Bridging the gap among publications, clinical trials and firm performance: The case of Cancer Nanocarrier Drugs

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Abstract

Despite the considerable amount of research on human health, relatively few publications develop into clinical trials and few clinical trials have an impact firm performance. In our research, we hope to fill the knowledge gap about the relationships among publications, clinical trials and firm performance. We will conduct a systematic literature review to justify the existing research gaps in the literature and propose a conceptual model of those relationships. Then we will collect data on firms’ publications, clinical trials and performance to verify the model. For feasibility, we will focus on the case of cancer nanocarrier drugs, one of the most promising techniques for the cure of cancer. We will also explore the moderating role of social capital on the publication-clinical trial relationship and on the clinical trial-firm performance link. We understand as social capital the capacity of the firm to establish connections with other agents in the health research system. This research highlights the importance of bridge the gap between basic research and industrial application in the medical field.

Key words

Publications, clinical trials, firm performance, knowledge transfer, cancer nanocarrier drugs

Main objectives of research

Until now, there are over 24 million publications about life sciences in MEDLINE, the U.S. National Library of Medicine, but there are only 276,509 clinical trials in ClinicalTrials.gov, which is a database of privately and publicly funded clinical studies conducted around the world. Until 2013, there are only 1453 new molecular entities approved as therapeutics by FDA, the U.S. Food & Drug Administration (Kinch et al., 2014). These are all the methods for human beings to cure all kinds of diseases in the world. The development of a new drug follows a
standardized chain of events and is presented in Fig. 1. The drug-development process starts with basic research and ends with the market launch of a new drug. The outputs of drug-development process are publications, clinical trials and firm performances respectively. There is a big gap among publications, clinical trials and firm performance.

In this research, we hope to bridge gap among publications, clinical trials and firm performance. We will explore the relationship between publication and clinical trials and the role of clinical trials on firm performance. Furthermore, we will also consider the moderating role of social capital. Social capital is regarded as an important value creation mechanism. The previous researches have pointed out that social capital entails beneficial outcomes including better group communication and knowledge sharing (Tsai et al., 2014), enhanced use of intellectual capital (Leana & Van Buren, 1999), and reduction of operations cost (Carey et al., 2011). Creating and maintaining scientific social capital will attract more interaction between university and industry and improve translational output.

Research questions

The main objective of this research is to bridge the gap among publications, clinical trials and firm performance. More specifically, this research concerns the interplay of knowledge and social capital dimensions to explore the following questions under the research framework shown in Fig. 2:

(1) Does publication lead to clinical trials?

(2) Does clinical trials lead to firm performance?
(3) What the moderating role of social capital in publication-clinical trials relationship?

(4) What the moderating role of social capital in clinical trials-firm performance relationship?

Methodology

In this research, we will base on the case of Cancer Nanocarrier Drugs (CNDs), which have emerged as alternative tools for targeted delivery of therapeutics, promising safer and more efficacious treatments most particularly in the cancer field (American Cancer Society, 2007). We will collect publication data from Web of Science, based on the content analyses in the topics using the following 5 CNDs-relevant topic terms: cancer, nano*, carry (or delivery), and medicine (or drug); cancer and polymer; cancer and liposome; cancer and dendrimers regarding; cancer and micelle. We will use ClinicalTrials.gov to collect clinical trials data based on the content analyses by the 5 CNDs-relevant topic terms. We will match the finical data of each firms which has published publication or clinical trials by ORBIS.

To answer our research questions, we will follow these empirical strategies:

(1) We will match publication and clinical trial data at the firm level. The number of publications will be used to measure publication, and the clinical trials will be measured by the number of clinical trials. We will explore whether publication has an effect on clinical trials.

(2) We will match the publication, clinical trials and firm performance data together to analysis the effect of clinical trials on firm performance. We will used profit rate to measure firm performance.

(3) We will build cooperation networks of publication co-authors and clinical trials collaborators, explore the potential overlap, and build degree centrality of network properties to measure social capital. This study will explore the roles of social capital on publication-clinical trials links and clinical trials-firm performance link.
Key findings or expected results

It is commonly accepted that universities are the main source of publications, however, the clinical trials always sponsored by companies. The conversion from papers to clinical is related to the knowledge transfer from university to industry. Knowledge transfer helps the promising drugs to reach the patient (Malhaire & Lagarce, 2015). Cooperation is an effective way of knowledge transfer from university to industry, especially in the area with huge amount of tacit knowledge, like medical. However, the previous research find that private companies collaborate with public organizations to mitigate development risks instead of exchange knowledge or technologies (Crispeels et al., 2018).

Hypothesis 1. Publications play a role on clinical trials.

In clinical trials stage, developer only need to make sure the new drug’s safety, quality and efficacy. The decision to enter phase 1 trials is critical and the probability of market launch rises to 21.5% (DiMasi et al., 2003). The positive news that a firm will enter human clinical trials is indicative of considerable improvement in the likelihood of the drug making it to the market place. The positive news of research development generates more abnormal returns for shareholders in stock market (McNamara & Baden-Fuller, 2007).


Scientific cooperation among organizations leads to social capital, which can be used for knowledge production. The more relationships a firm owns with others, the higher the chance to access to relevant information inputs. A central position in a network of scientific knowledge producers provides more information and resources to the organization, which is essential for its output.

Hypothesis 3. Social capital enhances (i) publication-clinical trials relationship and (ii) the clinical trials-firm performance relationship.

Potential conclusions and implications

This research is related to the knowledge transfer from publications to firm performance, and it offers a first quantitative approach to the measurement of the publication-clinical trial relationship and clinical trials-firm performance relationship. Furthermore, this research also identifies a key mechanism, social capital, to improve knowledge transfer. It will bridge the research gap among publications, clinical trials and firm performance, and
give some theoretical contributions on the benefits of clinical trials for firms. This research will provide some suggestions to companies and policy makers about knowledge transfer in Cancer Nanocarrier Drugs.

References


