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## Technovation

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# Innovation risks of outsourcing in pharmaceutical new product development

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## ARTICLE INFO

Available online 9 December 2011

### Keywords:

Pharmaceutical industry  
Outsourcing risks  
New product development  
Innovation

## ABSTRACT

New product development, which until relatively recently was a core activity within the pharmaceutical industry, is increasingly being outsourced (Howells et al., 2008). This is symptomatic of the transformation of product development towards a more decentralised, network-based and alliance-rich function. We have selected the pharmaceutical industry for this paper because it offers an excellent example of a research and technology intensive industry where outsourcing has led to problems in the innovation and new product development process. We examine the impact of the increase in outsourcing on the way firms manage the clinical trials process. The increasing role of Clinical Research Organisations (CROs) has dramatically changed the nature of the innovation process. CROs initially provided a limited service in clinical trials management, but have gradually evolved into organisations that have expertise across a much wider spectrum of the clinical development process. The fragmentation of the innovation process, which has arisen from the increased role of CROs, creates innovation risks for the pharmaceutical companies. In this paper we discuss the risks associated with knowledge losses for research and technology intensive industries that may arise from lack of integration of new product development activities and develop a number of propositions for further research.

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## 1. Introduction

The pharmaceutical industry is facing major productivity challenges. For example, over a 10 year period the number of new drugs reaching the market declined by 20%, while research and development (R&D) expenditure increased by 60% (CMR International, 2006). The cost of bringing a new drug to market has increased dramatically and is estimated to be in excess of \$1.2 billion (DiMasi et al., 2003; DiMasi and Grabowski, 2007). Competition remains high and lead times have fallen, with the average period of market exclusivity down to less than two years (DiMasi and Paquette, 2004). A key development has been the rise of the importance of the contract research organisations in response to large scale outsourcing of research activities around clinical trials. The pharmaceutical industry provides lessons for other research and technology intensive industries that have not yet developed their outsourcing activities to the same extent. The purpose of this paper is to examine the impact of the increase in outsourcing on the way research and technology intensive firms manage their new product development process and to discuss the potential harm that this may have for such industries.

Discovery research, the scientific laboratory research aimed at identifying new drug targets and novel pharmaceutical agents, is seen as the main driver of innovation. Indeed, much attention has been given to renewing technologies in this area, particularly in the fields of biotechnology, genomics and associated technology platforms (Siedlok et al., 2010). Organisational changes occurring as part of this transformation of the discovery research base are well described in the literature, with networks (Powell et al., 1996; Huston and Sakkab, 2006), clusters (Chiaroni and Chiesa, 2006; Casper, 2007) and strategic alliances (Deeds and Hill, 2006; Gutierrez de Mesa Vazquez et al., 2006) all contributing to a move towards 'virtual' research forms (Chesbrough and Teece, 1996; Jones, 2000; Gassmann and Reepmeyer, 2005). As argued by Chesbrough (2003a, 2003b, 2003c, 2006), the process of innovation has shifted from one of closed systems, internal to the firm, to a new mode of open systems involving a range of players distributed up and down the supply chain.

Less well described are the changes occurring in the later stages of the development process, more specifically within the management of the human clinical trials required for proof of drug efficacy and safety before regulatory approval and marketing. Clinical development is the longest and most expensive stage of the pharmaceutical new products process, requiring more than 10 years for completion and representing 50% of total R&D spending (Parexel, 2004). The clinical trials stage is characterised by relatively low levels of external technology sourcing or

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out-licensing (Bianchi et al., 2011; Malik, 2011). However, the management of clinical development has seen a move towards large-scale outsourcing to innovation service providers (rather confusingly for our purposes termed ‘contract research organisations’ (CROs), but the clinical research being part of late-stage ‘development’ as the term is more broadly understood). The CRO industry has grown to represent over 25% of the total spend on clinical trials, the leading CROs alone managing more than 23,000 clinical trials per annum and having revenues in excess of \$5 billion (Milne and Paquette, 2004; Parexel, 2004; Tufts Center, 2006a; Getz, 2007).

Outsourcing of product development can be seen as an attempt to manage a diverse range of technologies across different product classes (Coombs et al., 2003). It may also speed product development processes, thereby reducing time to market (Chatterji, 1996; Bayus, 1997; Mahnke et al., 2006). Such innovation outsourcing might reduce costs, particularly for incremental innovations (Piachaud, 2005; Huang et al., 2009). Outsourcing may also give access to global knowledge sources, so increasing development productivity (Gassmann et al., 2010).

However, these potential benefits of outsourcing product development are by no means certain. Despite the trend towards increased outsourcing of development activities and a growing market for external product development services (Chiesa et al., 2004) there is limited recent evidence to suggest that firms may be beginning to take back development activities in-house because of the difficulties in managing outsourced innovation processes (Zirpoli and Becker, 2011). There is a growing literature on the innovation risks associated with large-scale outsourcing, particularly where non-peripheral business functions are concerned (for a general overview see Quelin and Duhamel, 2003). Alexander and Young (1996) highlight the risk of supplier dependency. Barthélemy (2001) identifies a number of hidden costs of outsourcing, and Earl (1996) suggests potential problems in selecting service providers with the necessary capabilities, particularly in environments of rapid technology change. Hoecht and Trott (2006) draw attention to risks of information leakage and possible losses of technology-based core competencies. Similarly, Zirpoli and Becker (2011) suggest that outsourcing design and engineering tasks in new product development might lead to loss of architectural or whole-system knowledge. There is also the possibility that innovation outsourcing may hinder a firm’s ability to capture the full potential for new product ideas. The innovation management literature informs us that the capacity to absorb new knowledge, to transfer and diffuse knowledge and the ability to learn through interaction are crucial success factors in innovation (e.g. Cohen and Levinthal, 1989; Zahra and George, 2002). In a recent review of innovation outsourcing research Stanko and Calantone (2011) demonstrate the many unknowns in terms of the performance implications of outsourcing. Hsuan and Mahnke (2011) propose a number of pressing research needs in this area, including greater focus on the management of innovation outsourcing processes, analysing these processes at multiple levels, and exploring the role of service organisations in creating value in the outsourcing process.

Based on a number of key informant interviews with innovation managers from pharmaceutical companies and innovation service providers this paper explores the potential risks to a firm’s innovation capability. In particular we focus on the use of CROs to undertake part of the late-stage clinical development process. We address three broad research propositions. Firstly, innovation service providers (the CROs) have become key drivers of clinical product development in the pharmaceutical industry. Secondly, the absorptive capacity of pharmaceutical firms is the key to their success in product development in a business environment where the CROs have taken on many of the key tasks. Thirdly, the pharmaceutical firms need to maintain the integration mechanisms necessary to

uphold their absorptive capacity, diffuse knowledge and support interactive learning, and so avoid the risk of losing control and creativity opportunities for new products.

The paper is structured as follows: Section 2 characterises the clinical product development process in the pharmaceutical industry and the role played by CROs as innovation service providers; in Section 3 we review the literature on innovation outsourcing and develop research propositions; Section 4 explains the research approach used; Section 5 analyses the potential risks of knowledge losses, and Section 6 concludes.

## 2. Innovation outsourcing and pharmaceutical clinical product development

The main focus of pharmaceutical firm innovation is application of the scientific and technological knowledge emanating from fundamental research to the discovery of new medicines. This process of ‘science-driven drug discovery’ requires firm-level expertise across a range of medical, scientific and technological areas, the efficient management of which appears to be a significant source of competitive advantage (Cockburn et al., 2000). The clinical development stage of pharmaceutical innovation is by far the most investment intensive; representing 50% or more of total R&D spending (Parexel, 2004). Commencing research on human subjects is a key decision point in the innovation process; for it involves clinical trials undertaken by medical ‘investigators’ in hospitals and surgeries across multiple locations. These trials are conducted beyond the direct control of the pharmaceutical company. The management of these large-scale clinical trials has been considered a core competence (Cockburn and Henderson, 2001; Mehta and Peters, 2007), and even a firm such as GlaxoSmithKline, which has devolved its in-house discovery into semi-autonomous ‘centres of excellence’, has maintained a core of clinical trials management, manufacturing and marketing functions (Mehta and Peters, 2007).

Clinical product development consists of a number of sequential but inter-dependent phases, termed phase I–IV. Phase I clinical trials are conducted on relatively small numbers of healthy volunteers, in order to investigate how drug molecules are handled by the human body. Some of these studies may be undertaken by the pharmaceutical company itself, using its own facilities, and others may be conducted in hospitals or external clinical research facilities. Phase II clinical trials are the first to test the effects of the drug in treating diseases in patients. These ‘proof of concept’ studies are conducted in hospitals and patient numbers would typically be counted in the hundreds. Subsequent Phase III clinical trials are much larger, often with several thousand patients involved, and are conducted to assess the drug’s efficacy and safety relative to standard treatments. These clinical trials may be conducted in hospitals and general practices and tend to be multi-national in scope. Phase IV clinical trials are post-marketing studies conducted once the drug has received a Product Licence from regulatory authorities. These are intended to identify any rare adverse events apparent when treating large populations of patients, and to provide additional marketing support information. Again, the patient numbers and multi-national reach of these trials tends to be larger than the preceding phases.

Underlying the clinical development process are capabilities in designing and conducting clinical investigations, ensuring patient safety, monitoring compliance to the study protocol, collecting and analysing large volumes of data, interpreting study results and demonstrating regulatory compliance. In addition, there are the project management and logistics capabilities required to conduct multi-site and multi-national activities, and the programme

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