for economic reasons. However, after consolidation, the CMR continues at an adjusted scope and can be reinvigorated through later expansion.

Thus, the Consolidation Cycle, like the Anchoring and Expansion Cycles, can be run any number of times within the CMR's lifespan. When all planned adjustments have been completed, it

changes back to an Anchoring Cycle of stable production.

Due to the reduced related activities, the willingness to invest in the relationship decreases in the Consolidation Cycle since investments are less likely to pay off in the future. Management intensity initially rises at the beginning of the Consolidation Cycle due to the adjustments that can require project support. However, as transaction volume and scope decrease, so do the necessary management resources and practices.

For example, consolidation can eliminate the need for dedicated production lines or key accounts. During consolidation, the immediate management attention lies in implementing the operational adjustment. Moreover, the Consolidation Cycle represents a critical phase of collaboration. The downsizing may be perceived negatively by one of the partners and affect relationship quality. In the worst case, this can lead to opportunism, deteriorating performance, and a breakdown in trust and esteem within the relationship. Therefore, CMR management in consolidation must be transparent and seek dialogue to reduce potential adverse impacts, detect early and respond accordingly to prevent performance degradation. Thus, the management focus is on performance management and compliance.

Resolution Cycle:

The Resolution Cycle always represents the last cycle of a relationship and therefore has no successor. Like the Onboarding Cycle, it can only be run once within a relationship. It is triggered when one of the contract parties declares to end the relationship. There can be many reasons for dissolving a CMR, such as strategic realignment, dissatisfaction with the partnership, or lack of market demand. However, this does not mean that the separation is permanent. The contracting parties can later come together again in entirely new CMRs. Moreover, instant dissolution is not possible. Hence, the Resolution Cycle represents a period in which ties need to be entangled in a coordinated manner, and duties need to get fulfilled.

During the Resolution Cycle, management intensity first increases, as various organizational aspects need to be clarified before the final termination of the relationship. In addition, document and sample hold, information requests, or warranty claims, may still need to be provided after production ceases leading to an extended Resolution Cycle. The Resolution Cycle, therefore, requires intensive coordination and adjustment of working conditions. The parties also have to make agreements on the residual financial values of the relationship. Once all the considerations of the CMR dissolution are completed, management intensity decreases until it runs out.

During relationship resolution, management is mainly concerned with maintaining performance as long as production continues and safeguarding amid deteriorating partner commitment. Both parties usually focus on other projects and new partners in this cycle. However, they are in the dilemma that they still have to put considerable energy into terminating the CMR. Thus, parties are reluctant to invest in the Resolution Cycles since investments are unlikely to pay off. But still, investments might be required upon termination to restore changes made during the CMR's lifespan. Therefore, management must maintain a coordinated relationship termination despite shifting priorities and limit opportunistic behavior and reputational damage. Thus, communication intensity and transparency should be increased to account for the Resolution Cycle's sensitivity. Furthermore, potential incentives, e.g., concerning future collaborations, can be used to achieve compliance and effective CMR resolution.

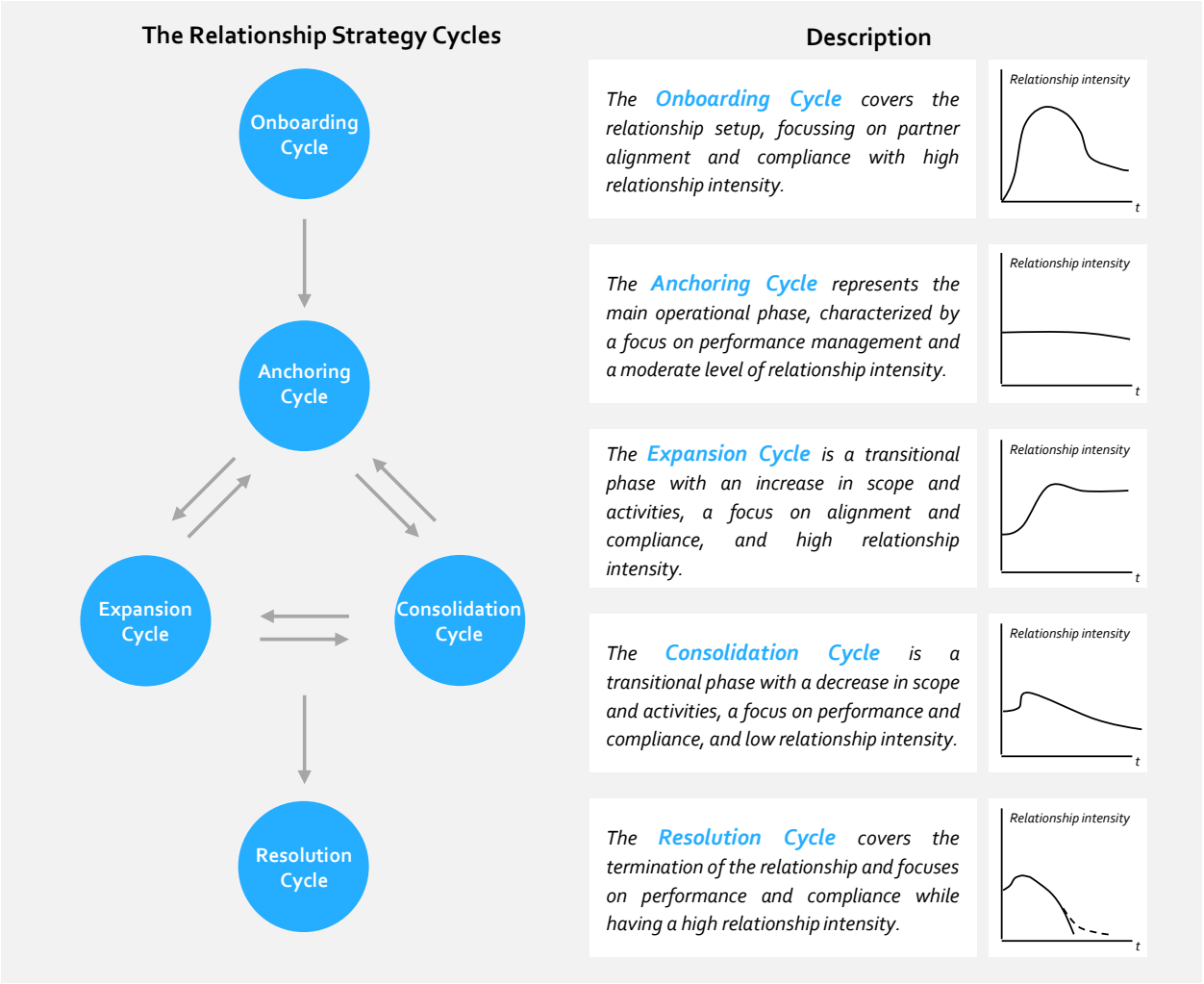

Figure 4: The concept of the Relationship Strategy Cycles

Figure 4 illustrates the possible sequences of the five Relationship Strategy Cycles and includes their key characteristics. Relationship Strategy Cycles can help companies to plan relationship progression and temporal allocation of management resources systematically. In addition, the visualization of planned relationship progression supports targeted preparation of relationship dynamics occurring along the CMRs lifespan. Relationship Strategy Cycles require partners to define the current relationship phase and think about current challenges and future ways of working together. Positioning in Relationship Strategy Cycles thus promotes open discussion about the CMR's envisioned trajectory and changes in the management changes approach.

Sources of Relationship Dynamics

Relationship dynamics are changes in the CMR or its environment that can change the CMR's planned trajectory. Therefore, they may require varying degrees of adjustment in relationship strategy or management. In addition, relationship dynamics are generally diverse, making it challenging to capture systematic management responses. For example, slow build-up or loss of trust, strategy shifts, performance fluctuations, and acquisitions of partners all influence the relationship in various ways.

For relationship managers, however, the decisive factor is how relationship dynamics influence CMR and what management response they require. The concrete solutions must then be developed individually with the partner in

each case. Thus, relationship dynamics can be divided into three groups requiring individual approaches based on their perceived impact and frequency of occurrence.

High impact dynamics require immediate response and permanent adjustment of the relationship to new circumstances. Hence, they are named *strategic dynamics.* However, not all relationship dynamic's impact is disruptive; usually, only operational or temporary changes are necessary. Thus, they can be referred to as *operational dynamics*. Most challenging to capture are *incremental dynamics* that gradually change collaboration over time. Concerning incremental dynamics, it is difficult for partners to identify the right time for action.

Figure 5 illustrates the three types of dynamics using examples practitioners have cited to indicate management adjustments in CMRs. The company-specific classification may differ depending on CMR's objectives and value proposition. For example, one participant pointed out that he usually considers inflation as an ongoing incremental dynamic monitored with limited

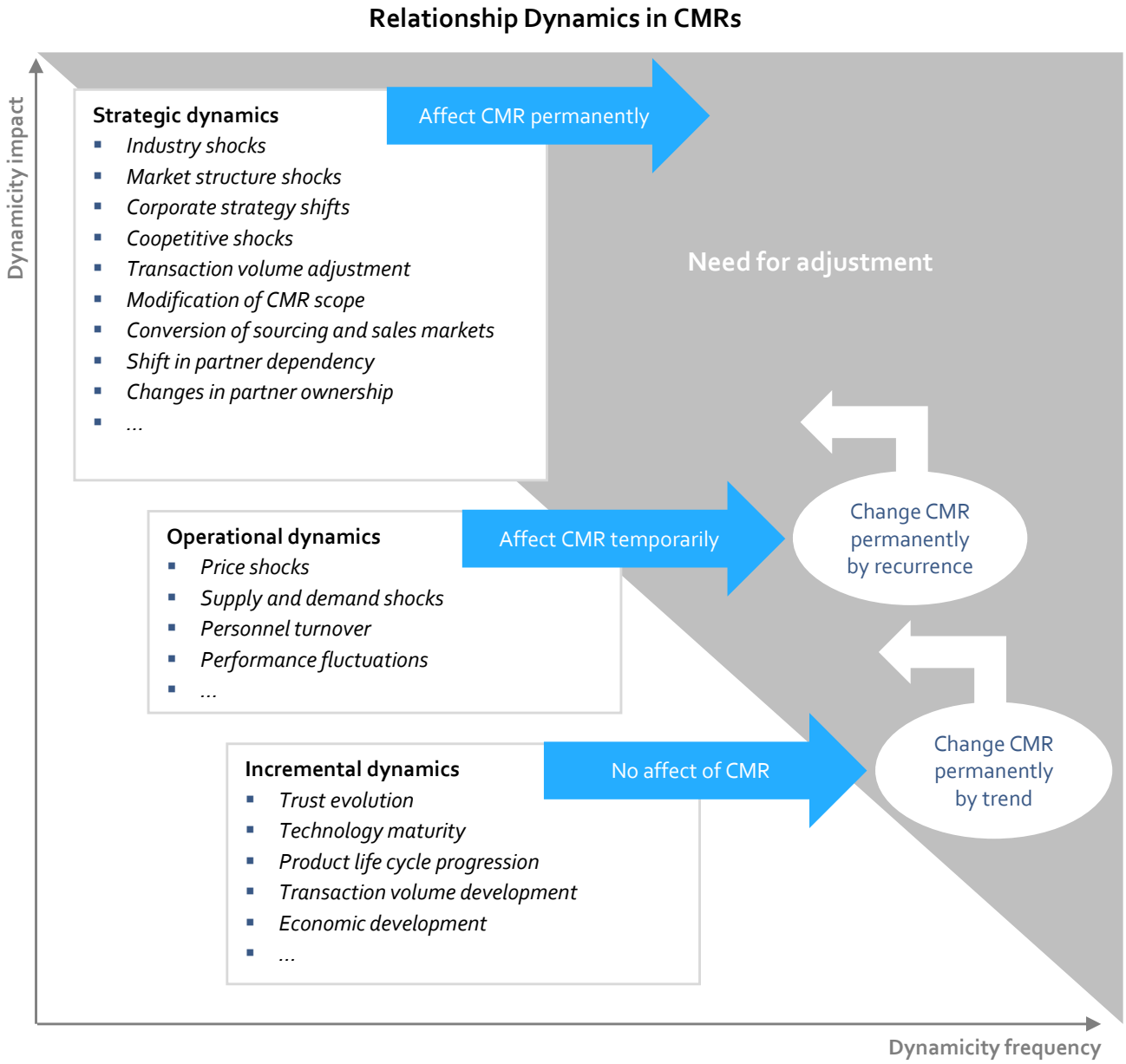

Figure 5: Relationship Dynamics in CMRs

management attention. However, the current market situation in response to the Russo-Ukrainian War ranks inflation under operational dynamics that can trigger temporary measures such as production cutbacks.

Moreover, depending on the CMR's value proposition and profitability, the question remains whether these are permanent shifts affecting cost targets and contract design. Thus, the segmentation of relationship dynamics can support the design of dashboards for prioritizing management resources to safeguard against disturbances. The following paragraphs outline the three types of identified relationship dynamics.

Strategic dynamics:

Strategic dynamics stand out for their impact on the relationship. Although strategic dynamics' effects on CMR management are significant, their occurrence is typically limited. Companies assess strategic dynamics, including strategic risks and opportunities, before entering CMRs. However, strategic dynamics cannot be completely ruled out, and a single occurrence is sufficient to trigger permanent changes in target achievement.

Consequently, the occurrence of strategic dynamics triggers a top-level response. In the context of the strategy cycles presented, the goals and achievability must be reassessed, and, if necessary, adjustments must be made in the relationship, strategy, and management. Such responses can go so far as to change strategy cycles and even terminate the relationship. Since only limited contingency plans can be made and tested for impacts of this size, a strong partner alignment is essential to manage strategic dynamics. Trusted collaborations pay off in turbulent times as partners can flexibly and transparently adapt outside prescribed routines and find individual solutions. Partnering companies should prepare for eventual disturbances through business updates, regular strategic outlooks, protocolled escalation management, and direct communication between executives.

Examples of strategic dynamics are the Pharma supply chain challenges by ramp-up and prioritization of Covid vaccines in 2020, market structure shocks due to innovations or acquisitions, or changes in corporate strategy. If, for example, one partner's corporate strategy changes, this impacts the company's overall goals and, thus, the respective CMR goals and expectations. Therefore, strategic shifts require a fundamental reassessment of CMR management, including an open conversation between both parties and even if no operational disturbances occur for the time being.

Operational dynamics:

Operational dynamics rank below strategic shifts in their impact. They typically represent temporary disruptions in the market (e.g., caused by price shocks or production-related events such as machine breakdowns or performance fluctuations). Consequently, they usually require only quick management adjustments, such as additional audits, closer KPI assessments, or troubleshooting projects. Usually, these dynamics are covered at the operational level by contingency plans and do not require strategic intervention. Once the dynamics have been resolved, the CMR typically continues in the underlying Relationship Strategy Cycle.

While operational dynamics are easier to manage than strategic dynamics because of their temporary effect, they can lead to strategic action when they reoccur. For example, personnel changes in the core positions of both partners are unavoidable over a more extended period. As a rule of thumb, personnel change in critical roles is associated with short-term start-up difficulties. However, the new personnel reaches the required performance level after familiarization, and adapted collaboration routines become established.

Yet, if personnel turnover is frequent, there may be a permanent change in how CMR collaborates. Each shift in personnel requires familiarization and effort for personal alignment and carries a risk that collaboration is permanently affected due to unfamiliar approaches and behaviors. Changes in executive positions often lead to changes in management style that affect collaboration, especially in CMRs, as they rely on robust alignment. Constant staff turnover may therefore be seen as a risk to the partnership. It may lead to a decline in performance and compromise the stability of the CMR.

Due to the more frequent occurrence of operational dynamics, contingency plans can be well developed, evaluated, and continuously improved. However, as recurring operational problems can make comprehensive measures necessary, documentation and review of operational issues are recommended. Performance targets and operation threshold values should be defined in the Onboarding Cycle and institutionalized in the Anchoring Cycle. Those should be reviewed, closely defined, and communicated in case of repeated operational problems to include the next escalation level in relationship management on time. Escalation is usually associated with partner misbehavior, a severe gap in achieving targets without a quick way to mitigate it. Still, due to complex supply chains, reasons for escalation can also lie outside of the partner's control.

For example, both partners should initiate a discussion on time when they think temporary dynamics, such as unavailability of materials, or price shocks, threaten permanent collaboration. Due to the different business models of clients and CMOs, the partners have little insight into the supply and financial impact on the partner. However, jointly and pre-emptively, measures can be taken to mitigate risks of CMR failure.

Incremental dynamics:

Incremental dynamics often escape CMR management because they change the relationship slowly and insidiously. Moreover, management attention is usually low because the changes are barely noticeable. For this reason, they often go unnoticed. Consequently, clients and CMOs face the challenge of finding the right time to change CMR management. Yet, in strategic and financial management, incremental dynamics such as exchange rates are already monitored to identify trends, exploit opportunities, and proactively avoid risks.

With advancing digitalization, incremental dynamics can also be monitored more and more effectively in supply chain management to detect trends and adapt proactively. In the current volatile business environment, the need is also visibly increasing. From a CMR management perspective, besides actual values, trends in key performance indicators on costs, quality, and service or economic data such as inflation and exchange rates can provide impulses for predictive CMR management. Furthermore, trust development plays a crucial role in CMRs developing strategic partnerships.

In practice, however, many companies expect technical innovations for cost-effective monitoring and trend analysis of incremental dynamics before they take action. Yet, first, relevant dynamics and thresholds for action should be actively identified as a basis in coordination with the CMR partner. Although automated analysis of gradual dynamics is not yet state-of-the-art in CMRs, partners can develop collaborative approaches to sample measurement and discussion for more stable relationships. For this purpose, the Chapter «Practices for Aligning Partners» describes an approach to managing incremental relationship dynamics.

In general, the distinction between the three dynamic groups should not be considered rigid but CMR-specific and dynamic. The examples of inflation and personnel changes described above illustrate that positioning is not immutable. Even dynamics with a more negligible isolated impact can cause profound changes through frequent occurrence. Therefore, the breakdown of dynamics according to occurrence and impact does not claim to be a complete and definitive classification of relationship dynamics. Instead, the study proposes jointly addressing the management of relationship dynamics in CMRs by openly discussing and classifying contingencies and developing respective structures and measures. The presented categorization of relationship dynamics can guide such exchanges.

Applying Relationship Strategy Cycles

Systematic development of CMRs amid the numerous interfering relationship dynamics requires focused management. The Relationship Strategy Cycles support targeted CMR progression by breaking the relationship into tangible development stages.

First, since each cycle is associated with different challenges and goals, companies can effectively target their management resources and practices. For example, during onboarding, partners should focus on production setup and relationship building. Consequently, performance measurement should account for the relationship's project nature and collaborative efforts. One consortium partner, therefore, proposed excluding KPI during onboarding and controlling the CMRs through milestones. Such an approach accounts for the high uncertainty during onboarding and fosters trust-building by sharing responsibility for relationship setup.

However, similar to project milestones, strategy cycle goals should also have deadlines. In particular, targets relating to production quantities and delivery can lose their credibility and, thus, their meaningfulness due to delays. Such a situation can have decisive consequences for the business case of the partners and thus for the stability of further collaboration. Therefore, these consequences must be disclosed, and countermeasures and possible compensation agreed upon early. Consequently, strategy cycles should be provided with termination criteria that trigger a strategic analysis of the CMR if the targets are not achieved in a given time frame.

In addition to the goals of a cycle, each cycle's specific risk factors should also be considered. As described above, preparation against all contingencies is infeasible. However, focusing on specific Relationship Strategy Cycles can help prioritize dynamics to shift management attention. As a result, more effective measures for contingencies can be prepared, and objectives pursued more closely.

Furthermore, consortium partners state that after the relationship is set up, the routine gradually increases while management attention decreases. As a result, alignment might degrade, and business opportunities might be overlooked. Therefore, it is appropriate to divide the CMR lifecycle in time to plan CMR development paths through regular course reviews and milestones and to reinvigorate management attention systematically. Consequently, Relationship Strategy Cycles provide focus and orientation in lengthy CMRs.

For example, suppose that after a long period of constant production, the production volume is increased in a CMR. By declaring an Expansion Cycle, strategic management attention can be strengthened. As a result, management resources can be reallocated and practices modified. For example, performance metrics thresholds can be eased during recalibration or line expansion. In addition, contingencies during the transition can be systematically incorporated into existing escalation levels in coordination

with top management, and communication paths can be temporarily shortened. Finally, the partner's performance criteria can be redefined, and different development paths outlined.

To implement Relationship Strategy Cycles, both parties must agree on their use for relationship planning. Next, the practice proposes recurring alignment of CMR management according to the following questions:

1. *What is our current cycle's relationship strategy?*
2. *What are our cycle goals, and what metrics do we use to measure goal fulfillment?*
3. *What potential risks and changes await us in this cycle, and how can we counteract them?*
4. *When do we complete the cycle, and how do we proceed?*

The complexity and duration of CMRs compared to normal buyer-supplier relationships is high. Therefore, it is crucial to focus management efforts on implementing and adapting relationship strategies. Strategic reviews and outlooks are well established in individual companies but often lack connection, focus, and agenda between CMR partners. As a result, strategic assessment is often supplanted by operational issues.

Relationship Strategy Cycles support systematic CMR development by embedding strategic relationship management in a project framework with milestones and subsequent activities. Consequently, strategic positioning should be repeated regularly. Figure 6 provides a template with illustrative examples of positioning CMRs within Relationship Strategy Cycles.

Repeatedly reviewing CMR's development prompts partners to think strategically and make deliberate directional decisions. At the same time, it prevents partners from treating different relationship phases the same way, despite their individual needs. Consequently, Relationship Strategy Cycles enable companies to reduce the time-dependent complexity of CMRs and achieve excellent CMR management.

Reviewed CMR	*CMR XYZ*	
1. Current cycle	*Expansion Cycle*	
2. Cycle strategy	**Cycle goals**	**Cycle key metrics**
	▪ *Setting up the proprietary production line #2* ▪ *…*	▪ *Project delay days* ▪ *On-time in full (OTIF)* ▪ *Rejection rate* ▪ *…*
3. Contingency plan	**Potential risks and dynamics**	**Contingency actions**
	▪ *Failure to transfer technology* ▪ *Demand development slows down* ▪ *…*	▪ *Secure safety stocks and try to buy line #1* ▪ *Bundle with product C to achieve capacity utilization* ▪ *…*
4. Cycle transition	**Cycle termination criteria**	**Development paths**
	The new line has been quality approved for operation	*CMO is considered as a development partner for product X if the transfer is completed successfully*

Figure 6: Template for positioning CMRs in Relationship Strategy Cycles

Info Page

Key findings

- *Product lifecycle-oriented development of CMR neglects collaboration quality and exploitation of business opportunities*
- *The development of CMRs is driven by actively initiated Relationship Strategy Cycles*
- *Relationship Strategy Cycles represent a temporal division of the CMR life span that transforms relationship planning into an ongoing project with milestones*
- *Relationship Strategy Cycles support the targeted use of management resources by prioritizing cycle-specific goals and contingencies*
- *Relationship dynamics can impact CMR in three ways: through strategic, operational, and incremental changes*
- *Segmentation of dynamics can help establish contingency plans and guard against selected dynamics*

Success factors

- *Look beyond the product! - CMR's product lifecycle-driven development neglects relationship quality and exploitation of business opportunities, fostering a «service by the book» mentality. Instead, focus on the relationship lifecycle.*
- *Be specific with goals! - CMRs typically pursue multiple formal and informal goals at different levels simultaneously. Define goals and set priorities to focus management efforts and closely track goal achievement.*
- *Give changes your full attention! - Due to the complexity of pharmaceutical CMR, every strategic change requires special attention, comparable to project efforts during onboarding.*
- *The world turns, and so do CMRs! - Management practices are often put in place to stay. Ongoing cultivation, review, and evolution of management approaches, methods and tools increase the fit to the latest management challenges.*
- *Routine crowds out focus! - In long-term CMRs, management attention must be strengthened from time to time in order not to omit business opportunities and mutual understanding. «Out-of-the-box activities» like creativity or role-swapping workshops help to regain focus.*
- *Break away fairly, it's a small world! - Tactics in terminating the relationship do not bring gains, get around in the industry and worsen future collaboration. Instead, involve the partner early and disengage collaboratively.*

Practices for tailoring CMRs

Limited management resources and heterogeneous, dynamic management requirements across CMRs make it necessary to tailor CMR management to individual relationships. Clients and CMOs are sometimes involved in a triple-digit number of CMRs. Therefore, partner classifications and segmentations are widely used to provide management transparency and focus. The study analyzed and challenged classification practices in CMRs with the consortium partners and derived recommendations to achieve more effective tailoring of CMR management.

Given the challenges of CMR management, it is natural that pharmaceutical companies are looking for CMOs with whom they can explore business opportunities broadly and establish trusted partnerships. However, contract manufacturing does not exclusively include strategic and innovative products. There are also long-term running commodities with low growth prospects but reliable and high margins. In addition, CMRs are established to supply countries requiring local manufacturing by authorities where the client does not hold manufacturing licenses or access key technology licenses. Furthermore, some CMRs cover diminishing products with unviable purchase volumes but medical importance for in-house production, stagnant product lines, or complementary products for the portfolio. And, as if the complexity was not significant enough, individual CMOs often cover several types of products for the client simultaneously.

Tailoring management of pharmaceutical CMRs

Differentiating between partnerships and other CMRs is already challenging. However, distinction alone provides only limited management guidance. Practitioners, therefore, resort to the segmentation of CMRs to concentrate their management attention and resources on specific relationships. Segmentation is the process of categorizing CMRs based on a defined set of criteria to assign resources, personnel, and management practices.

The study reveals that CMOs typically distinguish between two different partnerships, one considered strategic and one not. While the distinction generally does not influence the manufacturing service quality, CMOs associate strategic partnerships with joint development of business opportunities compared to service strictly per contract. Some CMOs furthermore link the assignment of key accounts to strategic alliances. Client company's approaches to tailoring management in comparison range from individual assessments without segments to six category segmentations. The diversity of CMR segments reflects the unique business needs of individual pharmaceutical clients and CMOs.

On the one hand, detailed segmentation enables precise management targeting. However, on the other hand, it becomes more complex to classify CMRs. Therefore, the ideal number of segments does not depend on the size of the CMR portfolio but on the selection of meaningful criteria that reflect the prerequisites for

particular management styles. Clustering CMRs through relationship characteristics provides transparency to the portfolio's current division. However, applying proper Tailoring Criteria connected to management needs can further indicate appropriate management styles for particular CMRs.

For example, geographic location or responsibility are transparent criteria to classify CMRs and create transparency in the portfolio. However, geographic location is only appropriate for tailoring CMR management if it provides specific guidelines such as organizational responsibilities or the inclusion or exclusion of investment programs. Likewise, ambiguous criteria such as relationship duration need to be clarified or avoided. For example, CMRs with a long relationship duration could indicate the trust level, routine, and established standards as a soft criterion but are inconclusive as a decision criterion.

Tailoring CMR management through segments means each segment must reflect a particular management approach. Therefore, differentiation of CMRs must be based on robust criteria that influence specific management decisions to allow for tailored management rather than the other way around.

In pursuit of best practices, tailoring approaches are often adapted from benchmarks, partners, studies such as this one, or other sources. However, this approach often leads to assigning CMRs to given segments rather than tailoring management to individual needs and strategies. Therefore, in order to establish purposeful CMR segments to tailor management and allocate resources efficiently, Tailoring Criteria with substantial explanatory power for management decisions must be consulted. Segments can then be defined after analyzing CMRs according to the Tailoring Criteria.

In the study, client companies and CMOs have applied similar Tailoring Criteria covering economic aspects, including business growth opportunities, commitment intensity, and risk level. Still, they presented diverse segmentation approaches based on how they interpreted and weighted the criteria.

Deriving meaningful Tailoring Criteria

Identifying and applying meaningful Tailoring Criteria to establish CMRs segments with great explanatory power in individual organizations is challenging. And the authors of this study do not want to suggest otherwise by proposing a simple, standardized segmentation. Since the key to tailoring management effectively lies in understanding the CMR's management needs, segmentations cannot be adopted. Moreover, they must be developed or fitted to individual requirements. Therefore, on the path to CMR management excellence, the study provides a guiding process and validation methods for deriving meaningful Tailoring Criteria. The four-step process approach presented in Figure 7 was tested with the consortium partners as part of the study. As a result, six Tailoring Criteria were identified that the consortium partners consider valuable for effectively categorizing CMRs for management purposes. The approach includes criteria generation, discarding overlapping criteria, evaluation, and visualization of CMR segments. Selected management methods support all process steps.

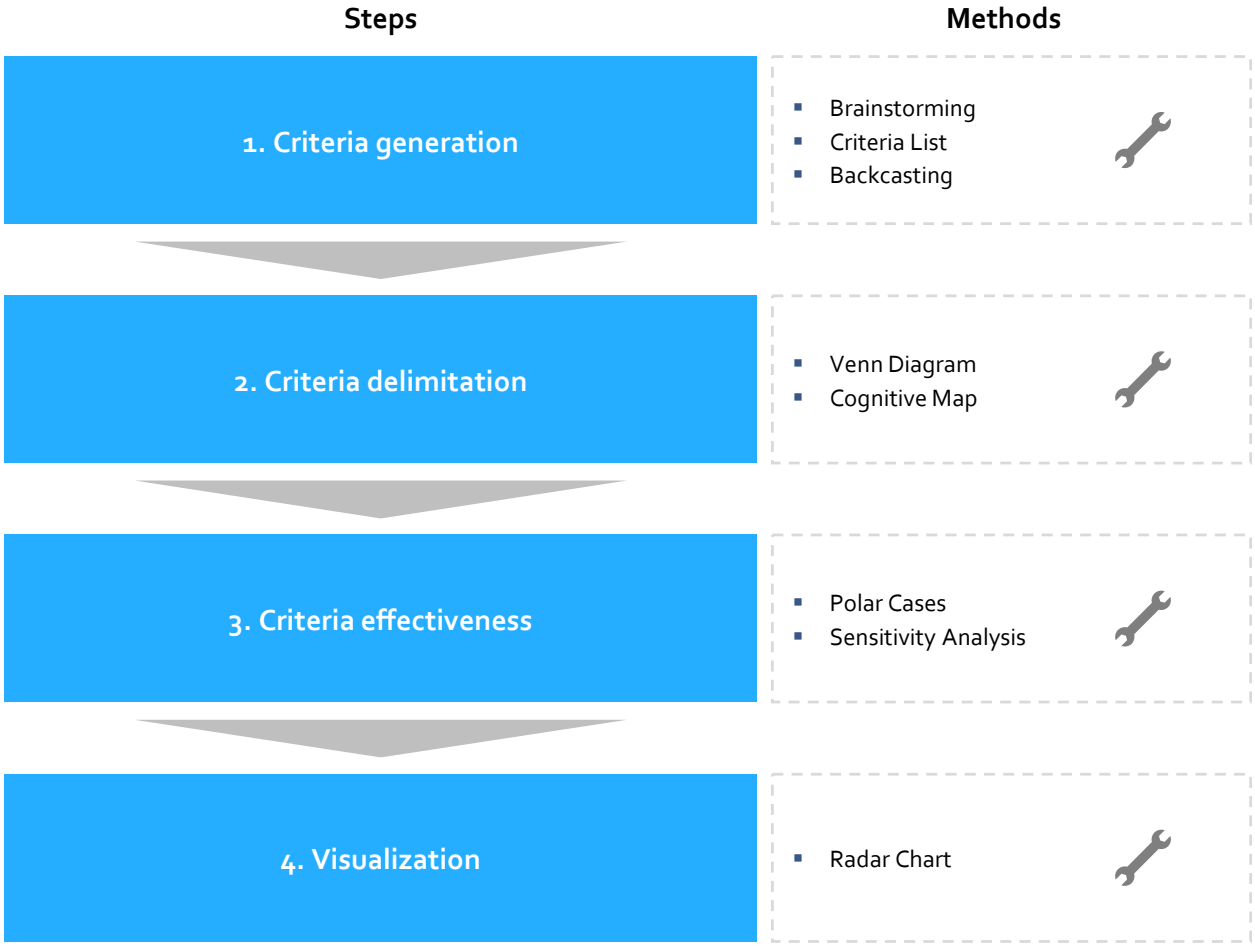

Figure 7: Approach to designing Tailoring Criteria for CMR management

Step 1: Criteria generation

The first step concerns the generation of Tailoring Criteria that can be measured across all CMRs and are believed to be relevant for segmentation. However, in practice, there is often a tension between the measurability and meaningfulness of the criteria. For example, the power relationship between clients and CMOs as a criterion usually cannot be simplified by comparison of company size or revenue share. Hence, to avoid losing any information in the first step, it makes sense to note down a slightly more abstract criterion with a proposed measurement. Measurement can be discussed later, but rash decisions should not compromise the criterion's effectiveness. The criteria can be derived from either brainstorming, existing or benchmarked criteria lists, or backcasting management prerequisites.

Brainstorming was popularized by Alex Faickney Osborn (1953) as a group creativity technique to generate ideas spontaneously. Since then, brainstorming has been adapted to various research, education, and business fields and has continuously evolved. Osborn suggested four brainstorming rules that can be applied to CMR Tailoring Criteria: «Go for quantity, withhold criticism, welcome wild ideas and combine and improve.» In the first step generating multiple criteria beyond practical application is encouraged, as criteria will be narrowed down later.

In CMR management, brainstorming groups should encompass the essential relationship stakeholders along the interfaces with CMOs, such as strategy, procurement, supply chain,

technical operations, quality, and product development.

Criteria Lists can be generated from fragmented information sources such as established segmentation procedures, good practices, benchmarks, or regulatory requirements. Considering existing or external sources is recommended as a control to creativity techniques to include potentially complementary impulses. Criteria lists can also serve as integration and documentation as they can be easily managed, shared, and supplemented. Therefore, they are beneficial for the refinement of existing tailoring approaches. Figure 8 shows an example of a criteria list derived from brainstorming and integration of various partners' Tailoring Criteria.

Backcasting is a planning method coined by John Robinson (1990) in which objectives are first established. Then the activities necessary to achieve the described objectives are defined. When applying backcasting to CMR management, the management practices can be understood as the objectives and the criteria as activities required to achieve the objectives. For example, the question posed by backcasting is: «What criteria must a CMR meet to involve the CMO in product development activities?» Answering this question for all applicable management practices yields a set of criteria as prerequisites for specific management practices. The segments can then be identified by clustering the management practices for each segment.

However, since backcasting connects Tailoring Criteria with specific management activities, it requires a transparent overview of deployable management practices. Therefore, backcasting often stimulates internal discussion about the particular objectives of management practices. Backcasting will also likely create many criteria that can be narrowed down later.

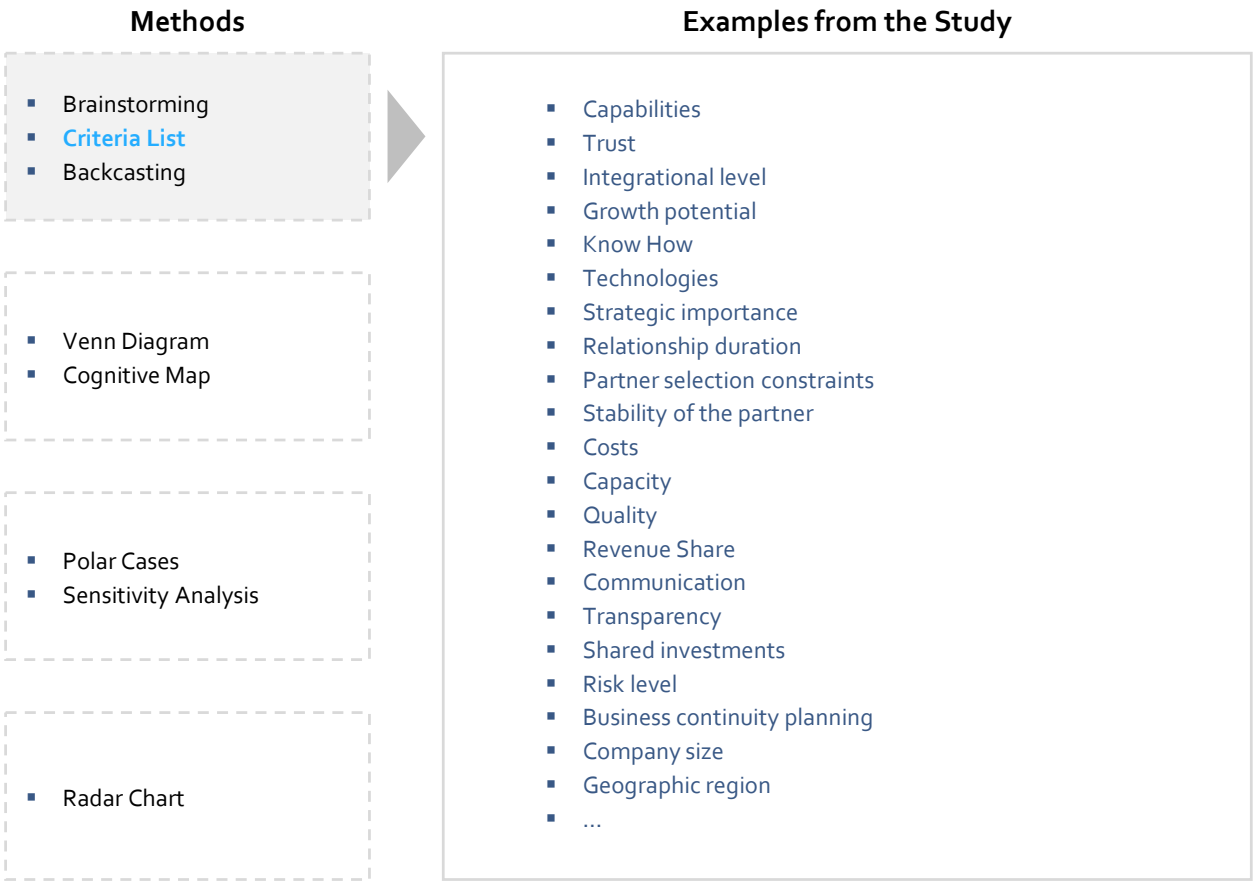

Figure 8: Derived list of Tailoring Criteria

Step 2: Criteria delimitation

Generating criteria that influence CMR management decisions can quickly lead to many results at different levels of consideration. In order to achieve an effective but also practical set, the criteria should be streamlined after the first step. Redundant and overlapping criteria should be removed. Visualization is a powerful tool to create transparency on complex issues. For this purpose, Venn Diagrams and cognitive maps are recommended to identify correlations graphically.

Venn Diagrams were developed by John Venn (1880) to highlight logical relations between data sets graphically. Since then, they have experienced widespread use. Applied to the tailoring of CMR management, they help organize criteria by showing overlaps and different levels of consideration. With the help of Venn Diagrams, redundant criteria and overlapping criteria can be reconsidered. To this aim, all criteria are noted on an empty page, encircled, and clustered according to their core statement. Then all overlapping criteria are reevaluated to determine whether they are redundant and can be dismissed without loss of information. For example, a criterion named «risk level» might fully cover the meaning of another criterion for financial partner stability. Another example is revenue share indicating power in the relationship overlapping with the partner's technological capabilities, which can refer to growth potential and dependency. For ambiguous criteria, tailoring should always adapt only one meaning and create an independent criterion of the second indication. Finally, a set of independent criteria that covers all relevant aspects of CMR management should remain. Figure 9 shows an example from the study.

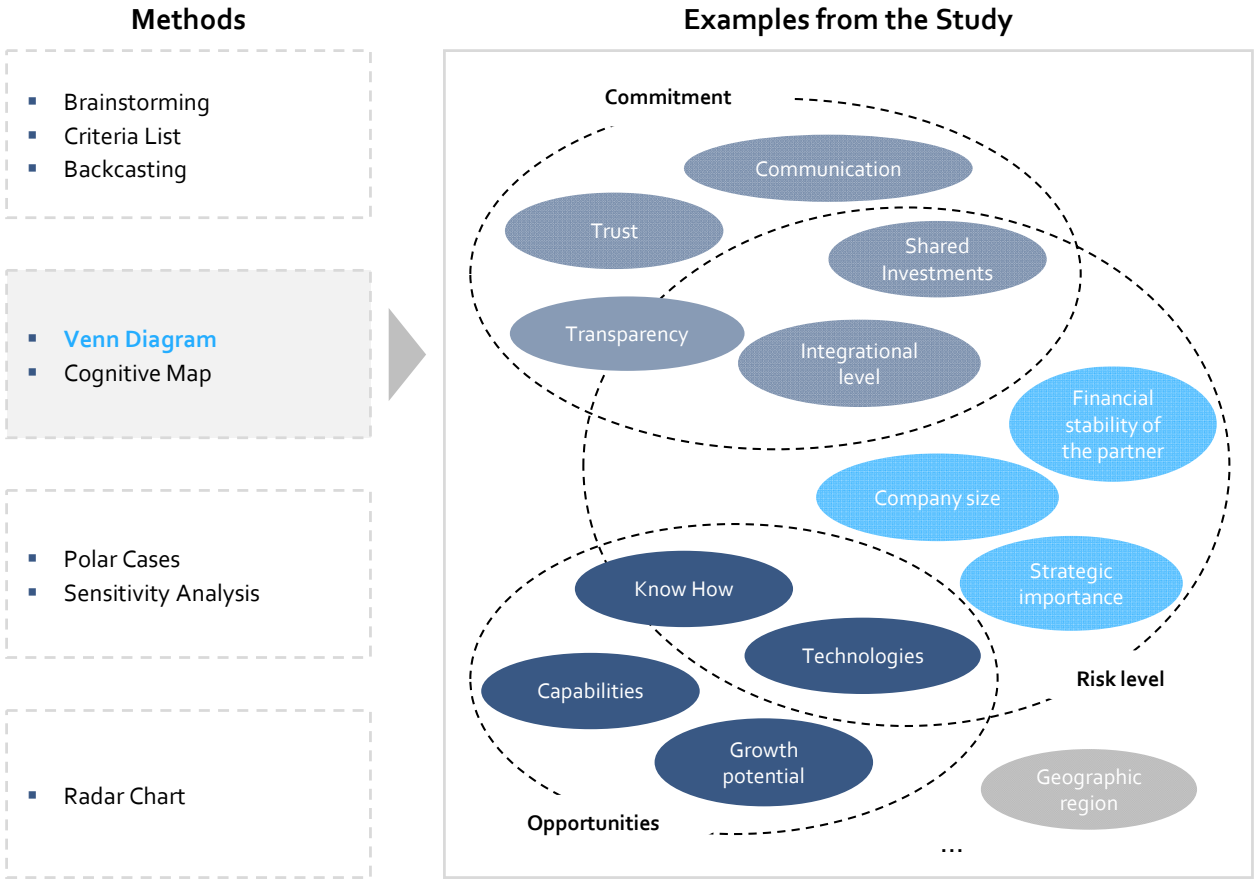

Figure 9: Organisation of Tailoring Criteria through a Venn Diagram

Cognitive Maps were introduced by Edward Tolman (1948) to visualize animal behavior. In management, cognitive maps are applied to analyze relationships between activities. Therefore, they can be used to evaluate the relationship between generated Tailoring Criteria. First, criteria are noted down, then connections between criteria are described, resulting in chains of cause and effect. Ideally, a lean set of criteria only uses one criterion per cause-effect chain to carry all relevant information.

Step 3: Criteria effectiveness

A crucial aspect of Tailoring Criteria is their explanatory power to indicate which management practices should be used in the corresponding CMR. Therefore, the defined set of criteria should be evaluated based on each criterion's influence on CMR management. Criteria that do not affect management should be dropped or reconsidered. Likewise, management practices independent of Tailoring Criteria form the underlying standard management approach. To this aim, polar cases and sensitivity analysis are recommended methods.

Polar cases refer to the selection of extreme examples in case studies to illustrate an issue in varying settings (Eisenhardt, 1989). In tailoring of CMR management, polar cases help test the effectiveness of Tailoring Criteria. To this aim, each criterion's relevance for CMR management design is assumed by its most extreme values. For example, when the manufacturing volume is considered a Tailoring Criterion, the effect of extremely low and high manufacturing volume on management must be evident. Therefore, the choice and design of relationship management practices for either case must be simulated.

If the results are ambiguous despite the delimitation of all other information on the CMR. In that case, the criteria cannot be considered effective for tailoring CMR management.

Polar cases are furthermore valuable for developing design options for fixed management practices. For example, KPIs are likely to be employed in all CMRs. However, polar cases can spark the discussion of how KPI should be customized to low or high manufacturing volume CMRs for example. High-volume CMRs might profit from additional risk-oriented KPIs, while a lean set of KPIs might be sufficient for low-volume CMRs. Figure 10 provides an example of polar cases discussed the study.

Sensitivity Analysis is a method used to evaluate the influence of single variables on a complex result. Transferred to the tailoring of CMR management, this means that effective criteria should be able to change the management approach towards a CMR. For this purpose, a real CMR can be taken as a reference. Only the examined criteria are assumed to be changed drastically. For example, the manufacturing site could be changed to another country in a given CMR. As a result, the imagined change should lead to a change in CMR management if the location criterion is viable for tailoring relationship management.

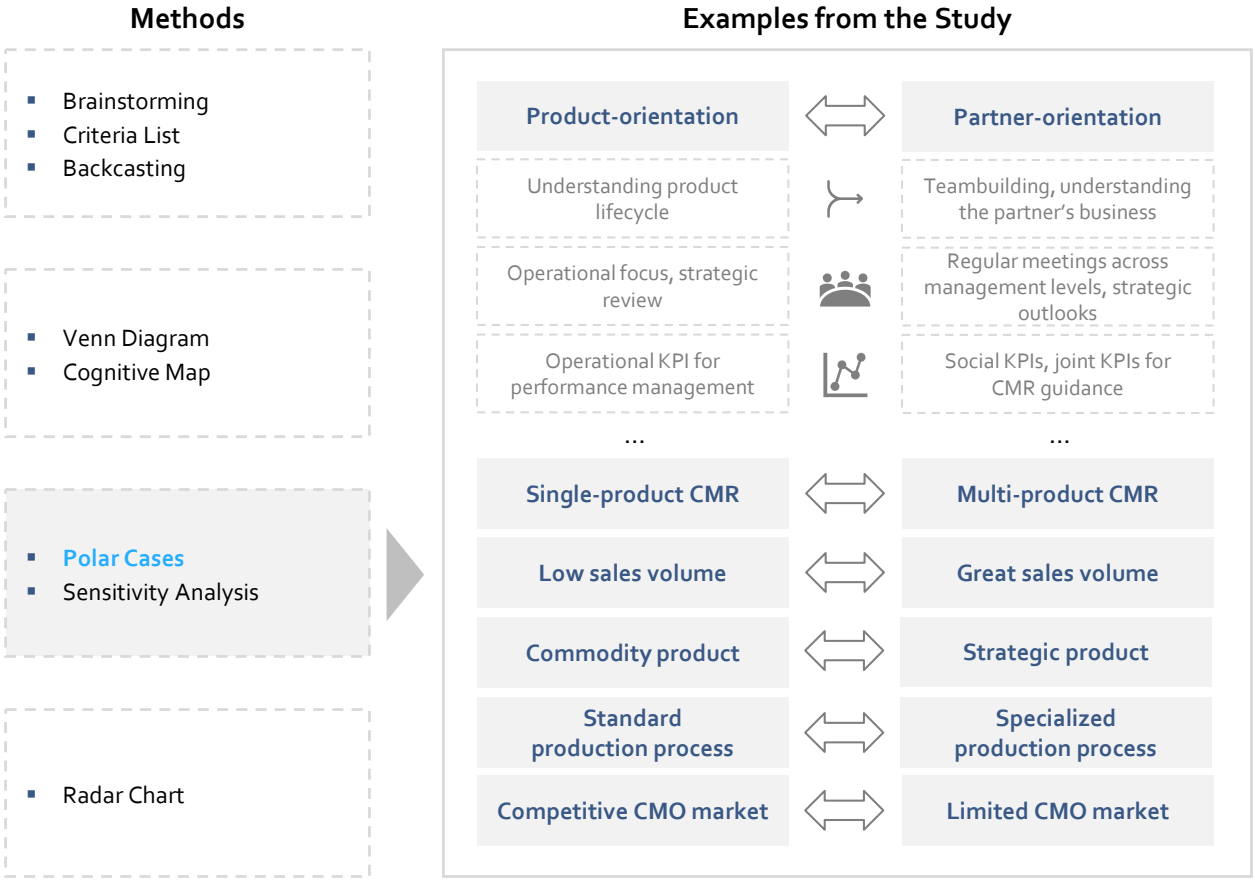

Figure 10: Evaluation of Tailoring Criteria through polar cases

Step 4: Visualization

Finally, visualization is recommended for any kind of management tailoring. Tailoring Criteria compress information to reduce complexity and create transparency. Because the human eye captures graphics more efficiently than text, visualization helps decipher the compressed data, identify errors, and discuss and compare segmentation with internal and CMR stakeholders. Discussion of a visualized classification of the CMR with the partners can help assess the partner's expectations and foster alignment.

For reasons of simplicity, many theoretically developed segmentation approaches are limited to one to three criteria to be represented graphically in pyramids or matrices. In the case of CMR segments, more than two criteria are likely necessary to tailor CMR management adequately. Therefore, a radar chart is suggested for visualization since it allows for multiple dimensions and transparent marking of segments.

Radar charts are diagrams that display data on axes that meet at the same point and form a spider-net-shaped form. Thus, they allow the representation of various criteria that can be connected to comprehensively show a CMR's management characteristics.

Radar charts allow CMR management to be tailored to predefined segments by specifying specific visual patterns in the diagram (see Figure 11). In addition, however, they also allow for transparent discussion and evaluation of the results of each Tailoring Criteria to more precisely tailor management and select more effective management practices. Consequently, the presented process approach supports tailoring CMR management based on segments and individually.

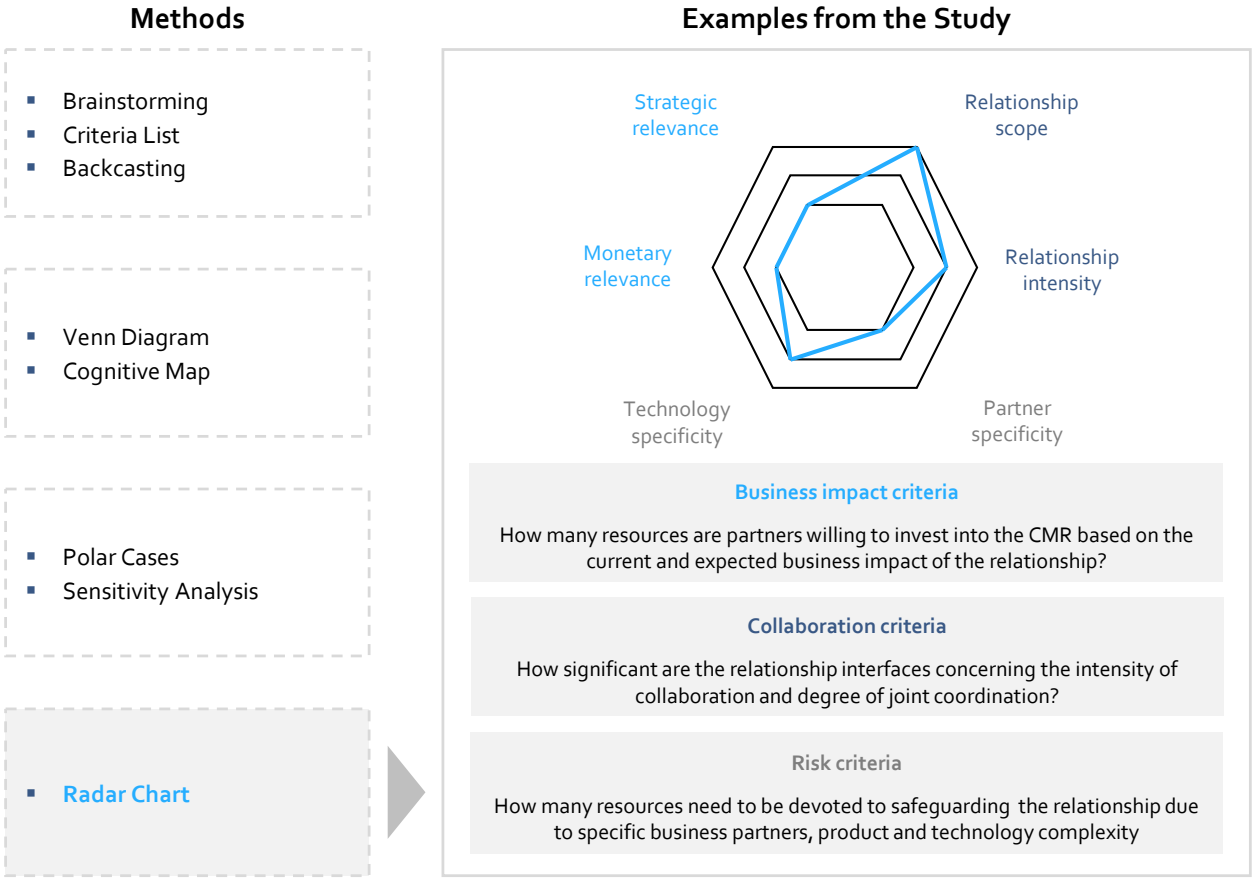

Figure 11: Visualization of Tailoring Criteria through a radar chart

Applying the Tailoring Criteria design approach

The suggested four-step approach has been applied in the study employing various presented methods to illustrate its use. The following paragraphs show how the process can be used to identify meaningful criteria as a basis for tailoring CMR management.

First, in step one, a criteria list approach was chosen. The partner companies disclosed criteria they systematically apply or recognize in tailoring CMR management. Thus, a list of various criteria was built, and duplicates were dismissed. Second, the criteria list was dissolved by creating a mind map of all criteria and encircling it to form a Venn Diagram. At this point, various criteria could be integrated or excluded due to partial or complete overlapping.

Furthermore, for some criteria, such as company size, no definite core statement about CMR management could be derived, and thus, it was dismissed. Finally, after narrowing down the criteria, a set of six remained. These six criteria covered relationship intensity, relationship scope, monetary relevance, strategic relevance, technology specificity, and partner specificity. Third, polar cases were applied to validate the criteria's effectiveness for tailoring CMR management. To this aim, all criteria's extreme values were compared against KPIs, business reviews, and partner alignment. The three named management practices were tailored to each criteria's extreme value as part of the evaluation. Finally, the criteria were visualized in a Radar Chart. Visualization was the basis for discussing potential management segments.

In the following, the derived Tailoring Criteria are displayed and explained. However, these criteria are dedicated to the consortium and, therefore, neither exhaustive nor universal.

Relationship intensity entails whether the CMR's primary focus lies in one specific product or the partner's capabilities that are considered valuable across products. In the polar cases, product-oriented CMRs were considered to employ a more standardized and lean management approach focusing on exact measures, technical details, and performance management. However, partner-oriented CMRs targeting the social relationship layer were considered more intensive. These CMRs use team building, foster mutual business understanding, conduct relationship health assessments and employ jointly responsible KPIs.

Relationship scope refers to the number of products and production stages covered in the CMR. The criterion thus makes statements about the organizational complexity, involved stakeholders, and interfaces. Regarding tailoring of CMR management, it is therefore relevant for selecting communication practices and assigning responsibilities.

Monetary relevance depicts the quantitative business value of the CMR. Thus, it indicates investment willingness since the return on investment can be estimated. High sales volume or gross margins can justify investment into equipment, IT integration, personnel, and team building to increase CMR performance.

Strategic relevance refers to CMR's outlook and non-monetary contribution to the company's success. A CMR's strategic value can be securing future business areas through access to technologies and markets, the prospects of the included products, or contributing to supply chain resilience. Consequently, strategic relevance concerns the internal management attention and practices used for relationship development. These practices can include, for example, team building, strategic outlooks, product development, and joint investments.

Technology specificity covers several risk aspects of the manufacturing process and the complexity of the technology as such. First, it covers the risk of operations disruptions due to high requirements to maintain operations (e.g., specific zoning needs and complex Bills of Materials for Biologics and Steriles), process robustness challenges, or component supply bottlenecks. Second, it concerns the necessity to evaluate partner and CMR performance. For example, suppose the partner has superior technical knowledge. In that case, the CMR management approach likely affects performance KPI, quality control, and incentives. Lastly, if the technology specificity entails intellectual property risks, dedicated safeguarding measures are embedded in CMR management.

Partner specificity relates to the dependency on the CMR partner. For client companies, the partner specificity is typically defined by the CMO's capabilities and licenses. At the same time, the revenue share primarily marks the CMO's dependency. Therefore, partner specificity directly influences the contracting policies, safeguards, communication practices, and willingness to compromise in case of conflicts. Furthermore, client companies and CMOs with significant partner dependency will aim to bind partners by further integration and collaborative business development.

Tailoring CMR management to individual relationships is paramount to allocating resources efficiently and supporting external manufacturing properly, based on risks and partner capabilities. Segmentations are beneficial for reducing the complexity of tailoring CMR management. However, segmentation is a complex process that requires a great understanding of the CMR's contribution to the business strategy. Furthermore, valuable information is often lost during segmentation. Therefore, defining meaningful Tailoring Criteria is the basis for customizing management to CMRs or segments.

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Key findings

- *Management must be tailored to the needs of CMRs, not CMRs to specific standards and segments.*
- *Establishing and exploring the right relationship criteria is the key to tailoring management to CMRs*
- *Tailoring criteria guide relationship managers to ask the right underlying questions regarding the CMR, rather than simply describing it*
- *Tailoring criteria highlight CMR characteristics that require specific management approaches and practices*
- *Tailoring criteria are unique to each company and reflect that company's supply and CMR strategies*
- *Scientific methods can support the development and evaluation of meaningful Tailoring Criteria for individual companies*

Success factors

- *Unique CMRs require individual tailoring! – No benchmarked segmentation or partnership definition can replace a self-developed approach. The success factor of tailored management is understanding one's own goals and transforming them into management practices.*
- *Segmentation is useful but has limits! – Segmentation supports efficient relationship management with limited resources by CMOs. However, segmentation is a gross simplification of reality and is of limited in its ability to develop individual relationships on its own.*
- *Does it serve the purpose? – Regarding tailoring criteria, quality trumps quantity. Regardless of formal or informal criteria, the underlying meaning needs to be understood (e.g., company size for the stability of the partner).*
- *Visualize it! -The human eye is far better at grasping and evaluating complex concepts such as tailoring CMR management through images than through text. Visualization furthermore drives transparency and can be discussed with the partner.*
- *Management grows with the relationship! - Management goals and requirements of CMRs change over time. Therefore, management tailoring should be performed regularly to align CMRs and their management.*

Practices for aligning Partners

Due to the scope and complexity, trust-based collaboration and self-control in CMRs can provide benefits compared to end-to-end control by the client. In order to align the partners within the joint relationship management, both parties must first clarify their goals and expectations for the collaboration beyond the contractually agreed issues. Next, the expectations must be shared and evaluated with the partner to incorporate reasonable expectations as joint goals in relationship management. Expectations can then be aligned, defined, and tracked with suitable management approaches. Since CMRs require trust-based collaboration and not all expectations can be fixed contractually, excellence in managing CMRs requires comprehensive expectation management.

The Concept of the Relationship Gap

Contracts are the basis for service provision in CMRs. However, despite their comprehensiveness, they cannot regulate all contingencies and soft factors of cooperation. In addition, the pharmaceutical industry is a highly regulated sector where the continuous extension of contracts can be a bureaucratic burden to flexible collaboration. Contracts, therefore, merely control the central cornerstones of cooperation and ensure a minimum level of collaboration and service provision acceptable to both sides. Since reliable self-governance and partner-oriented cooperation can only be demanded to a limited extent, aligning the partner's individual goals in a relationship is necessary.

However, the partners' objectives are frequently only insufficiently documented in the contract. Insufficient fixation of objectives is because achieving specific goals cannot be guaranteed, clashes with partners' interests, or does not need to be jointly pursued. However, as CMRs have outgrown purely cost-, quality-, and delivery-measurable goals, the expectation of achieving intangible goals influences the commitment and relationship management of CMRs. Expectations management is therefore paramount to align with the partner and direct all management efforts on valued-adding activities rather than partner control. Yet expectations are rarely openly communicated nor systematically managed. Thus, many CMRs experience a Relationship Gap between partners' desired and actual alignment, consistent with recent industry surveys on strategic partnerships (see BCG, 2018).

The Relationship Gap describes the discrepancy between partner expectations of collaboration and actual CMR outcomes. The more significant the Relationship Gap, the more dissatisfied the partner is with the collaboration, which affects CMR performance and stability. However, because expectations are rarely communicated transparently, clients and CMOs have little knowledge of each other's goals, how they are being met, or overall satisfaction.

In practice, Relationship Gaps are often bridged by personal relationships between individual employees at the company interfaces. These employees create transparency internally about the partner's goals and perceptions, act diplomatically and ensure that the partner's goals are taken into account. However, against the backdrop of personnel turnover and compliance regulations, bridging the Relationship Gap just through personal relationships is undesirable. Consequently, the basis of trust must be institutionalized, and the Relationship Gap closed at the corporate level.

The Relationship Gap can be divided into an Expectation and a Perception Gap, as Figure 12 shows. First, the Expectation Gap describes the difference between each side's expectations concerning business development and partner behavior. Second, the Perception Gap includes each side's perception of whether the CMR will fulfill mutually agreed objectives in the future. Differences in perceived CMR performance and partner behavior can then be openly discussed and targeted before the relationship deteriorates.

The Expectation Gap is future-oriented and aims to create transparency about possible relationship development paths. Complementary to this, the Perception Gap encompasses past and present relationship quality to identify and remedy problems. Consequently, the Relationship Gap can be systematically addressed as a management practice to align partners for excellent CMR management.

Closing the Expectation Gap

In order to close the Relationship Gap, partners should first share their expectations and agree on common tangible and intangible goals. Then, based on aligned expectations, either partner can respect the partner's interests in their actions and actively support them if possible. Furthermore, commitment to the aligned expectations should be regularly evaluated. However, since expectations are intangible reliable measurement is based on each partner's perceptions of how the relationship develops and whether partners are living up to their commitments.

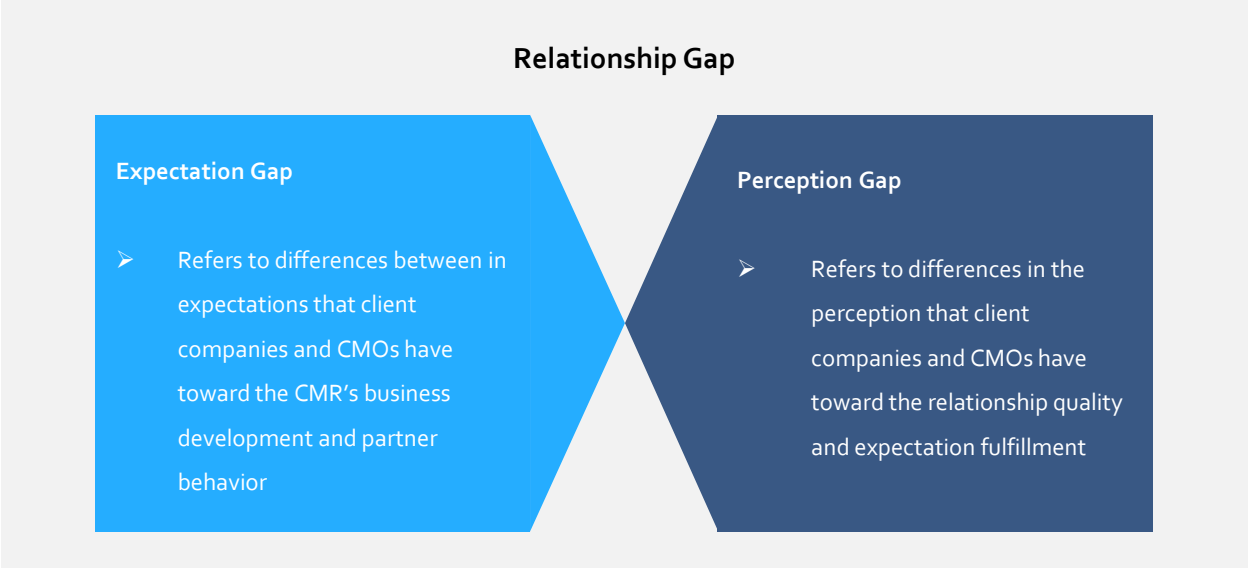

Figure 12: The Relationship Gap

The Expectation Gap encompasses partners' expectations of the business side of the CMR and partner behavior. Business expectations from the client's perspective may relate, for example, to planned sales volume development, technological improvements through the CMO's know-how, building a good reputation in new markets, or hedging against another CMO. However, the CMO could expect to take over additional production stages, products, or regional production responsibilities as the CMR progresses. In return, the CMO might be willing to accept lower compensation during bidding to win the contract. In extreme cases, either partner might have clearly defined entry and exit criteria based on cost and quality metrics or specific technology or market licenses. Consequently, failure to achieve uncommunicated business expectations not defined in the contract can severely limit the value a partner derives from the collaboration.

The partner expectations relate to concrete day-to-day collaboration. Consortium partners emphasize that strategic partnerships grow out of existing alliances and that cultural fit plays an important role. Consequently, risk-taking, innovation and knowledge management, communication behaviors, diligence, critical faculties, and transparency play a significant role in CMR development prospects.

Mismatched partner behavior expectations can be associated with lost business opportunities, distrust, and additional control efforts making the collaboration less valuable than initially expected.

Therefore, disclosing expectations is crucial to clarifying false hopes early and jointly working toward realizing realistic objectives. Closing the Expectation Gap can be supported through a systematic process conducted in a joint workshop between the client and CMO. An in-person workshop is explicitly recommended to facilitate open discussion and the mutually agreed list of common objectives. Figure 13 illustrates the process of assessing the Expectation Gap.

Figure 14 provides templates that can be used to structure the expectation workshop and document results. Both tables contain examples to illustrate their application. In the business expectation example, a CMO strives to take over manufacturing the same product in another region within the next decade. The CMO also states that this expectation is a primary reason for the collaboration. The client knows the CMO's intentions and can assess the likelihood, provide feedback, and support or reject the expectation. As a result, the expectation is documented in the goal list and follow-up actions.

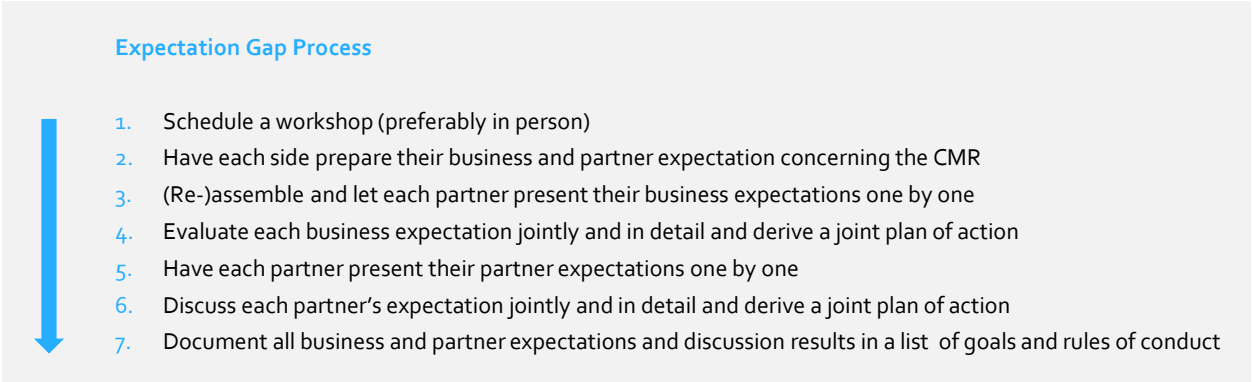

Figure 13: The Expectation Gap Scan

Business expectations					Action plan	
Partner	**Business expectations**	**Expected time frame**	**Probability estimation**	**Signification statement**	**Joint evaluation**	**Comments**
CMO	*Take over production responsibility for APAC*	*Eight years*	*Likely*	*Considerable significance for development plan*	*Possible, the client plans new biding*	*The client will inform the CMO over bidding personally*
…	*…*	*…*	*…*	*…*	*…*	*…*

Partner expectations			Action plan
Partner	**Partner behavior expectation**	**Partner's statement**	**Comments**
Client	*Permanent access to manufacturing line to monitor new technology*	*Reject, no access due to third party contractual obligations*	*The CMO will provide the client with additional process data*
…	*…*	*…*	*…*

Figure 14: Templates to guide Expectation Gap workshops

For example, because a contract product is highly innovative, the customer might expect the CMO to provide easy access to the production line to observe the manufacturing process and monitor specific metrics. However, the CMO might not be able to meet these expectations due to contractual obligations with other customers at the same site. In the context of the workshop, alternatives could now be found together. For example, the CMO could compile and provide specific additional data for the client. As a result of the Expectation Gap workshop, both partners have a clear overview of the business development potential and limitations of the CMRs. The target list can serve as a firm agreement on specific development directions and guide concrete actions in relationship management.

Monitoring the Perception Gap

However, strategic alignment is ineffective if it is not adequately implemented. The study partners stress the necessity of acting on behavioral promises and implementing them across interfaces and relationship cycles. Client companies and CMOs find that commitment is high during onboarding and relationship expansion but decreases with rising routine streamlining efforts consciously or subconsciously. Therefore, closing the Relationship Gap requires regular assessment of whether aligned goals that are not part of the commercial agreement are realized.

Yet, achieving intangible goals such as transparency, communication, fairness, or performance readiness is challenging to verify. Such relationship goals cannot be objectively measured compared to KPIs. Nevertheless, partners' perceptions of the intangible aspects of CMR play a critical role in partner alignment and satisfactory collaboration. Individual perceptions may be unpopular as a basis for decision-making because they are subjective. Still, they are a powerful tool for alignment. People ultimately drive the course of CMR. While objective metrics support decision-making, perceptions, experience, and subjective evaluations influence decisions and behavior at a subconscious level. For example, discrepancies in perceptions of collaboration between partners may indicate hidden disagreements and misalignments that can lead to performance degradation or CMR failure.

An example of such a Perception Gap is the degree to which the client dictates the process. For example, clients often pursue well-intentioned

internal goals of managing external manufacturing as an extension of internal operations. Client companies perceive this practice as a sign of appreciation, establishing CMRs on equal footing next to internal manufacturing. Managing CMRs as extensions of the organization involves rolling out standards and management programs as specifications for the CMO. However, CMOs may perceive this practice as a sign of distrust and interference with entrepreneurial freedom, limiting their flexibility and innovativeness of service provision.

Therefore, the study proposes regularly assessing how both partners perceive particular aspects of the collaboration and comparing perceptions. Since perceptions are subjective, comparing the perception values will spark a debate about whether each partner's scores are justified. The solution to closing the Perception Gaps is grounded in the emerging discussion. It requires listening to and understanding the partner's perspective and jointly evaluating possible actions. In this way, both partners can determine whether the strategic alignment is only on paper or actively pursued by the partners and act accordingly. Figure 15 presents the process for conducting the Perception Gap Scan.

The selected relationship health KPIs should be ambiguous to include different intangible but relevant topics in the discussion. Consortium partners emphasized that misunderstandings about the exact content of relationship health KPIs are beneficial because they promote dialogue. Therefore, the study proposes five broad metrics that cover various intangible aspects of CMR management. In practice, an adjustment or addition is recommended based on the list of specific goals and rules of conduct from the Expectation Gap Scan. For example, if both partners agree to share market knowledge about specialized fields or geopgraphies in which they have particular expertise. In this case, knowledge sharing could be a valuable metric. The five suggested relationship health KPIs are briefly explained below.

1. *Management practice effectiveness* rates the strength of organizational coordination and the usefulness and appropriateness of the established management routines
2. *Communication* addressed the openness of communication and the effectiveness of communication routines
3. *Relationship growth potential* reviews the CMR's future business prospects, including the likelihood of fulfillment of aligned business expectations
4. *Collaboration quality* assesses the trustful interaction across interfaces, the perceived fairness, and the adherence to rules of conduct
5. *Economic satisfaction* relates to the CMR's profitability for the partners and the exploitation of business opportunities

Perception Gap Process

1. Define relationship KPIs tailored to the CMRs needs and partner's expectations
2. Establish a scoring system (e.g., 1 point = low / bad, 10 points = high / good)
3. Have each side fill in their perceptive scores of the relationship health KPI
4. Calculate the perception gap as the difference between each partner's scores
5. Discuss the perception gaps jointly with the partner and document the reasons for deviations
6. Decide on further actions and document the discussion results
7. Update the expectation gap's list of goals and rules of conduct

Figure 15: The Perception Gap Scan

The deliberate room for interpretation in the presented relationship KPIs makes it likely that both partners provide different perception scores. If these scores cannot be balanced in the discussion, a Perception Gap exists in the CMR. Perception Gaps signal the need for action and must be clarified. Since evident managerial problems can be jointly addressed in the CMR, Perception Gaps are more critical. Figure 16 provides a template for documenting the Perception Gap Scan and an example for illustration.

For instance, if both partners agree that the communication is ineffective, they will look into ways of improvement. Let's assume that the client estimates the returns of a niche product to be very satisfactory from an economic point of view. At the same time, however, the CMO achieves only mediocre utilization and profitability due to a lack of growth in production volume. In this case, the CMO might decide to raise prices significantly at the next negotiation or not renew the contract and move on to other customers. The Perception Gap Scan can help to uncover such discrepancies early on by continuously reconciling perceived profitability. Subsequently, joint discussions on mitigating measures such as renegotiation or product bundling can be encouraged.

The key to closing the Relationship Gap is to be forced to write down and openly discuss expectations and perceptions that are intangible or taken for granted. In practice, such discussions often lead to surprising results. For example, the discussion on the relationship gap with consortium partners revealed different perspectives regarding implementing the process through questionnaires. On the one hand, client companies supported the possibility of streamlining the assessment to apply it across the board. On the other hand, CMOs emphasized the one-sidedness of questionnaires and the need for open discussion. Thus, a Perception Gap between client companies and CMOs was uncovered.

Applying the Relationship Gap Scan

Applying the Relationship Gap Scan to all CMRs consumes management resources. Therefore, its implementation should be tailored to the relationship. Figure 17 presents design options for the Relationship Gap implementation to adjust the practice to specific partnerships and Relationship Strategy Cycles. These design options are valid for implementing both the Expectation and Perception Gap Scans.

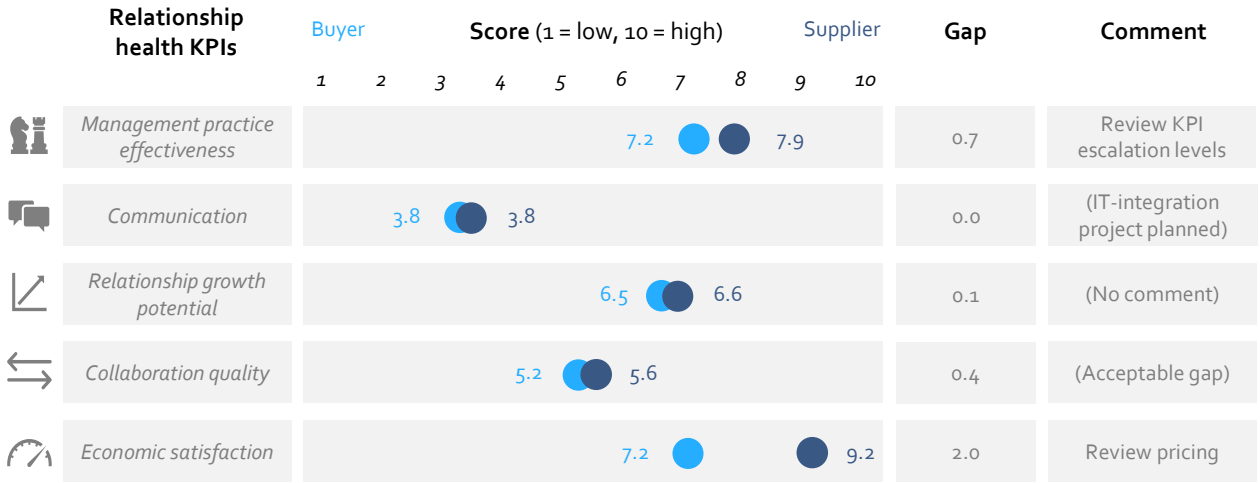

Figure 16: Template for a Perception Gap dashboard

The *frequency* of the assessment can be based on the CMR's strategic relevance and the Relationship Strategy Cycle. The more integrated or new a CMR, the more critical active partner alignment. For example, an Expectation Gap assessment can be conducted yearly since strategies take time to adjust. In contrast, Perception Gap discussions can be integrated into quarterly reviews. It is recommended to allow time between assessments, as the Perception Gap is fed by perceptions whose judgment takes time to manifest.

The *procedure* should be adapted according to the CMR's scope. For example, a decentralized preparation of internal expectations and perceptions with subsequent integration of results is appropriate in large organizations or decentral locations. However, a discussion of the Expectation and Perception Gaps should be conducted with the partner comprehensively.

The *medium* should allow for open discussion. In-person workshops are both the most promising and the most resource-consuming choice. Remote workshops and video calls can ease budget and time constraints. However, personal interaction is strongly recommended for open and sincere exchange. Despite the disadvantages described, questionnaires are a viable option to capture expectations and perceptions within the company in preparation for discussion with the partner.

The selection of *participants* should consider all relevant stakeholders, practical feasibility, and the occasion. In the Onboarding and Expansion Cycles, a broad group of participants is beneficial to support team building. A selected group of functional representatives, relationship managers, and executives are sufficient for a regular Relationship Gap Scan. In order to facilitate trust building, the group should remain staffed with permanent individuals. The choice of hierarchical levels involved should always be considered a subtle statement of the participant's esteem.

Location of in-person assessments are opportunities to familiarize themselves with the partner's organization and business. The location choice can therefore be actively designed for teambuilding and organizational exchange. Furthermore, a neutral location can be chosen if it is most practicable or if the relationship is strained.

Finally, *moderation* of the workshop and process can be designed to engage the partner actively. Moderations do not necessarily need to lie with the partner who introduces the practice but can alternate between partners or a neutral moderator.

Category	**Design option**			
Frequency	*Quarterly*	*Bi-annually*	*Annually*	*Needs-based*
Procedure	*Decentral*		*Integrated*	
Medium	*Questionnaire*	*Video call*	*In-person workshop*	
Participants	*Strategic apex*	*Process owner*	*Operating core*	
Location	*Client site*	*CMO site*	*Neutral location*	
Moderation	*Client*	*CMO*	*Neutral moderation*	

Figure 17: Design options for implementing the Relationship Gap Scan

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Key findings

- *Satisfactory CMRs have an alignment beyond contractual obligations to achieve flexibility, reduce oversight effort and create additional value*
- *Clients and CMOs often have unspoken expectations of the relationship and partner that influence their perceptions of CMR success*
- *Clients and CMOs often have different perceptions of behavior and management practices that can damage the relationship of trust if left unspoken*
- *The Relationship Gap between partners can be overcome by aligning expectations and perceptions through targeted discussion as part of a management routine*

Success factors

- *Give your partner a voice! - Transform the CMR from a service into a partnership by jointly managing the relationship through shared goal setting, KPI monitoring, and communication facilitation.*
- *Be a good relationship ambassador! - A partnership means representing the partners' interests within the organization (e.g., toward less involved functions such as compliance, legal, and finance). Make sure that all interfaces are aligned and avoid contradictions.*
- *Expectation management is vital! - Make an effort to understand the partner's business model, expectations, challenges, and exit criteria as part of your relationship management approach. Even if the partner is not cooperative, you will gain valuable insights into the nature of the CMR.*
- *Define the CMR's creative scope! - Innovation is desired, but partners' ideas about which changes are beneficial and which are not are often unspoken and contradictory. Clarify your understanding of innovation to channel creativity and resources.*
- *Take your partner's point of view! - Management practice benefits and efforts are often out of proportion: questionnaires create one-sided transparency, bundling can fail to deliver economies of scale, and process specification can conflict with the partner's value proposition.*
- *Simplicity is the key! - Efficiency is useless without effectiveness. Open, personal communication is more effective than excessive standardized information gathering (open workshop vs. detailed questionnaire, five key questions vs. 28 topics).*
- *Acknowledge structural complexity! - Regulation of the pharmaceutical industry leads to strong background complexity. Instead of adding new rules, ask: What can we leave out? What can we challenge? What really adds value?*

Achieving Excellence in Management of CMRs

The previous chapters reveal how practitioners can focus on critical goals and challenges, allocate resources, and align partners in CMR management. However, to achieve excellence in CMR management, it is necessary to apply the proposed management practices comprehensively in the identified action areas. Therefore, this chapter integrates the previously presented findings into two interlocking strategic and tactical management Cycles.

Managing CMRs is characterized by long-term strategic goals and return on investments. At the same time, the relationship's scope, operational complexity, and dynamics intensify management needs in day-to-day operations. Relationship intensity is the source for the three fields of achieving excellence in CMR management - *developing*, *tailoring*, and *aligning* CMRs.

Interlocking strategic and operational management cycles

Targeted CMR development is critical to capitalizing on business opportunities. Therefore, companies should address it explicitly and should not be marginalized by operational issues. At this point, the concept of the Relationship Strategy Cycles can provide benefits to CMR management. First, binding Strategy Cycles should be established and followed. The temporal separation in Strategy Cycles allowed a close pursuit of relationship goals and focused, lean use of management resources. Like project management, cycle goals are monitored and managed across the board, much like milestones. This strategic frame guards against losing control over long-term goals and the degradation of management attention and partner alignment. Strategic positioning and evaluation of cycle goals, contingencies, and development paths should be conducted yearly.

Within the underlying Strategy Cycle, CMR management should be tailored to the relationship based on the cycle's goals and characteristics. Once the management approach to the CMR has been drafted, the Expectation Gap Scan should take place to align partners on business and behavioral expectations. The assessment of the Expectation Gap is an excellent opportunity to discuss the outlined management approach and receive feedback from the partner.

On the one hand, the principal can reconsider and adjust the management approach to best benefit the relationship. On the other hand, the partner can better understand the motivation concerning specific practices, such as qualification programs, and prepare for joint implementation. Such an approach can foster partner alignment since it emphasizes the collaborative management of the relationship over the client's need to control the CMO. In order to continuously adapt the management approach to the relationship, streamline excess practices, and to further develop successful ones, a regular adjustment of the segmentation is recommended. The symbiosis with the Expectation Gap Scan can be exploited if the tailoring of CMR management and Expectation Gap Scan are performed annually after the Strategy Cycle assessment.

Lastly, whether a Perception Gap exists should be checked up to multiple times within a year, depending on the type of relationship. Again, a regular assessment and discussion with the partner make it possible to align the strategic goals and management approach to changes early.

Success factors of excellent CMR management

Excellence in CMR management can be achieved by systematically addressing the three core complexity drivers of relationship dynamics, partner alignment, and relationship oversight. Consequently, in pursuing excellent CMR management, the study suggests a four-step yearly management process embedded in overarching Relationship Strategy Cycles. The resulting «artifact» in the language of the chosen DSR methodology should serve as a management frame to structure CMR management activities. In addition, the artifact solution explicitly addresses the action fields of systematically developing, tailoring, and aligning CMRs.

Finally, the customization framework can be broken down to incorporate other legislative, commercial, and operational management activities and milestones into the cycle perspective. Figure 18 provides an overview of the interlocking cycles and developed practices for excellent CMR management.

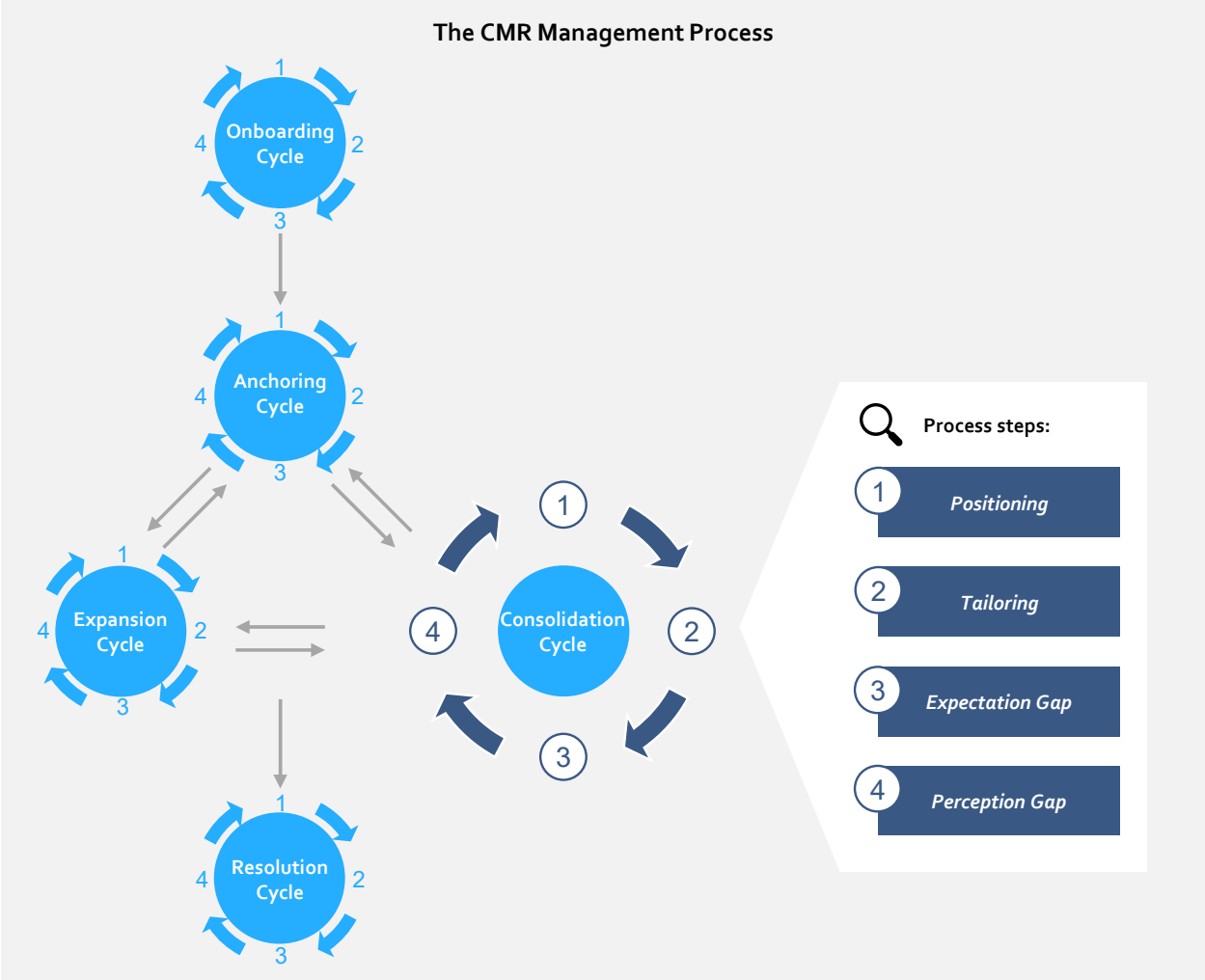

Figure 18: The CMR Management Process

Info Page

Key findings

- *CMR management comprises strategic and operational management cycles that are interlocked*
- *The interlocking of CMR management cycles provides a frame of reference for management decisions and feedback loops to continuously align the relationship and its management*
- *Continuously reviewing your own goals and their fit with your partner's expectations provides the framework for excellent CMR management*

Success factors

- *No partnership without top management support!* – Top management must lead the way in CMR management by driving a unified vision across internal interfaces and creating scope for flexible cooperation outside existing standards.
- *Don't tap into the strategy trap!* – *CMR strategies often fail because they are not implemented properly. Instead of formulating new strategies, make an effort to monitor, review and adjust the implementation of the strategy in discussion with your partner.*
- *Don't let today spoil tomorrow!* – *Since operational issues crowd out joint future planning in strategic meetings, strictly separate strategic planning from operational issues. Instead, set clear agendas and escalation levels and stick to them.*
- *Partnership goes beyond the business relationship!* - Issues not covered by the contract will inevitably arise in CMRs. Therefore, personal relationships are critical for genuine problem-solving efforts and transparency to collaborate outside of the contract.

Conclusion

Managerial Implications

Through close collaboration with renowned industry partners, the study sheds light on the primary challenges of CMR management and presents tangible practices for overcoming them. The alignment of partners is considered the most crucial success factor of excellent CMR management by client companies and CMOs. Furthermore, through the introduction of the Relationship Gap, the study encourages practitioners to develop systematic approaches to develop CMRs beyond contractual obligations.

Meaningful partnership definitions and segmentations are ongoing topics in CMR management. Due to the relationship intensity, practitioners must prioritize CMRs to deploy management resources and practices as required. The balance between informative value and simplicity of segmentations is not always given, especially in adopting good practices, which is why customized approaches based on a profound understanding of the contract manufacturing strategy are recommended. Thus, the study presents a methodologically supported approach that enables practitioners to develop and test meaningful segmentations individually.

Finally, the duration and dynamics of the relationship make CMRs prone to social fatigue as management attention is replaced by routine. As a result, CMRs are gradually shifting from active development to more reactive collaboration stewardship. To exploit business opportunities and strengthen partner alignment, the study emphasizes dividing the partnership into Relationship Strategy Cycles and reassessing the status regularly.

Limitations and Future Research Directions

The study serves as an exploratory investigation of selected topics decided upon by the research consortium. Contract manufacturing business models and relationships in the pharmaceutical industry are diverse and constantly changing. Therefore, the study deliberately simplifies the formulation of its results as not all eventualities can be covered. Thus, implementing the proposed practices requires adaptations to specific management needs and structures. In addition, the study looks at the management of CMRs from a supply chain management perspective. As a result, the technical, quality and legal constraints of the pharmaceutical industry are acknowledged but not considered in detail.

This study is intended as an exploratory look into CMR management from a supply chain management perspective. However, in addition to the study results presented, further research directions arise with the progressive development of pharmaceutical contract manufacturing. First, the question regarding the organizational anchoring of CMR management in partnering companies emerges. The dynamic alignment of management along the Relationship Strategy Cycles also raises the question of adapting organizational structures and resource allocation, for example, through temporary project organizations. With increasingly volatile supply chains, contract manufacturers and CMOs furthermore face the challenge of integrating their information sources into a collaborative forecasting, sales, and operations planning process. Consequently, CMR management remains a promising field for researchers and practitioners to develop management practices.

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Appendix

Further reading:

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