

## What Drives Biopharmaceutical-CRO Relationships?

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### **Short Abstract:**

Literature on biopharmaceutical (biopharma) firms engaging contract research organisations (CROs) is scarce. This is despite business to business (B2B) alliances being a well-established field in marketing and industry reports predicting CRO industry will rise to \$54.7 billion by 2025 (Grand View Research 2019). A systematic literature review (SLR) was undertaken to examine the relationship between biopharma firms and CROs. This revealed that literature is still captivated by new product development (NPD) and clinical trials. Opportunity to the biopharma-CRO relationship from broader strategic perspectives including how digital marketing influences CRO partner selection is proposed. From a practical implication standpoint, such findings hope to inspire academic scholarship, policy makers and practitioners to view commercialisation more holistically, as a process where NPD runs simultaneously to strategic management, marketing and fund-raising imperatives.

*Keywords: CROs – Biopharmaceuticals – Strategic Marketing*

## Introduction and Research Aim

Biotechnology involves the “application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services” (Friedrichs & van Beuzekom 2018, p. 8). Biotech firms engaged in R&D and commercialisation of pharmaceuticals (pharma) and medical devices (medtech) are classified as biopharma firms (Frost & Sullivan 2017; Frost & Sullivan 2016). Contract research organisations (CROs) provide R&D and commercialisation services to biopharma firms on an outsourced basis. There are over 1,100 CROs operating globally in a market estimated to be worth more than \$56.3 billion (Dezzani 2018). Despite their potential value and importance to small biopharma firms, little is known about their relationship with CROs, and the factors motivating their use. The aim of this study is to determine:

What does the literature suggest influences biopharmaceutical firms (biopharma) to outsource to CROs?

Recent literature suggests that CROs have proliferated to such an extent that they now offer services along the entire commercialisation pipeline from discovery to clinical and post-clinical, infiltrating early stage research once the domain of public sector university research and spin-off biopharma firms (Ilancheran 2017; Getz & Vogel 2009). We address two research questions in line with this aim:

**RQ1: How has academic literature characterised what influences biopharma firms to use CROs?**

**RQ2: What opportunities exist for future research?**

## Methodology – Systematic Literature Review

In order to understand why CROs are gaining a stronghold in drug development a systematic literature review (SLR) broadly following steps outlined by Tranfield, Denyer and Smart (2003) was undertaken. Scopus databases searches combining terms relating to CROs (i.e. “service provider” and “clinical research organization”), the type of services provided (i.e. “R&D outsourcing”), and the type of relationship (i.e. “B2B”, “partnership” and “alliance”) were conducted.<sup>1</sup> This producing 375 search results from 1992 to present. These were filtered, only including English language literature. Duplicates were removed. Papers reviewed only included those addressing CROs in a biopharma context, producing 219 results. Results were placed into Word documents and set-up for Leximancer analysis. Stemmed words were merged like “CRO” and “CROs”. Research specific and common language words were removed like “used”, “paper” and “findings”.

## Results and/or Discussion and Contributions

The Leximancer analysis revealed the dominant theme “**pharmaceutical**” was linked to themes “**companies**”, “**clinical**”, “**services**”, “**outsourcing**” and “**R&D**” (in this order). This clearly shows that there is an overemphasis in literature on traditional, clinical CRO roles. The theme “**pharmaceutical**” included traditional NPD concepts relating to, *research, industry, development, drug, biotechnology, and support*, defining CROs as:

“A CRO is a service organization that ... offers a wide range of "outsourced" pharmaceutical research services to aid in R&D process and is thus an essential tool for undertaking clinical trials ... when high stakes are involved in the drug discovery process.” (Drabu, Gupta & Bhadauria 2010)

Likewise, the theme “**clinical**” concerned concepts like *trials, study, regulatory, medical, global, and quality*, suggesting that biopharma firm reliance on CROs for clinical studies has

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<sup>1</sup> See authors for full explanation of the search strings and methodology.

evolved because drug development operates in a highly complex global regulatory environment (Beach 2000, p. 245). The theme “**companies**” included concepts like *CROs*, *process*, *management* and *work* support this view. Literature showed that drug development is costly, risky and uncertain, which impacts on CRO selection where bespoke technical skill-sets and relational soft-skills (Suarez-Villa & Walrod 2003) are sought to mitigate challenges:

“Outsourcing practices among small, medium, and large sponsor companies remain inconsistent and deliver mixed levels of satisfaction and performance.” (Wilkinson et al. 2019)

The themes “**R&D**” and “**outsourcing**” were associated with *technology* and *innovation* concepts respectively, which unearthed the emerging role that digitalisation plays in distinguishing CROs from other innovation services providers:

IT is gaining greater significance at each stage...CROs are able to maximize work within the CRO global development, to support the notion of a fully integrated outsourced company; facilitate the use of similar business processes and norms, reusing established CRO standards and improve CRO operational decision making within outsourced studies by providing consistent and current information across outsourced and in-house activities.” (Stamenovic & Dobraca 2017, p. 203).

Industry data characterises CROs as high adopters of digital technology, which has aided their growth and breadth of services beyond traditional clinical studies (The Business Research Company 2018). Yet academic studies are yet to examine this phenomenon.

### **Conclusions: Implications for Theory and Practice**

*Strategic Marketing and Management:* The Leximancer analysis suggest there is general absence between biopharma-CRO alliances and strategic marketing and management. The theme “**services**” includes the concept *market*, which has been primarily concerned with the size of the CRO market, rather than marketing activities. Sismondo (2009) suggests CROs are largely “ghosts” in marketing activities. This is despite earlier recognition by Hecker, Preston and Foote (2003) that CROs could play a pivotal role in marketing.

“The timely production of high-quality new drug marketing applications requires close collaborations between the drug company and the CRO.” (Hecker, Preston & Foote 2003)

*CRO eMarketing:* It is acknowledged that there’s no “gold standard” CRO provider (PwC 2014), making locating CROs problematic. Traditionally CRO selection was conducted in a “decentralized way not a priori” where CROs sought to convince biopharma firms to use their services (Haour 1992). Since that time, the process of selecting CROs has slightly altered, with firm’s also taking a proactive role in seeking out CRO services (Balconi & Lorenzi 2017). As such future research exploring the use of electronic word of mouth (eWOM) and other signalling activities offers another avenue to consider the impact of how digital technology impacts on biopharma firm outsourcing decision-making.

The SLR revealed ample opportunity to extend academic research in biopharma-CRO alliances, particularly as it relates to strategic marketing and management. The evolution of CROs into “fully integrated outsourced companies” (Stamenovic & Dobraca 2017, p. 203) has direct and important implications for both the CRO and contracting biopharma in the oversight of activities and leveraging of respective capabilities.

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