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Research Paper
R&D Spin-outs in the Pharmaceutical Industry

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The high number of research and development (R&D) spin-outs in the pharmaceutical industry during the last 10 years focusing on drug development or offering specialised services demonstrates that pharmaceutical companies believe, through doing this, they can improve R&D performance. In a study, 43 European drug development as well as service oriented R&D spin-outs were analysed with regard to background, impact, realisation and the underlying strategy of the pharmaceutical parent companies. Spin-out creation can help to refocus the company strategy. Following a merger or simply complementing a strategic realignment on core areas, spin-outs provide a valuable option to leverage assets of low strategic importance, or under-exploited assets in their parent companies. Key aspects are strengthening the entrepreneurial spirit, a clear focus on core activities, performance-oriented controlling through cash-driven key indicators, high identification with the company, and appropriate financial incentives for management and staff.

1. Introduction

Global competitiveness is becoming increasingly important to the pharmaceutical industry. Pharmaceutical companies are exploring options to enhance the efficiency of the resources they are using at all stages of the value chain, from discovery research to production and logistics as well as sales and marketing. Especially the expiration of a high number of their blockbuster patents, the high failure rate of new drugs or active pharmaceutical ingredients (Findlay, 2007), and the rising costs of pharmaceutical R&D have led to a growing pressure to refocus on core activities to increase the output together with the realisation of cost saving potentials (Parhankangas and Arenius, 2003). Furthermore, literature on the impact of size on R&D productivity has not been conclusive and the convincing evidence that inventiveness improves within an ever-increasing size of R&D infrastructure is lacking for the pharmaceutical industry (Dewdney and Smith, 1998). In that context, pharmaceutical companies are increasingly considering the divestment of non-core activities in order to concentrate management attention as well as financial and other resources on focus areas. Furthermore, companies are increasingly recognising that some operations can be performed more effectively by a third party, for example, on a superior scale, with lower costs or through direct access to proprietary know-how. An alternative strategy to the specialist group in-house is to introduce business flexibility in the organisational structure.

On the other hand, spinning out non-core activities towards new ventures also increases coordination costs (Clarysse et al., 2005) and potentially hampers spillover effects and destroys potential benefits of mutually reinforcing activities (Audretsch and Lehmann, 2005; Lockett et al., 2005). Furthermore, the new venture spun out from the parent organisation might, over time, could potentially develop into a new competitor for the parent organisation (Steffensen et al., 2000).

The pressure to reassess their mode of R&D operation has fostered the spin-out of activities within pharmaceutical companies - as part of the notion of corporate entrepreneurship (Sharma and Chrisman, 1999). As Chemmanur and Yan (2004) indicated, companies in rapidly changing industries are more likely to spin-out divisions. As a result, the number of corporate R&D spin-outs in the pharmaceutical industry has increased significantly during the last years (Chemmanur and Yan, 2004). The common definition of spin-out is when a part

(department, business unit division or even a project team) of a company or organisation becomes an independent business (De Cleyn and Braet, 2009). The spin-out company takes personnel, assets, intellectual property, technology, and/or existing products from the parent organisation. In many cases the management team of the new company originates from the same parent organisation. In contrast to the term R&D spin-out, an R&D spin-off is a new company based on the findings of a research group from academia (De Cleyn and Braet, 2009; Mustar et al., 2006). But the two terms are not always used unambiguously, as sometimes the term corporate spin-off is used instead of spin-out or spin-off is used for a small company which has been split-off from a larger, parent organisation (De Cleyn and Braet, 2009; Mustar et al., 2006).

This paper describes how R&D spin-outs can support drug discovery and development strategies of pharmaceutical companies by creating flexible R&D resources and structures. In a first effort, interviews were conducted with managers and experts of 19 different pharmaceutical companies and 12 pharmaceutical service providers. Subsequently, 43 European spin-outs of pharmaceutical companies were analysed using empirical data and case studies obtained from desk research, and detailed interviews with R&D managers of 11 of these R&D spin-outs.

The aim of the paper is twofold: [1] adopting a more conceptual or theoretical perspective, it aims at discussing the pros and cons of spin-out ventures from both the viewpoint of spin-out management (the entrepreneurs) and parent company and [2] it intends to provide empirical evidence from the specific situation of the pharmaceutical industry to support these conceptual arguments by using interviews and illustrative case studies. At a more detailed level, this paper addresses the following research questions:

1. What are the main conceptual arguments to (dis)favour the use of spin-outs, from both the spin-out's and the parent organisation's perspective and to what extent are the arguments valid according to the empirical evidence?

2. Do spin-outs increase R&D performance and flexibility in the pharmaceutical industry?

3. What are best practicescritical issues for stakeholders in the spin-out process that can be identified from the empirical evidence?

This paper will firstly discuss the theoretical background on the use of R&D spin-out ventures. The paper will then present the methodology applied to obtain a better insight of the use of R&D spin-outs in the pharmaceutical industry, and look at the reasons for and effects of R&D spin-outs from the parent company's point of view. Furthermore, the paper will outline critical issues and for the realisation of a spin-out (conceptual design of R&D spin-outs) and how they could be handled. The paper closes with two case studies as illustrative example and a discussion of the implications and conclusions.

2. Theoretical Background

There are various reasons for realising a R&D spin-out. This section provides conceptual arguments (both potential benefits and downsides) of R&D spin-outs, while empirical evidence with regard to these arguments will be discussed in the results' section. In the case of redundant capacities or non-core activities (e.g. after a merger of two pharmaceutical companies), a spin-out can be used to reduce costs as an alternative to closing or selling the unit (Bergh and Lim, 2008; Chemmanur and Yan, 2004; Parhankangas and Arenius, 2003). Another reason could be the reduction of capital requirements and risk, if R&D projects are not in the strategic focus of a pharmaceutical company (Chemmanur and Yan, 2004).

But spin-outs can also be used from a strategic point of view as a method to make R&D more flexible for increased effectiveness and efficiency (Krishnaswami and Subramaniam, 1999). There are often innovation hurdles in companies with established structures, like bureaucratic thinking, fear of cannibalism or the well-known 'not invented here' syndrome. R&D spin-outs can overcome these hurdles through their different cultures (Bergh and Lim, 2008; Jagersma and van Gorp, 2003; Parhankangas and Arenius, 2003). All the energy of the new spin-out's management team can be put into the commercialisation of the R&D activities. R&D spin-outs can more easily pick up external impulses and serve as a mechanism to explore revolutionary ideas in a setting apart from mainstream business (Jagersma and van Gorp, 2003; Parhankangas and Arenius, 2003). For example, competencies from other companies or top-class scientists from universities and public research agencies can be brought together to form excellent teams. Spin-outs can also be beneficial from the spin-out's management team's view, given the increased potential to develop a profitable business model (more or less) independently from the parent organisation. This can be done by expanding the customer base substantially to other companies and bringing the development of the technologies

and accompanying services further in the development than would have been the case in an internal project within the parent organisation. Furthermore, the spin-outs (top management) team may have stronger incentives to make the spin-out project successful and benefit from potential upsides. Besides spin-outs focussing on drug discovery and development, there is a second group of spin-outs offering specialised services (e.g. for drug discovery services like lead optimisation, toxicology or analytics, or drug development services like clinical studies or formulation services). They are often outsourcing partners for established pharmaceutical companies. Outsourcing in pharmaceutical R&D requires specialised businesses that understand the strict regulatory barriers and high risk associated with the development lifecycle (Clark and Newton, 2004; Findlay, 2007; Van Arnum, 2008). Therefore, understanding outsourcing mechanisms in the pharmaceutical industry is important for the analysis of the spinning out of service based activities.

This is especially true, if outsourcing is used to strengthen internal competencies by combining internal know-how development and external sourcing (Veugelers and Cassiman, 1999). There are good arguments to stress the complementarity between in-house R&D and external know-how (Arora and Gambardella, 1994; Cockburn and Henderson, 1998; Cassiman and Veugelers, 2002). For example, Arora and Gambardella (1990) examined the complementarity among external sourcing strategies of large firms in the biotechnology industry. At the same time the access to external know-how may leverage the productivity of the internal R&D activities, at least when the organisation exhibits a willingness to take on external ideas (Veugelers, 1997). An important task in innovation management, therefore, is to optimally integrate internal and external knowledge within the innovation process, to be able to benefit from the positive effects each activity has on the other.

Besides these potential benefits for both entities (parent and spin-out), some downsides may appear as well. Spinning out non-core activities towards new ventures bears the risk of increased coordination costs, as the spin-out now serves other interests than an internal project would do (it is no longer a 'cost centre', but should be profitable as any other business) (Clarysse et al., 2005). Furthermore, the independent trajectory of the spin-out potentially hampers spillover effects and destroys potential benefits of mutually reinforcing activities (Audretsch and Lehmann, 2005; Lockett et al., 2005). For the spin-out team, the new project bears the risks associated to any other new entrepreneurial initiative. The 'certainties' and benefits associated to working for a large company might be diluted (temporarily). Lastly, a strategic risk for the parent organisation emerges: the new spin-out might over a longer term potentially develop into a new competitor for the parent organisation (Steffensen et al., 2000).

3. Methodological aspects

The empirical data and case examples were obtained during two independent investigations. In a first investigation between 2002 and 2005, in order to gain a better insight into outsourcing activities within the pharmaceutical industry, interviews were conducted with managers and experts of 19 different pharmaceutical companies and 12 pharmaceutical service providers. Some of these companies had also been independently interviewed within the second investigation, which was performed between 2004 and 2008 (first round in 2004 and second round including the companies from round 1 in 2008). Here, 43 European R&D spin-outs from different European countries (Austria (3), Belgium (1), Denmark (1), France (4), Germany (14), Italy (6), Spain (1), Sweden (2), Switzerland (7) and U.K. (4)) were analysed through desk research, and R&D managers from 11 of these spin-outs were interviewed (between 2004 and 2005).

Each company was interviewed in one or two sittings of approximately one hour each. A reference set of questions was developed as a guideline for the interview, thereby leaving enough room for spontaneous answers, which gave a semi-structured nature to the interviews. Before each interview, the authors had gathered in-depth information on the company through various public sources (e.g. juridical databases) and company disclosures (website, press releases etc.), enabling an efficient conducting of the interviews. Afterwards, the same information sources were used for reasons of data-triangulation (Eisenhardt, 1989).

Based on the desk research and interview data, analyses were conducted which are presented and discussed in the following sections. First, for each of the spin-outs, some basic information was collected (year of founding, tpye of parent company, development of the spin-out from foundation to 2008, development of the number of employees form foundation to 2008, position in the pharmaceutical value chain).

Important is the separate evaluation of drug development spin-outs and service oriented spin-outs. To assign spin-outs to one of both groups, the business model and end products were analysed: the first group discovers, develops and commercialises new drugs, whereas the second group acts as service provider for the pharmaceutical

Figure 1 Year of founding the spin-outs.

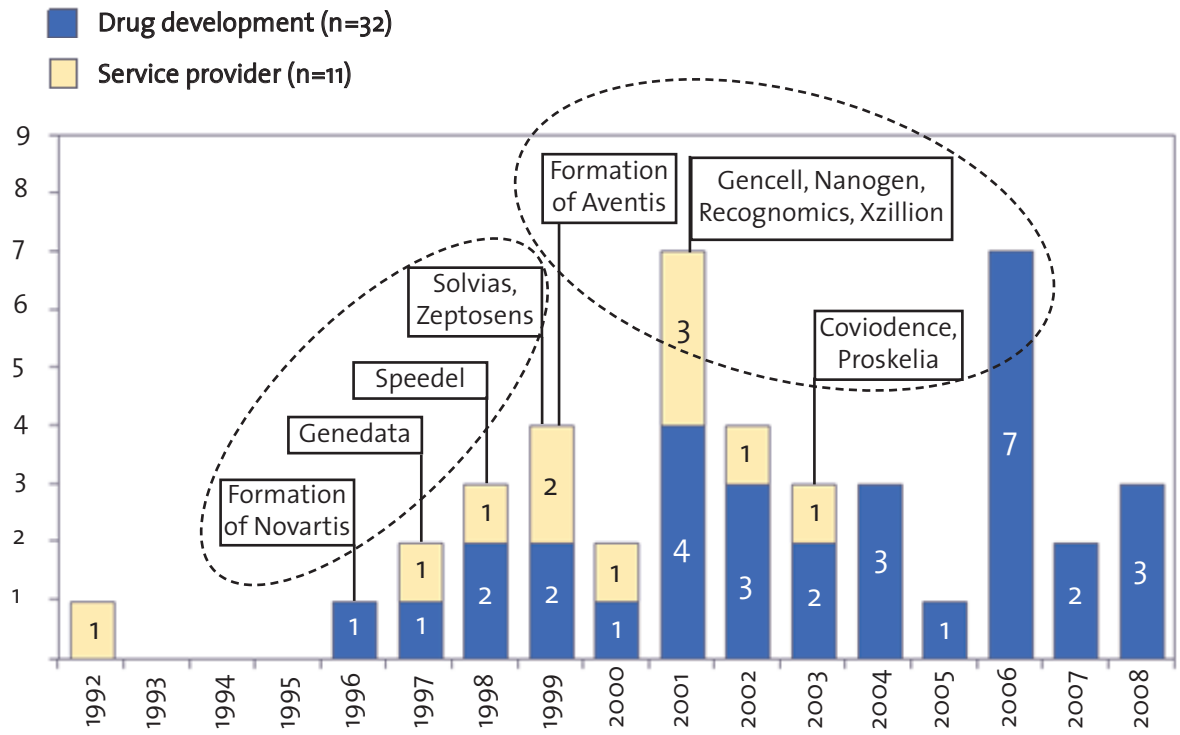


Table 1 Relevance and weighting factors for the analysis of the spin-out reasons.

Dimensions	Criteria	Relevance for		Weighting factors	
		Drug development	Service provider	Drug development	Service provider
Costs	Less overhead costs	+	++	8%	12%
	Less personnel cots		+	0%	8%
	Better economies of scale		++	0%	12%
	Better economies of scope	+	++	8%	12%
Risks	Lover investment risk	+	+	8%	8%
	Lower risk of losing focus	++	+	12%	8%
	Lower risk for other activities	++		12%	0%
	Lower risk for image	+		8%	0%
Performance	Higher committment of people	+	+	8%	8%
	Clear strategy and targets	++	++	12%	12%
	More flexibility	++	++	12%	12%
	Better co-operation possibilities	++	+	12%	8%
				100%	100%

and biotech industry (including the development of new technologies and tools to offer their services).

To understand the reasons and success factors of R&D spin-outs a standardised questionnaire was used during the interviews within the first investigation. This questionnaire included nine questions each for reasons and success factors, which could be answered on a Likert scale from 1 to 4 (impact: 1 = not true, 4 = true; success factors: 1 = not important, 4 = important). The answers were evaluated separately for drug development and service spin-outs. Two further answers were collected from each interviewee: one answer as spin-out and one reflecting the perceived answer of the parent company.

Within the interviews the questions regarding the reasons to spin-out activities were answered with general answers like "lower costs", "more flexibility" or "better quality". Therefore, a comparable analysis of the different spin-outs was not possible. For a better understanding of the reasons for the spin-outs, an evaluation model to identify and quantify underlying reasons was developed based on the interview results. Within each of the three dimensions, costs, risks and performance, four main drivers were identified. For each driver, the relevance for a drug development and a service provider spin-out was assumed and correlating weighting factors defined (Table 1): high relevance + gave the weighting factor 8% and very high relevance ++ the weighting factor 12%, so that with 5 +'s and 5 ++'s, the weighting factor, in total, is 100% in both cases. A score between 1 and 5 was assigned for each spin-out based on the interview results and desk research (1 = very low, 2 = low, 3 = medium, 4 = high, 5 = very high) and a total score for each dimension calculated. This gave a typical value for each business model along the three dimensions, costs, risks and performance.

3. Results of the analysis and interviews

Background information regarding the R&D spin-outs and their parents

First spin-out within our analysis was Focus Clinical Drug Development, which was founded in 1992 (Figure 1). The highest spin-out activity was in 2001 and 2006 with six spin-outs respectively. Analysing the examples of Novartis and Aventis, spin-outs occur two and three years after mergers and acquisition (M&A) activities of large pharmaceutical companies.

- Novartis was the result of the merger of Ciba-Geigy and Sandoz in 1996. After spinning-out Gendata in 1996, Speedel followed in 1998 and then Solvias and Zeptosens in 1999.

Figure 2 Type of parent company.

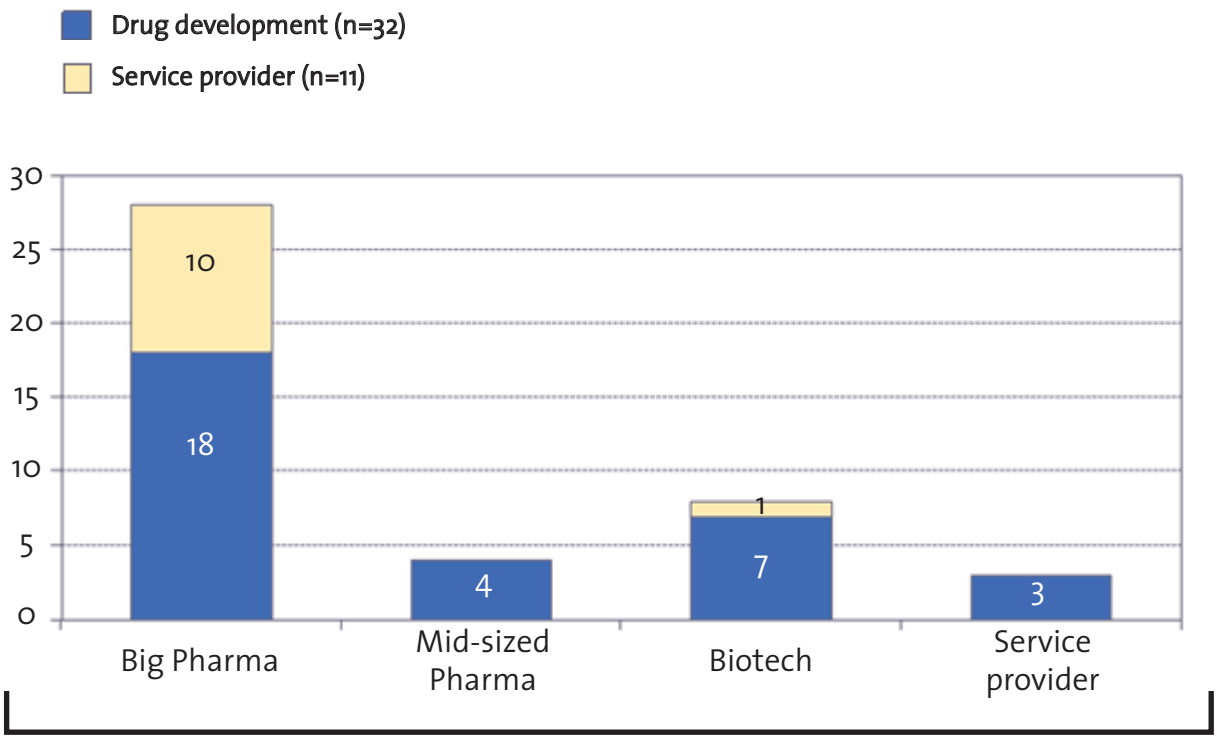


Figure 3 Development of the company from foundation to 2008.

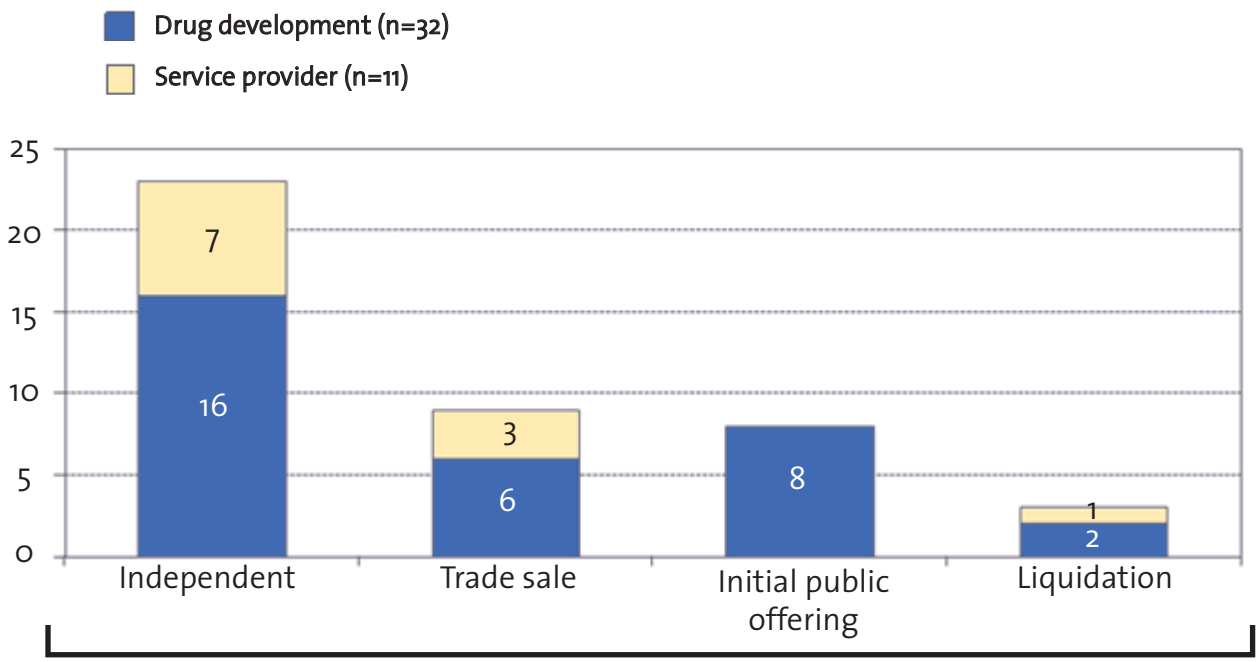
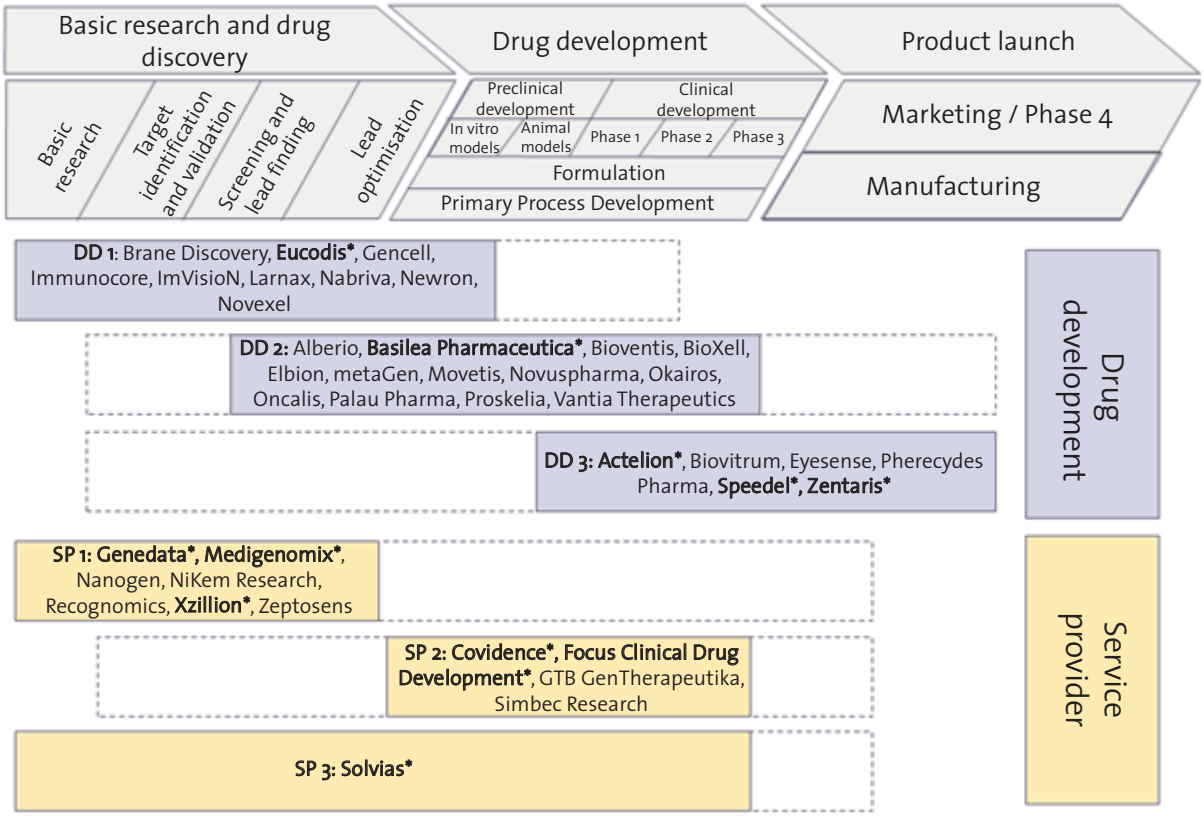
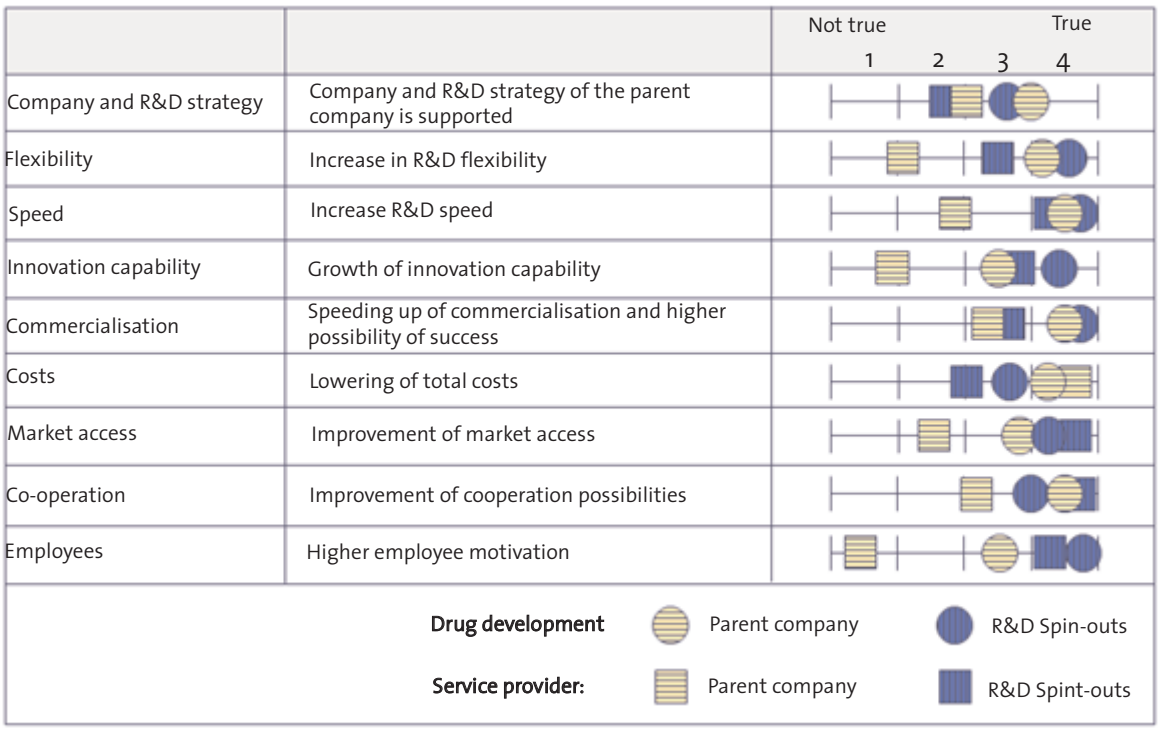


Figure 4 Positioning in the pharmaceutical value chain.



* = interviewed in data collection effort 2

Figure5 Interview answers regarding reasons for and effects of R&D spin-outs.



- Aventis was formed in 1999 as a merger of Hoechst and Rhone Poulenc. The first spin-outs were Gencell, Nanogen Recognomics and Xzillion in 2001 and then Covidence and Proskelia in 2002.

Most of these spin-outs were service providers and this could be an indication that the major intention was to reduce overcapacities after the M&A transaction. But there are also examples where spin-out activities are not the result of M&A activities, like the Roche spin-outs Actelion (1997), Novuspharma (1999), Basilea Pharmaceutica (2000) and BioXell (2002).

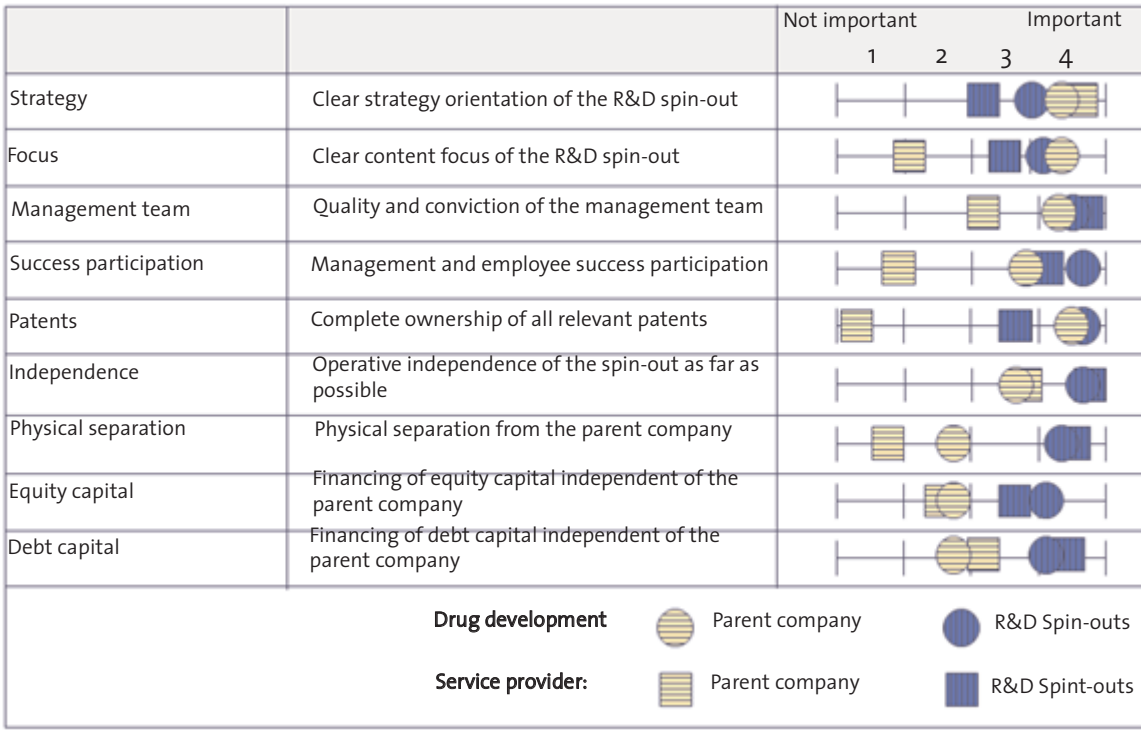
Parent companies are large pharmaceutical companies ("big pharma"), mid-sized pharmaceutical companies, biotech companies and pharmaceutical service providers. The phrase "big pharma" is often used to refer to companies with revenue in excess of US$ 3 billion, and/or R&D expenditure in excess of US$ 500 million. Smaller companies are categorised as mid-size pharma. With regard to the type of parent company, most of the spin-outs and almost all service providers came from "big pharma" (Figure 2) and only a few from the other types of parent company.

Analysing the development of the company from foundation up to 2008 shows that more than 50% of the spin-outs are still independent (Figure 3). Nearly one quarter had been sold to a new owner and one fifth (only drug development spin-outs) had gone public via an initial public offering (IPO). Only two companies no longer exist. Therefore, the survival rate is rather high. Reasons are the high qualification of the employees (especially of the management) in the sense of higher practical experience in the relevant industry and assets from the parent company, patents or laboratories, reducing the capital requirements significantly. Consequently, spin-outs do not have to invest time and money in building-up infrastructure and their intellectual property (IP) position, so that they can pay much more attention to business development from their foundation onwards.

The development of the number of employees from 2003 to 2008 within spin-outs founded in 2003 or earlier is positive. The data of only 19 companies could be found in publicly available data. Of the 19 companies, around 67% of drug development spin-outs and 57% of service provider spin-outs had increased the number of personnel since their founding

Only three of the spin-outs showed static growth in personnel. A decrease was mainly seen at drug development spin-outs with 25% (five out of 19) of them having a lower number of personnel since their founding. The average personnel growth was 113 employees from drug development spin-

Figure 6 Interview answers regarding success factors of R&D spin-outs .



outs (min. = -47 and max. = +1104 in absolute figures; average of +67% in relative terms, min. = -40%; max. = +213%) and 20 employees for service providing spin-outs (min. = -6 and max. = +58 in absolute figures; average of +62% in relative terms, min. = -30%; max. = +232%). This shows that the majority of the spin-outs manage to establish a successful business model within a 5-year period and successfully attract a profitable customer base enabling them to grow.

Business models and reasons for R&D spin-outs

The analysis regarding the positioning in the pharmaceutical value chain shows that R&D spin-outs can be found in all areas of the pharmaceutical value chain, forming typical groups with specific business models (Figure 4). In the drug development area there are companies like Eucodis and Gencell with focus on basic research and drug discovery (DED 1), companies, like Alberio and Basilea Pharmaceutica, with focus on drug development without own marketing resources (DD 2) and companies, like Actelion and Biovitrum, which have grown to fully integrated pharmaceutical companies covering drug development and marketing (DD 3). Within service providers there are groups focusing on drug discovery with companies, like Genedata and Medigenomix (SP 1), or drug development with examples, like Covidence and Focus Clinical Drug Development (SP 2). Most of the companies in group SP 2 are clinical research organisations (CRO) with core activity in management of clinical trials. Companies covering both areas with the same priority, like Solvias, are very seldom (SP 3).

Figure 4 indicates that all aspects of the value chain are susceptible to new business models and risk isolation from the part of big pharmaceutical companies. The examples indicate that mostly the spin-outs focus on selected activities within the value chain (rather than trying to cover various aspects, with the exception of Solvias). Furthermore, Figure 4 suggests that in the area of service provision during the product launch, marketing and manufacturing phase, low spin-out activity is currently registered. This might have several underlying reasons: [1] the big pharmaceutical companies consider these activities as part of their core, [2] these activities require substantial investments in large-scale production facilities, marketing budgets and sales and distribution channels, making them less suitable for new ventures or [3] new spin-out initiatives have not found a workable business model (yet) to operate in this part of the value chain. As Figure 4 indicates, R&D spin-outs are used by parent organisations in (almost) all parts of the

value chain to increase flexibility and lower risks associated to new developments.

The interview results regarding the reasons for R&D spin-outs shown in Figure 5, such as support of the company and their R&D strategy, provide mixed evidence for the theoretical arguments set forth earlier. Spinning out R&D activities increases the performance in specific fields of R&D through higher flexibility and innovation capability. By reducing the management complexity of the parent company the full entrepreneurial energy of the management team can be spent on commercialisation. The interviews showed that, in general, total costs are lowered through a reduction or variabilisation of fixed costs, R&D flexibility and speed increase. Commercialisation speeds up and there is a higher possibility of success. Drivers are cooperations and increased employee motivation. In a disinvestment case, a restructuring is easier to carry out with spin-outs. Last but not least, financial risks for the parent company can be reduced. Overall, Figure 5 provides empirical evidence that the benefits of using R&D spin-outs in the pharmaceutical industry are perceived more beneficial by spin-out managers than by parent organisations. On most statements, both spin-out managers and parent organisation perceive positive effects, except for service providing spin-outs from the parent organisation's viewpoint. The results thus suggest that using R&D spin-outs for drug developments seems to provide more benefits for the parent organisations, while from the viewpoint of the spin-outs themselves, any of the two types has positive perceived effects.

To get a better understanding of the reasons for R&D spin-outs, they were evaluated using the evaluation model described in the previous chapter. It could be shown that a spin-out is not only created to reduce costs as an alternative to closing or selling the unit. The reasons are more complex and can be shown by the three dimensions:, costs, risks and performance. These three dimensions are, of course, interrelated. From the interviews, some trends appear. Service providing activities are mainly spun out for cost cutting reasons, while for drug development spin-outs the main driver appears to be isolation of risks. In either of the two groups, enhancing the parent company's performance seems to be a main driver in the spin-out decision process.

Overall, these results suggest that R&D spin-outs are, in most cases and in many regards, beneficial for both parent organisations and spin-outs. On average, spin-outs achieve high survival rates and manage to grow substantially over a relatively limited time period (5 years). Furthermore, from both the parent company's asand the spin-out's perspective, the spin-out process receives a positive evaluation and seems to be beneficial to both parties (except maybe for the service providing spin-outs from the parent company's viewpoint). The strongest effects can be found in speeding up the commercialisation process of new technologies, reducing the overall cost for all entities and improving cooperation possibilities from both perspectives. Other strong positive effects relate to increasing R&D speed and flexibility in the R&D process.

Some fundamental issues are to be considered when structuring an R&D spin-out (Figure 6). The results from the interviews reveal some interesting facts. It is important to focus the new enterprise on a few core activities. For non-core activities partnering and/or outsourcing on the basis of strategic make-or-buy decisions is necessary. Otherwise the spin-out loses focus. The build-up of heavy bureaucratic structures must be avoided and a transfer of all relevant assets (i.e. laboratories, equipment, patents and other IP rights like copyrights and trademarks) as well as key personnel (tacit knowledge) to the spin-out is essential.

The interview partners stated clearly that a new company with its own legal entity, including logo and name, must be established to demonstrate the independence from the former parent company. The management and scientific team are key components. They must believe implicitly in their science, they must be willing to commit their careers to the exploitation of this science and they must have the entrepreneurial, risk-taking drive. Generally, a very important aspect of designing an R&D spin-out is staffing and incentives for the key people. Therefore, an adequate and transparent profit-sharing model between parent company, management and employees of the new company as well as financial investors is fundamental. This includes a well-balanced and transparent profit sharing model for management and employees, equity or option programmes. Management should hold a significant equity stake in the company which is in the range of between 10 and 30% (depending on the size of the spin-out company).

Managing remaining ties between the spin-out and its parent company is essential to the success of the spin-out. While the parent company should retain limited equity and product rights in the spin-out company, excessive product trumping or management interference from the parent company deters investors and impedes the spin-out entrepreneurial attitude. It is extremely difficult to put a monetary value on early phase research. Without patent protection, value becomes even more intangible. In order to be fundable, the spin-out must have the complete right to use the transferred IP for its intended field of use, subject

to termination only under very limited conditions. Whether structured as an assignment or a license, defining the terms of the technology transfer from the parent company to the spin-out is an important aspect. Issues to focus on include detailed regulations regarding the IP (e.g. kind of transfer including covering of costs, exclusive use in special technology fields, therapeutic areas or regions, "first right of refusal" or veto rights for the parent company).

The issues discussed in this section based on the interview results seem to suggest, however (see Figure 6), that large differences exist in the priorities and concerns risen by parent organisations and spin-out managers during the spin-out process. The main concern for the parent organisation seems to be of strategic nature. On the other hand, spin-out managers are confronted with many crucial aspects and preconditions which shape the potential and future of the spin-out. Especially the operational independence from the parent company, the quality and conviction of the spin-out's management team and their participation in case of a successful spin-out seem crucial.

Positioning as external service provider

One major intention of pharmaceutical companies, especially regarding service spin-outs, is the establishment of an efficient external market for pharmaceutical services. If, however, there is high complexity in the processes between service provider and customer, or interfaces, which are difficult to define, the tendency towards outsourcing declines. Therefore, it is important for service providers to define highly standardised and transparent processes and contracts. Those service providers with laboratory resources out of Europe or North America should be able to offer project management services to European and North American customers close to home. It is also important for service providers to ensure a flexible project execution with stringent quality control and establish full cost transparency and an easy invoicing process. Companies prefer contracts with fixed prices (mostly attached to milestones), which allow a better cost calculation of the project. In order to remedy the concerns customers have regarding IP, exclusivity and secrecy, a cooperation agreement should include that all critical IP remains with the customer and there should be clear and transparent rules regarding the engagement in projects of direct competitors (De Cleyn and Braet, 2008).

4. Case studies of successful spin-outs

The Speedel/Solvias case is a good example to show the advantages of flexible structures. This case study combines the drug development and service provider view as Solvias as well as Speedel are both spin-out companies from the Swiss pharmaceutical company Novartis. The second case, Accovion, nearly doubled the number of employees within 6 years, which shows growth potential of a CRO. The information presented on both cases is the result of publicly available information collected through desk research and the interviews with managers of both cases.

Speedel and Solvias: Success through partnership

Solvias was founded in 1999 as a management buyout from Novartis in Basel, Switzerland, offering many different services to the pharmaceutical industry with special expertise in chemical synthesis, which is the synthesis of chemical compounds in drug discovery (lead structures and lead compounds, lead optimisation) and drug development (substances for preclinical and clinical trials). Furthermore, this is combined with process development know-how, covering operations and services associated with the development of an industrially feasible process, such as process research (including supply of first product lots for preclinical and clinical trials), process development and process optimisation.

The pharmaceutical company Speedel, also based in Basel, Switzerland, was founded by a group of Novartis managers to realise a development project which Novartis had stopped. They started as a virtual company with only project management in-house and, therefore, relied on outsourcing partners. Speedel's first project was SPP 100 with Aliskiren, an oral renin inhibitor licensed from Novartis, as new chemical entity. The challenge was to develop a cost-effective synthesis route for Aliskiren – a task where Novartis with its in-house resources failed. Speedel's strength compared to Novartis was the flexibility to select the most suitable partner for solving the synthesis problem. Solvias was selected to bring in special synthesis and catalysis technology as well as the ability to follow up with analytics. The number of Solvias staff involved in this project varied over time.

After Speedel's successful and rapid development of the project to phase II, Novartis agreed to license the product back for final phase III development and commercialisation. In July 2008, Novartis started a take-over process to become majority shareholder in Speedel. From Novartis' viewpoint, the advantages of spinning out the SPP 100 project to Speedel and using the flexible resources of Solvias are obvious. Novartis could reduce and control its develop-ment risks for SPP 100, and at the same time keep the project in its portfolio. Speedel selected an excellent

partners and was able to quickly allocate resources (staff and equipment) to match the variable project needs. The improvement in flexibility was twofold: capacity-wise it was possible to adjust the necessary resources the development need and progress without building-up additional fixed costs and expertise-wise, Speedel had the opportunity to chose the most promising technical approach independent from company internal restrictions.

The Speedel/Solvias case is a good example to show that the cooperation with spin-out companies allows a rapid and flexible combination of skills, resources and know-how, thus speeding up the development process. Furthermore, it illustrates the potential benefits for both parties involved.

Accovion: Success through growth opportunities

Accovion, formally Covidence, is a CRO formed in 2002 from the global clinical research, medical writing, pharmaceutical covigilance, biostatistics and data management departments of Aventis Pharma in Frankfurt, Germany, which was formed through the merger of Hoechst and Rhone Poulenc. Accovion's core business is regional and global projects ranging from phase I to IV clinical studies and global submission. The spin-out process started in February 2000 and some 2 years later, Accovion started business with about 120 employees. Venture capitalist 3i held a 30% stake in Accovion as a financial investor, 30% was held by the management of Covidence, and the remaining 40% by Aventis. Meanwhile, Aventis, now Sanofi-Aventis, has sold its stakes and Accovion is currently owned by its management, Heidelberg Capital and Creathor Venture.

Since its foundation, Accovion is on a growth path through the acquisition of external teams. In 2003, Accovion acquired more than 30 Oracle Clinical data management and biostatistics experts from Aventis Behring, making Accovion the long-term preferred clinical development services provider for Aventis Behring. Accovion also formed alliances, e.g. with OSMO, the largest oncology site management organisation in France, or with US-based ReSearch Pharmaceutical Services (RPS), a pharmaceutical resource organisation. Meanwhile, Accovion has 200 employees and is established as a partner for all major pharmaceutical companies on a global scale. The Accovion case shows the possible growth potential if an internal project is spun-out and has the opportunity to commercialise its technology and knowledge for a broader customer base than only for internal parent company activities. Specialised expertise was built up or acquired which now can be used by the whole customer base.

5. Implications and conclusion

Today, many areas of the R&D process chain can be outsourced and covered by external service providers. Over the past five years, the number of spin-outs in the pharmaceutical industry has increased and seems set to continue to grow further, as pharmaceutical and biotechnology companies view, with an increasing interest, the possibilities offered by spin-out deals. Especially the future cost pressure and need for new products will boost the trend towards R&D spin-outs. The reason for this is that for more and more R&D projects, which are neither to be stopped nor sold, there are not enough company internal resources (capital, management capacity) available. Spin-out creation can also help to refocus the company strategy. Following a merger or simply complementing a strategic realignment on core areas, spin-outs provide a valuable option to leverage assets of low strategic importance, or under-exploited assets in their parent companies. Another possible reason to opt for a spin-out is the isolation of a high-risk core business project, in order to prevent the project from affecting the riskiness of the core company. The empirical evidence seems to support these conceptual arguments to a large extent.

These developments enable pharmaceutical companies to concentrate on own core activities, without having to abandon new products coming from the spin-outs and the correlating value creation potential (Cooke, 2001). Especially service-oriented spin-outs contribute towards this, as these provide external services to support pharmaceutical research. But also spin-outs focussed on the development of pharmaceuticals, which represent the majority of the R&D spin-outs, support this change, as they prefer to use such services. Drug development spin-outs are potential assets for spin-out initiatives or as currency with which to 'do deals' with other companies. The discovery function may even become a revenue-generating centre rather than a cost-centre. This is not an unrealistic vision; small companies already operate in this way, using research assets as currency in setting up deals and alliances (Dewdney and Smith, 1998).

Also, highly specialised research service providers will play a more important role and integrative part of the processes in the pharmaceutical industry. The result is a professional market for highly specialised services, which benefits all research-based pharmaceutical companies. The more flexible structures within the services networks make pharmaceutical research more efficient. This correlation could be made, due to the increase in drugs introduced to the market over the past years, after the number reached a low point shortly after the turn of the millenium. Contributing to the

increase are the many successful spin-outs, which have developed new products and, alone or together with partners from the established pharmaceutical industry, have brought these onto the market (e.g. Actelion, Speedel).

The empirical evidence provided by this study suggests that the theoretical benefits from using spin-outs in the pharmaceutical value chain, amongst other reasons, to increase flexibility and reduce costs, to a large extent seem to be avid from both the parent company's and spin-out management's perspective. The effective realisation of these benefits is especially true for drug development spin-outs. For service providing spin-outs, the outcome is mainly perceived beneficial from the spin-out's perspective, while the parent organisations are more sceptical. However, overall, R&D spin-outs do seems to have a positive impact for both the parent organisation and the spin-out team, in terms of flexibility, motivation and overall performance.

6. Limitations and further research

Limitations

An important limitation of our study relates to the data gathering methodology. In most cases, data have been obtained with a single respondent per firm. Data-triangulation then becomes difficult, especially for inside company information. A second limitation relates to the geographical diversity of sample firms in our research. The predominance of German and Swiss spin-outs, which is (probably) a distorted sample of the real population, might have influenced our findings. In order to fully understand the dynamics of spin-outs in the pharmaceutical industry, it might be necessary to investigate spin-outs outside Europe. A last limitation relates to the measurement of perceived relevance based on personal perception rather than on actual importance. Respondents' perceptions might distort actual results, as their lens on the world might lead to a faulty perception of reality. Especially in combination with the first limitation (single respondent), this measurement choice might affect the strength of our conclusions.

Further research

In a more longitudinal setting, future meso-level research could evaluate if spin-outs really contribute to increasing effectiveness over the entire value chain in the pharmaceutical indus-try. More on a micro-level, an interesting line of research could assess the viability and performance of individual spin-outs and eventual differences between service-oriented and drug development ventures in this regard. Finally, more in-depth knowledge is needed on the strategic motives for parent company to spin-out a certain activity and how they deal with eventual successful development of their spin-outs afterwards. Understanding the process of spinning out and reintegrating the venture could contribute to the knowledge base on industry dynamics and corporate spin-out ventures.

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