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Aphorisms

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1. *"What is research but a blind date with knowledge?"*
   (Will Harvey)

2. *"You can't catch trout with dry breeches"*
   (Miguel de Cervantes)

3. *"Understand life's mysteries - as mysteries to be lived"*
   (Robert Zemeckis)

4. *"If they give you ruled paper, write the other way"*
   (Juan Ramon Jimez)

5. *"I am not discouraged, because every wrong attempt discarded is another step forward"*
   (Thomas Alva Edison)

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Selected papers

R&D management in the pharma industry: the strategic role of CROs[1]

Received
14th December 2015
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4th May 2016
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9th November 2016

Roberto Parente - Rosangela Feola - Valentina Cucino
Anna Gimigliano

Abstract

Purpose of the paper: *In recent years, the Pharma Industry (PI) has undergone radical changes in R&D management. It is estimated that between 1/3 and ½ of every dollar spent on R&D from pharma companies now goes to Contract Research Organizations (CROs). The main purpose of our paper is therefore to interpret major features and changes underpinning the CRO's role in the PI.*

Methodology: *The starting point for our work is a literature review on structural changes affecting the PI. Then, by means of a structured questionnaire, key data on Italian CROs was gathered. Finally, we collected additional first-hand information to better define emerging CRO business models.*

Findings: *Our study highlights that in the beginning, CRO development was mainly driven by large pharma outsourcing strategies. Currently, CROs also represent an ideal, ready-to-use technological infrastructure for small emerging biotech companies. Moreover, we have identified four business models that describe CROs' strategic approach, i.e. a transactional outsourcing model, a functional outsourcing model and virtual outsourcing models mode 1 and mode 2.*

Research limitations: *Further investigation will be useful to understand emerging business models in Italy and in other national innovation systems and to appreciate the changing role of CROs in the strategic management of biopharmaceutical innovation.*

Research and managerial implications: *Results could indicate CRO's next step towards so-called "virtual model", to meet the expectations of the most dynamic open innovation approaches in PI.*

Originality/value of paper: *The article, to the authors' best knowledge, is the first study related to the strategy and structure of Italian CROs.*

Key words: pharmaceutical industry; open innovation; contract research organization; business model

1. Introduction

The Pharmaceutical Industry (PI) is a particularly interesting case set when observing the evolutionary dynamics linked to a shift from a closed to an open model of innovation. It is, in fact, hard to find an industry that

[1] While this paper is the result of the authors' joint reflections, in terms of its final drawing up, paragraphs 1 and 3 are attributed to Roberto Parente, paragraphs 2, 5.2 and 6 are attributed to Rosangela Feola, paragraphs 4 and 5 are attributed to Valentina Cucino and paragraph 5.1 is attributed to Anna Gimigliano.

has been experiencing the same intensity and speed of change in the innovation model as the PI (Lowman *et al.*, 2012). As the first step of the revolution, Big Pharma outsourced most of their clinical study phases for newly proposed drugs to external services companies. Contract Research Organizations (CROs) are companies that have the delivery of services along the chain that leads to the development and validation of new drugs or new medical devices as their core business (Lowman *et al.*, 2012; Bryde and Joby, 2007), and have long been flourishing in the first wave of Open Innovation (Chesbrough, 2003). In the more recent second wave, the growing role of academia and young biotech start-ups can be observed in the discovery and pre-clinical innovation pipelines of Big Pharma. Such trends are consistent with the view that the locus of innovation is shifting from in-house R&D to small firms (Munos, 2009; Kneller, 2010) and public organizations (Powell *et al.*, 1996). Accordingly, Big Pharma is increasingly becoming the "network integrator" rather than the prime locus of drug discovery (Rafols *et al.*, 2014). The latter is moving from Big Pharma to small firms, but start-up companies are often too small and too inexperienced to accompany their product candidates throughout the validation process and to become appealing for a big company, so they often try to partner with CROs (Hecker *et al.*, 2003).

As a result, the structure of the PI has profoundly changed and CROs are at a crossroads in rethinking their strategic role in the innovation process of the PI.

Starting from these premises, the objective of this study is to analyze how CROs intercept and exploit opportunities arising from the evolution of the PI. In particular, the specific objective of the article is to ascertain how CROs are adapting their market strategy to respond to the development of start-up biotech and technology transfer activities in Public Research Centers.

2. Theoretical framework

Hierarchy and the market were conceptualized (Coase, 1937; Williamson, 2010) as the two opposing basic alternatives to organized economic transactions. Many structural factors play a role in the choice of one of the two modes when structuring economic transactions. Changes concerning such structural factors can push towards a shift in the dominant organizational model (Tushman and Nadler, 1978). The impact of such changes are particularly evident in relation to one or more elements of the value chain (Porter, 1985). Among others, the change in the perception of risk/uncertainty profiles (Knight, 1921), arising from the development of new technological paradigms (Dosi, 1982), may force incumbents to reorganize their processes of technological innovation in favor of a more decentralized one (Arora *et al.*, 2001). Specifically, there might be an accelerated shift from a model of "closed innovation" to that of "open innovation" (Chesbrough, 2003). The model of open innovation has overcome the old view of innovation as a specialized activity developed in the firm's R&D laboratories and favored a new vision in which innovation increasingly stems from external sources of knowledge.

This process of change calls the concept of core competencies in R&D itself into question (Torkkeli and Tuominen, 2002). In the open innovation model, a key competence is managing *Inbound* and *Outbound* sources of technology innovation.

The adoption of such inbound and outbound strategies in managing technology innovation by incumbents in an Industry create new entrepreneurial opportunities for new ventures that have specific know how in performing particular R&D activities (Chatterji, 1996; Roberts, 2001). Furthermore, such entrepreneurial opportunities are accumulative or additive in nature. New entrepreneurial ventures looking for opportunities in the market for technologies become entrepreneurial opportunities themselves for other players that have the capability of offering them valuable services.

As demonstrated by the literature on the topic, there are many organizational modes through which these R&D-based entrepreneurial opportunities might be exploited (Granstrand, 2004; Lichtenthaler, 2004; 2005). Such modes are distinguished by very dissimilar requirements in terms of acceptable levels of risk and uncertainty by partnering organizations (Chiesa, 2001).

From this point of view, the Business Model concept, as has been defined in the managerial literature, is a very useful tool to analyze how opportunities are exploited (George and Bock, 2011). According to Amit and Zott (2001), the Business Model "depicts the content, structure, and governance of transactions designed so as to create value through the exploitation of business opportunities".

Even if there is no single definition, the literature has conceptualized the business model in terms of value creation and value capture (Baden-Fuller and Haefliger, 2013; Zott *et al.*, 2011; Gambardella and McGahan, 2010; Casprini, 2015).

Baden-Fuller and Haefliger (2013) and Baden-Fuller and Mangematim (2013) distinguish four business model dimensions, two for value creation and two for value capture: customer identification, customer engagement, value chain linkages and monetization.

Customer identification refers to the firm's targeted user and customer groups. This dimension involves the identification of specific features of each customer group and, based on "who pays", distinguishes between the firm's targeted user and customer groups.

Customer engagement concerns the type and level of involvement of the customer and it distinguishes between "projects based system" and "pre-designed based system", often described as the "taxi" and "bus" system. Business models using the former create value by interacting with customers to solve specific problems, while business models using the bus system add value by producing one size fits all goods or services in a repetitive manner via standardized mass production processes (Baden-Fuller and Mangematin, 2013)

The third component, value chain linkages, can be described as the architecture of information flows and system governance. This dimension concerns the mechanisms the firm uses to deliver its product or service to the customer and refers to the well-known literature on vertical integration

(Williamson, 1985), and on hierarchy versus network (Lorenzoni and Baden-Fuller, 1995)

The last component of the business model, monetization, is often labeled as value capture with reference to the source of revenues. This dimension includes systems determining the timing of payments and methods of collecting revenue.

3. Structural change in the Pharmaceutical Industry

With the term "Pharmaceutical Industry", we refer to any industrial activity whose goal is the development, production and marketing of drugs licensed for use as medication (McGuire *et al.*, 2007). The PI is a very complex sector with several unique characteristics. It is highly globalized and diversified, strongly dependent on policies for drugs approval; it is also a knowledge intensive, highly innovative driven industry based on large investments in R&D, which has grown into one of the main sectors in the world. The global PI is currently worth US$ 300 billion a year. North and South America, Europe and Japan represent 85% of the global pharmaceuticals market. The 10 largest pharmaceutical companies control over one-third of this market, several with sales of more than US$10 billion a year and profit margins of about 30% (World Health Organization, 2015). The global Pharmaceutical and Biotechnology industry invests almost 15% of its total sales value in R&D making them the number one sector in R&D investment (Aamir *et al.*, 2014).

Over the past few decades, the PI has been characterized by a series of radical changes that have made it a favorite scenario in terms of shift in the innovation paradigm.

The main trigger for these changes was the decline in R&D productivity in the industry during the first decade of the 21st century (Dimasi *et al.*, 2003; Munos, 2009). On the one hand, investment in research and development had been increasing substantially. R&D investments represent 16% of sales in the 2000-2010 period, with a 60% increase compared to the previous decade (Lo Nigro *et al.*, 2014). At the same time, the risk associated with the development process is increasing as a consequence of two main factors: the focus of investments in new and more risky therapeutic areas (Pammolli *et al.*, 2011) and the more restrictive regulation for drug approval (Angell, 2005). In addition to this, the expiring of patents between 2010 and 2014 have put more than US$ 209 billion in annual drug sales at risk, resulting in $113 billion in sales of unlabeled drugs.

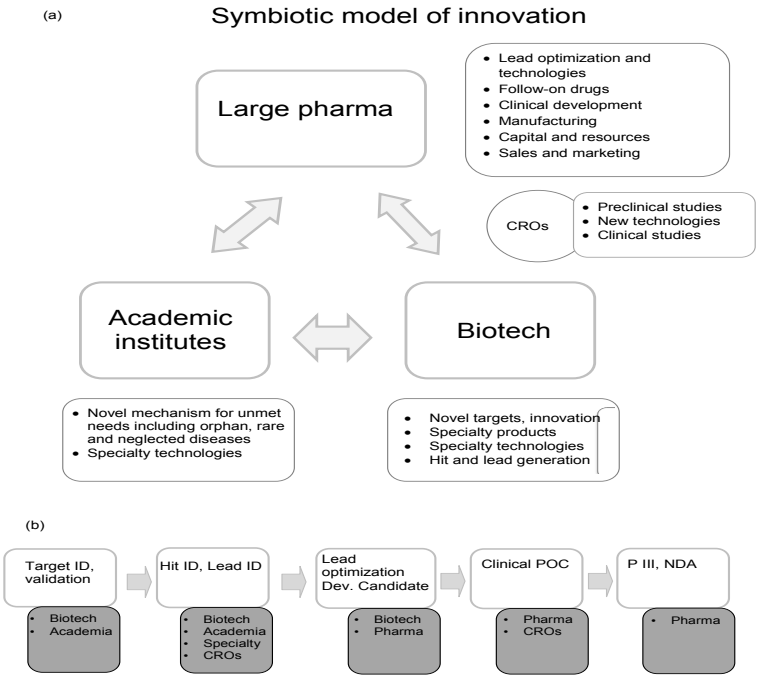
The cumulative effect of such challenges is reflected in a redesigning of the way development processes have been conducted inside pharma companies.

The first wave was that of outsourcing the R&D activities involved in the clinical steps of the validation of a new therapeutic target to third service companies, or Contract Research Organizations (CROs). The main goals of this strategy were to reduce overall costs and to concentrate internal R&D capabilities in filling the pipelines with promising new drugs. In addition, more recently, the partnering strategy of Big Pharma has been

extended to the enrichment of the pipeline itself, with the acquisition of promising new targets that have been discovered and initially developed outside. The key players of this second wave in redesigning the R&D process in the PI have been essentially a cohort of new small biotech start-ups. Often coming directly from academia, they are mainly focused on the drug discovery stage. Thanks to their scientific knowledge, and with the support of financial professionals specialized in high-risk investment, these spin-offs have proved themselves particularly effective in the operations of identification and preclinical validation of new therapeutic targets (Barden and Weaver, 2010). Licensing deals, co-development projects and M&A between pharma companies and young start-ups, have flourished in the last decade as a result. More recently, further developments in the acquisition strategies of Big Pharma have been noted: they are now more cautious in the selection process of their partners, choosing small biotech companies that have demonstrable relevance to tangible R&D problems (Mittra, 2007).

As a final consideration, the PI structure is becoming more and more complex (Khanna, 2012) and CROs appear to be a crossroads between large pharma and young start-ups (Fig. 1).

Fig 1: Pharmaceutical value chain and actors



Source: Khanna, 2012

4. The CRO Industry

The activities that are carried out by CROs spread all along the value chain of drug development, from applied research to pre-clinical, up to

clinical study and the complex regulatory procedures that are necessary for the approval and marketing of the drug, the phase of post-marketing surveillance (phase IV), strategic advice and a range of related services.

In general, the CRO primarily provides support in activities related to the central phase of clinical trials of biopharmaceuticals or diagnostic medical devices and in particular: study design, drafting of the medical protocol, selection of clinical sites, enlisting of patients, site monitoring, data collection and analysis of results according to bio-statistic parameters. In these cases, the term CRO is also used as an acronym for Clinical Research Organization.

The advantages of outsourcing to CROs can be better understood by identifying the strategic drivers that guide Pharma companies today, in particular (Piachaud, 2002):

- accelerated time to market, which is now a critical factor in the process of drug development. Thanks to their efficiency, due to a specialization strategy, CROs can more easily compete in a market where the life cycles of products are getting shorter;
- need to achieve the rapid global development of new products. Many CROs have now extended to a multinational presence and are able to help the development process through a combination of the local knowledge of mechanisms for authorization and the ability to follow project management at the global level;
- rapid access to the most advanced technologies and knowledge. Using technologically advanced infrastructure provided by the CRO will greatly reduce costs and eliminate the time of purchase and installation, as well as the training of company staff.

The biggest advantage for a company that outsources is in any case the opportunity to have a window on new science and technology findings, thus exploring the results of innovative research conducted globally in the field in a more rapid and effective way (Bianchi *et al.*, 2011).

At the same time, Pharma companies can take advantage of greater flexibility in the reallocation of the budget and internal resources to research and development, and therefore reduce fixed costs and business risks related to the various stages of experimentation of the new drug candidate.

The outsourcing of R&D in fact allows companies to continue development without long-term investments in core competencies (Torkkeli and Tuominen, 2002) and to stop the process, thus avoiding the repercussions that would otherwise occur if the process were entirely conducted in house. Despite being a very young industry, the service sector of medical research has grown dramatically over the past 15-20 years and assumed a key role in the PI, which is now turning to CROs as part of their processes innovation. It is estimated that one out of every two dollars spent in drug development is spent for CROs services (Cavalla, 2007).

Flexibility, technological expertise and cost consciousness, are therefore the main features of CROs, which is why they represent a key resource for the PI, which is facing increasingly challenging competition.

The market of CRO services is in constant growth, with forecast features that indicate a value of about 56 billion dollars for 2018, with a

CAGR (Compound Annual Growth Rate) of 12.8% from 2012 to 2018 (GBI Research, 2012).

CROs have also expanded their service portfolio over time, covering almost every segment in the value chain of drug development from clinical trials onwards.

Notwithstanding, unfortunately, except for a few notable exceptions (Lowman *et al.*, 2012; Bryde and Joby, 2007), CROs remain a rather underestimated subject in the literature.

5. Objectives and research methodology

The objective of this research is to analyze how CROs intercept and exploit the opportunity arising from the evolution of the PI. In particular, the specific objective of the article is to ascertain how CROs are adapting their market strategy to respond to the development of start-up biotech and technology transfer activities in Public Research Centers.

Our study is explorative in nature and aims to be the starting point for a more in-depth analysis of the business model of CROs.

The research is focused on the Contract Research Organizations involved in the registration procedures of clinical studies carried out by the Italian Observatory of Clinical Trials (OsSC) and listed in the Eleventh National Report on clinical trials of medicinal products in Italy that was published online by the Italian Drug Agency (AIFA) in 2012. The report indicated 96 CROs in Italy.

The research was divided into two steps.

In the first step, we collected data about the main features of Italian CROs by means of a questionnaire sent through the SurveyMonkey platform to 50 CROs operating in Italy. 22 questionnaires were received.

In the second step of the research, key players in the industry, including some of the above mentioned 22 respondents, were approached to investigate the business model they are applying and how they have evolved.

The second step was conducted through a telephone interview based on a semi-structured questionnaire.

5.1 Results: the structure of the Italian CRO Industry

The group of respondents was composed only of CROs located in central or northern Italy (in the group of 50 surveyed CROs, only one was located in the South), highlighting the importance of geographical proximity to major corporations and to the national technological districts as a factor of competitive advantage (Parente, 2008). Over 80% of respondent CROs were born in Italy in the 1990-2009 period, which is the period of maximum expansion of CROs.

About 68% of the CROs originated in Italy as start-up companies, a small percentage (14%) as industrial spin-off companies, but none as academic spin-offs. The remaining 18% had other origins, presumably from company merger operations. With respect to the size of the company, 50% of the sample was represented by small CROs with less than 50 employees,

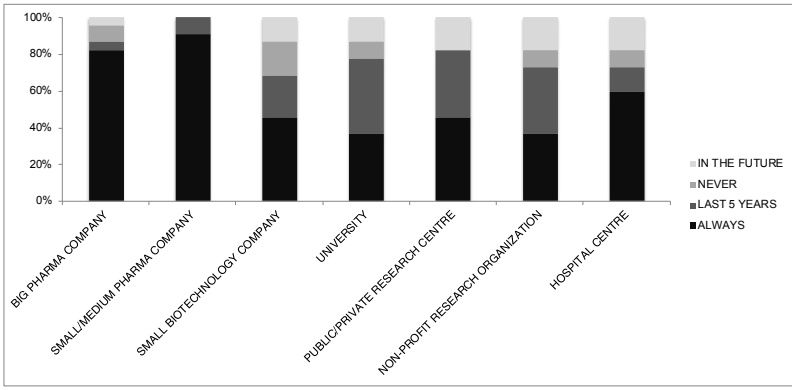
followed by micro CROs (27.3%) with fewer than 10 employees. The weight of medium-sized CROs, with fewer than 250 employees, and large CROs, with more than 250 employees, has amounted to less than 25%.

Almost all CROs served either Big (80%) or SME (90%) pharma companies.

Hospitals (59.1%) are the second most diffused typology of clients, probably because of the growing direct involvement of medicinal products for volunteers and patients in clinical trials.

Small Biotech is an expanding market segment for CRO. Almost 40% of the responding CROs have recently added this segment (23%), or are planning to do so in the near future (18%) (Fig 2).

Fig. 2: The customers of CROs in Italy



Source: Our elaboration

Recently, CROs have also intensified their collaborations with universities and public/private research centers. Our data revealed that CROs have established stronger relationships with universities (40.9%), public and private research centers (36.4%), and non-profit organizations (36.4%) involved in non-profit research on the safety and effectiveness of drugs over the past 5 years.

In particular, in accordance with previous research (Bonaccorsi and Daraio, 2007), our study highlights increasing interest in universities as a place of knowledge production and therefore as an important subject to work with on the technological transfer and development of results obtained from academic research. The respondent CROs provided in fact a total of 500 publications, 132 of which were based on studies carried out with university staff (26.4%).

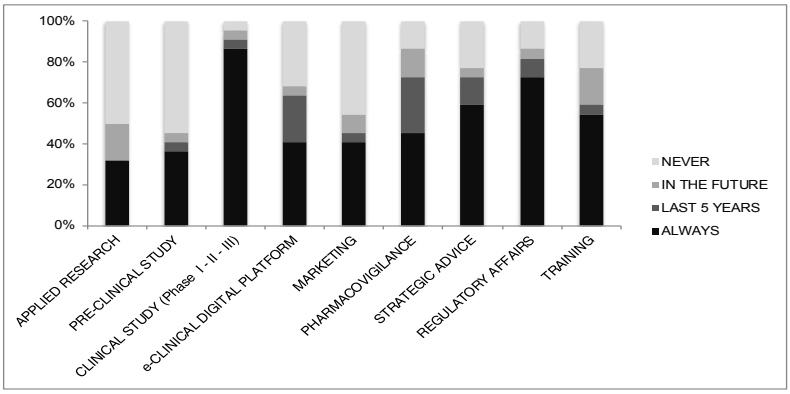
In order to rebuild current and prospective business positioning over time, the CROs were then investigated on the services offered to customers.

In line with the international context, analysis of the data showed that support for clinical trials in phases I, II or III has been the core business of CROs in Italy since their birth. In fact, more than 90% of the respondents said they had always been involved in the provision of services for clinical trials, followed by regulatory affairs (72% of the respondents), strategic consulting (59%) and training (54.5%).

The services that have grown in the last five years are related to pharmacovigilance (27.3%) and the supply of digital e-clinical platforms (22.7%). The former is probably due to the recent changes in the regulatory level for post-marketing drug safety; the latter is a service that can make the performance and control of clinical trials, as confirmed by international trends, easier and more efficient.

As regards future services to be included in the CRO's product portfolio, those in the field of applied research and professional training were highlighted (both at 18.2%). Such perspectives seem to be consistent with the previously showed data about the rising relevance of biotech and research centers that are increasingly looking forward to these kinds of services (Fig. 3).

Fig 3: The activities of CROs in Italy



Source: Our elaboration

5.2 Results: CRO Business models

Findings deriving from the first step of our research highlight the evolution of the PI where the key players in the second wave of R&D process redesign are essentially new small biotech start-ups and universities involved in technology transfer processes.

Starting from this evidence, our objective is to investigate whether and in what way CROs are adapting their business models to respond to the development of new players in the PI.

Based on the literature on the business model (Amit and Zott, 2001; Baden-Fuller and Mangematim, 2013; Baden-Fuller and Haefliger, 2013; Zott *et al.*, 2011; Gambardella and McGahan, 2010; Casprini, 2015) and considering the specific role of CRO organizations in the PI (the role of CROs have mainly developed along with companies specialized in providing services to pharmaceutical companies to support the development and market launch of a pharmaceutical product), we define the CRO business model on the basis of two main dimensions: value creation and the value capture.

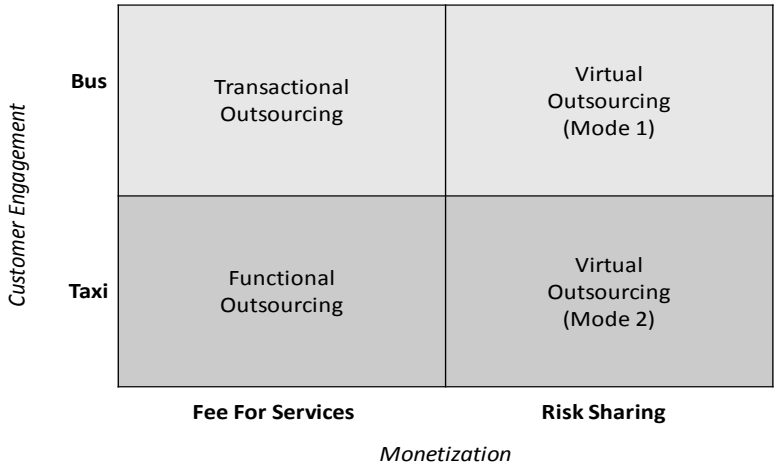
In particular, as concerns value creation, we take into account the customer engagement dimension analyzing the kind and intensity of

relationship that CROs entertain with different types of customers. We thus distinguish two types of customer engagement, the "Taxi" and "Bus" system (Baden-Fuller and Mangetamin, 2013) based on the capacity and disposition of CROs to adapt their services to specific customer needs.

As regards value capture, we focus our attention on the monetization dimension, analyzing the way in which CROs appropriate the value created in the activity, distinguishing between the fee-for-service approach (the company pays the CRO that provides the company with a fixed number of work-units that can support various activities based on the objectives of the project), and the risk sharing approach (where the CRO provides services in return for a participation in future profits related to a successful project).

Starting from such premise we distinguish between four different types of Business Models: transactional outsourcing; functional outsourcing; virtual outsourcing (Mode 1); virtual outsourcing (Mode 2) (Fig. 4).

Fig. 4: CRO: the business models of the firm



Source: Our elaboration

Transactional Outsourcing model

The transactional model is the initial, generally short-term, approach that is established between the CRO and the company. It is a tactical model, which was introduced with the first research contracts and determines that CROs offer services and competences as required within predetermined times and costs and according to the resources dedicated to a specific project by the company.

In terms of customer engagement, this model is suitable for a traditional outsourcing approach with no or limited involvement of the customer. The CRO offers its services to clients without any particular adaption to their specific needs, following a "one-size-fits-all" approach.

In financial terms, it is a fee-for-service model in which the CRO requires a payment calculated according to standard procedures, in relation to the resources used for the project-work.

In this kind of model, there is no stable and durable relationship between the customer and the CRO, and this usually entails drawbacks for both.

For the customer, this solution enables the company to assign multiple projects or more activities related to the same project to different CROs which are selected through various mechanisms: on the one hand, the company has to manage a complex situation with high fixed costs imposed by each CRO; on the other hand, the CRO has access to limited areas of the company and little opportunity to optimize the management of corporate business.

For the CRO, this model implies greater operational autonomy but, at the same time, an increase in costs due to the continued search for new customers.

Functional Outsourcing model

In this model, also defined as Functional Service Provider (FSP), the company relies on a CRO for one or more specific functions in support of various study protocols, for one or more products, in most therapeutic areas.

Companies choose to outsource specialized services to a very limited number of carefully selected "favorite" CROs (preferred providers). In this model a bond between the CRO and the customer is created and the services are defined on the basis of the customer's specific needs, following a "bespoke" approach. In financial terms, like the previous model, the payment system is based on a "fee-for-service" approach.

This mode of interaction enables the establishing of longer-term relationships between the CRO and the company, encouraging greater familiarity with projects and internal processes.

In general, the functional model favors the integration of the CRO in the R&D of pharmaceutical companies, enhancing the efficiency of services, but also the scalability of the process and the productivity of the firm.

The employment of CROs may lead to cost reduction by means of an incremental business and the customer benefits by leveraging costs and improving the management of activities that are necessary for the rapid and effective development of a biopharmaceutical product.

The FSP model has been widely adopted over time by CROs, according to different operational schemes that have proven to be all highly integrated and aligned to the objectives of the company, in order to facilitate the decision-making process.

Virtual outsourcing model - Mode 1

This model is characterized by a low level of customer involvement, with a limited personalization of offered services. From a financial point of view, the risk sharing model is the adopted approach.

This model, which is more difficult to verify in practice, follows a financial investment logic. The CRO funds the project with the objective of obtaining a capital gain, but it is not intended to build a stable relationship based on shared strategic goals.

In this case, the CRO's investments are finalized towards a potential exit opportunity to sell the technology to a third party (usually a big pharma company).

Virtual outsourcing model - Mode 2

In the virtual model - Mode 2 the CRO has further strengthened its positioning in the management of core and non-core activities for the "virtualized" biopharmaceutical company that very often decides to outsource globally.

The virtual CRO (vCRO) offers a comprehensive platform of collaborations and competences that a client/partner may have access to for the R&D process of a product: the strength of the CRO is to coordinate and optimize the entire study according to an end-to-end partnership model, also known as a "one stop shop".

The company preserves the task to create value and then to monitor the entire process, ensuring a fair exchange between partners, as well as good communication and transparency. This minimizes the fixed costs for infrastructure and staff, producing value quickly and therefore a faster return on investments.

The main difference compared to transactional and functional models concerns the revenue approach. In this model, partnerships evolve from a contract based on inputs/activities to payment based on output/performance, with the sharing of business risk among collaborators.

The virtual model applies well to biotech start-ups that generally do not have the financial resources to sustain projects, and in this way companies can focus on their asset innovation, leaving the other functions that are important for the launch of the product on the market, to the global CRO, whose experience can ensure much lower time and costs than those normally registered by an internal management.

Potential sources of risk still exist in this type of virtual organization and are linked to the significant tangible and intangible resources that are put together in a network. In any event, the latter also functions as a driver of profit sharing, which is determined by the contribution of each partner in the network to the project (Lo Nigro and Abate, 2011).

6. Conclusions

The data obtained from the questionnaires and the collection of information from public and private sources in the field enable some concluding remarks with regards to the structure of CROs in Italy.

CROs experienced a period of maximum expansion in Italy in the '90s and 2000s, in line with the globalization of markets, while the decline in the birth of new Italian CROs has become evident over the past five years, when only new offices of multinational CROs have started up in Italy.

The geographical position of our sample showed a significant concentration of CROs in northern Italy, in line with the ideal and the real distribution of large pharmaceutical centers and science parks nationwide.

CROs in Italy have also shown a profile of micro-small enterprises based on the number of employees and average annual sales, which are in line with the typical Italian industry.

In addition, the CROs stated that they were born in Italy especially as start-up companies through business ventures that are far from the

university sector. In this context, it must be mentioned that the workforce of these companies showed a growing connection to the academic field through the employment of high-profile people with a doctorate degree, as well as through the co-production of scientific publications.

Multinational CROs in Italy have appeared as dynamic companies that are ready to operate as full service providers with respect to Italian niche CROs, probably also due to frequent extraordinary merger and acquisition transactions over the conservative approach of Italian CROs.

The core business of a CRO was primarily related to clinical studies, although a diversification of services has recently been applied, including research at an early stage in the R&D process of pharmaceutical products and digital tools, like the e-clinical platform.

This study has made it possible to identify potential business models adopted by CROs in the framework of open innovation applied to life sciences and a structural change in the global biopharmaceutical industry.

What seems to emerge from the first study we carried out and from the information collected by interviews to some key players in the industry is that these models can co-exist within the same organization, but the discriminatory criterion between the choice of one model rather than another is not based so much on the type of customer but rather on the objectives and the specific strategy of the CRO itself.

The data analysis showed that the observed CROs in Italy are slowly changing their strategic perspectives and strive for an open model, in particular by shifting the outsourcing model from a transactional model to a functional outsourcing model.

In fact, growing collaboration has been recorded among CROs in Italy and their customers, moving away from the "fee for service" system in the direction of medium and long-term relationships based on the development of projects with the sharing of risks and returns.

The evaluation of the data could indicate the next step of the CROs in Italy towards the so-called "virtual" outsourcing to meet the most dynamic markets. Further investigations will be useful to analyse the entire landscape of CROs in Italy and the multiple variables involved in the onset of the CRO in the strategic management of pharmaceutical innovation.

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