

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry

Qiang Wu

Aston University, United Kingdom

Engineering Systems & Management, School of Engineering & Applied Science, Aston University, Birmingham, B4 7ET, United Kingdom

q.wu3@aston.ac.uk

Qile He^{*1}

University of Derby, United Kingdom

College of Business, Law and Social Sciences, University of Derby, Kedleston Road, Derby, DE22 1GB, United Kingdom

q.he@derby.ac.uk

+44 (0)1332 591 208

¹ *Corresponding Author: **Qile He**, College of Business, Law and Social Sciences, University of Derby, Kedleston Road, Derby, DE22 1GB, UK. Email: q.he@derby.ac.uk, tel: +44 (0)1332 591 208

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

Abstract

This paper conducts an embedded case study to verify a conceptual framework by which biopharma research in Do-It-Yourself (DIY) laboratories can be integrated into Research and Development (R&D) networks of the pharmaceutical industry. As an early attempt to extend the perspective of business innovation ecosystem into the research on DIY laboratories, this study reveals three major findings. First, DIY laboratories, contract research organizations (CROs) and pharmaceutical firms interdependently position and link with each other in an innovation ecosystem for new drug development. Second, through properly managing the issues of resource utilization and innovation appropriability, CROs play important hub and knowledge broker roles in coordinating and aligning different priorities and expectations of the key players in this innovation ecosystem. Third, this study maps and verifies two knowledge transfer models through which novel research findings in DIY laboratories can be converted into real commercial returns.

Keywords: DIY laboratory; Contract research organization (CRO); Pharmaceutical firm; Pharmaceutical R&D; Innovation ecosystem.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry

1. Introduction

The Do-It-Yourself (DIY) science movement has emerged in early 1990's (Ferretti, 2019). Different from the mainstream research carried out in universities and official institutes, the DIY science movement encourages independent scientists, science hobbyists and even amateurs to "do science" in their own DIY laboratories (Meyer, 2013). It thus democratises science by reducing barriers to entry into the field of scientific research (Landrain *et al.*, 2013). Because the DIY science movement challenges conventional research settings by introducing fresh scientific ideas from a "grassroots" level (Fox, 2014), its potential to extend current outreaches of various scientific fields has received an increasing attention from academia, practitioners, media and the general public (Ferretti, 2019; Sarpong and Rawal, 2020).

Biopharma research is an important stream in the DIY science movement, in which freelance researchers use DIY laboratories to conduct increasingly complex experiments and generate innovative findings in fields, such as generic engineering, medicine, and bioinformatics (Landrain *et al.*, 2013; Sleator, 2016). Biopharma DIY laboratories open the gate for laypersons to practice their scientist ideas for biopharma innovation (Sarpong *et al.*, 2020). However, because biopharma research requires significant investment in both technologies and equipments (De Beer and Jain, 2018), the "grassroots" nature of these biopharma DIY laboratories means that additional financial and technical supports will be needed (Landrain 2013; Revill and Jefferson, 2013). Moreover, DIY laboratories used to be outside the boundary of mainstream biopharma Research and Development (R&D) networks (Dana *et al.*, 2019). The innovativeness and the commercial value of the findings generated in these rudimentary premises are thus difficult to be accessed and understood by relevant stakeholders, such as pharmaceutical firms (Schillo and Robinson, 2017).

To address the financial, technology and commercialisation challenges involved in biopharma DIY laboratory research, some recent studies propose the possible integration between DIY laboratories and mainstream pharmaceutical networks dominated by pharmaceutical firms (e.g. Schillo and Robinson, 2017; De Beer and Jain, 2018). However, our extant review of literature suggests that so far there is lack of detailed frameworks depicting mechanisms of such an integration. Limited empirical studies, if at all, have attempted to clarify the integration between DIY laboratories and mainstream pharmaceutical networks. To address this research gap, this paper conceptualises a framework and uses it to empirically examine how the innovative findings of biopharma DIY laboratories can be transferred in existing pharmaceutical R&D networks, and eventually be converted into marketable products.

From a business ecosystem perspective (Adner, 2017; Jacobides *et al.*, 2018), we propose that, since DIY laboratories and pharmaceutical firms are previously isolated entities, an agent hub should be in place to connect these two parties into the biopharma innovation ecosystem. We further propose that contract research organization (CROs) can act such a hub role. The reasons

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

are twofold. On the one hand, as strategic partners of pharmaceutical firms, CROs understand and can facilitate pharmaceutical firms' entire R&D process (Masri *et al.*, 2012; Hassanzadeh *et al.*, 2014). On the other hand, CROs actively search for new biopharma technologies in possible fields to expand their business range (Hassanzadeh *et al.*, 2014). We use an embedded case study to verify our conceptual model and research propositions.

This paper is structured as follows. Section 2 reviews the relevant literature and develops a conceptual framework which proposes a potential routine by which DIY laboratories can be integrated into R&D networks of the pharmaceutical industry. Section 3 explains the research method adopted in this study. The conceptual framework is examined, verified and extended by an embedded case study in Section 4. Section 5 further discusses how a CRO act as a hub to manage resource utilization, knowledge transfer and innovation appropriability among DIY laboratories, pharmaceutical firms and the newly introduced venture capitals in a biopharma innovation ecosystem. This paper concludes by summarising the main findings, limitations and future research directions.

2. Literature review

In this section, firstly, the R&D outsourcing trend in the global pharmaceutical industry, as the main research background, is outlined in which the important role of CROs is highlighted. Secondly, we review the literature regarding the emergence of DIY laboratories in biopharma research and discuss both the opportunities and challenges involved from an inclusive innovation perspective. Thirdly, based on the business ecosystem literature, we develop a conceptual framework which depicts a potential routine by which DIY laboratories can be integrated into R&D networks of the pharmaceutical industry.

2.1 The R&D outsourcing in the global pharmaceutical industry

2.1.1 Biological revolution as the driver of the R&D outsourcing

Leading firms in the global pharmaceutical industry used to regard internal R&D capability as their core competence (Ramirez, 2006; Hu *et al.*, 2015). As such they normally keep a large-scale R&D team to conduct and manage the entire process of new drug development from initial laboratory discoveries to later pre-clinical and clinical trials (Hassanzadeh *et al.*, 2014). This in-house R&D strategy used to be successful for large pharmaceutical firms to not only protect their intellectual properties, but also keep their competitive advantages (Malerba and Orsenigo, 2015).

Entering the 21st Century, such an in-house exclusive R&D strategy has been seriously challenged by the so-called biological revolution, which introduced various biological innovations, such as DNA technologies and molecular generics, to the pharmaceutical industry (Malerba and Orsenigo, 2015). These state-of-the-art biotechnologies enabled scientists to develop new drugs targeting at longstanding, complex diseases, such as cancer and HIV (Lowman *et al.*, 2012; Coccia and Wang, 2015). At the same time, these new technologies also challenged pharmaceutical firms' in-house R&D strategies in terms of time and cost. Because of the complicated application of biotechnologies to the pharmaceutical R&D, recently discovered drugs demonstrated higher levels of sophistication, and required costly and time-consuming

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

clinical trials to ensure safety and efficacy (DiMasi and Grabowski, 2007; Hassanzadeh *et al.*, 2014). As a result, the development period of a new drug in global pharmaceutical industry was doubled from 3-5 years to 8-10 years (Gassmann *et al.*, 2008; Hassanzadeh *et al.*, 2014). Moreover, the expenditure in discovering and developing a new drug increased from 1.5 billion US dollars to over 2.5 billion US dollars (Gassmann *et al.*, 2008). Stated differently, along with the biological revolution, the average productivity of the in-house pharmaceutical R&D has greatly decreased.

Facing the profound technology transformation brought by the biological revolution, large pharmaceutical firms understood that their internal R&D bases for new drug development needed to be reconfigured (Malerba and Orsenigo, 2015; Marques *et al.*, 2019). With the aim to not only reduce operational costs, but also concentrate internal resources on core functions in R&D processes (Hassanzadeh *et al.*, 2014), pharmaceutical companies gradually outsourced their relatively simple, routine-based R&D functions to other organizations, such as contract research organizations (CROs) (Masri *et al.*, 2012).

2.1.2 The emergence of contract research organizations (CROs) in the global pharmaceutical industry

During the wave of R&D outsourcing in the global pharmaceutical industry, a novel form of business, namely contract research organizations (CROs) emerged and flourished. These CROs, such as Medpace Holdings Inc. and Paraxel International Corp., are mainly responsible for taking R&D tasks outsourced by multinational pharmaceutical firms (Mirowski and Van Horn, 2005). As pharmaceutical firms increasingly used CROs to support their new drug development, the CRO industry rapidly grew. In 2010, the CRO market size was estimated at 24 billion US dollars (Masri *et al.*, 2012). By 2018, the value of the global CRO services market was estimated to be valued at 37 billion US dollars (ISR, 2017).

Generally, the CRO industry has experienced two development periods. Initially, by narrowly targeting at offering primary outsourcing services required by their clients, CROs quickly built up their specific routines and competencies in certain pharmaceutical R&D functions (Masri *et al.*, 2012). Thus by using the expertise of CROs to supplement their own capabilities, pharmaceutical firms could complete drug research projects faster and at a lower cost (Masri *et al.*, 2012; Hassanzadeh *et al.*, 2014). During this period, the research services provided by CROs were largely restricted at the clinical trial stage, which is a relatively peripheral part in the entire drug development process (Hassanzadeh *et al.*, 2014). However, in the subsequent period, some major CROs expanded their business range to all four main stages of the pharmaceutical R&D pipeline, namely drug discovery, pre-clinical research, clinical trial, and Food and Drug Administration (FDA) review (Masri *et al.*, 2012; Hassanzadeh *et al.*, 2014). Typical research services that can be offered include laboratory testing, protocol design and management, clinical trials monitoring, medical and safety reviews, and data and statistical analysis (Shtilman, 2009; Masri *et al.*, 2012). Meanwhile, these full-service CROs began to establish strategic partnerships with world-leading pharmaceutical firms (Masri *et al.*, 2012).

Through outsourcing part of their R&D functions to CROs, large pharmaceutical firms can downsize existing R&D teams, and reduce operational time and costs involved in new drug

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

development. However, they still face another profound challenge brought by the biological revolution, i.e. how to effectively transform latest findings in biopharma research into real R&D outputs (Lauto and Valentin, 2016). In fact, over the last two decades when advanced biotechnologies were intensively applied to the pharmaceutical R&D, the success rate of new drug development projects dramatically declined (Tierney *et al.*, 2013; Malerba and Orsenigo, 2015). As a result, the internal rate of return of the biopharma R&D in the industry dropped from 25% in 1993 to only 1.9% in 2018 (Deloitte, 2018).

Some recent studies investigated this paradox of “more bioscience investment leading up to less commercial returns” and began to question the current R&D business model adopted in the pharmaceutical industry (e.g. Tierney *et al.*, 2013; De Alcantara and Martens, 2019). Pharmaceutical R&D activities used to be performed at a uniform platform based on a single chemical monomer technology (Tierney *et al.*, 2013). However, the biological revolution led to a fundamental technological discontinuity (Sabatier *et al.*, 2012; De Alcantara and Martens, 2019), in that the discovery and the development of new biochemical drugs require a completely different set of bioscientific technology competences (Bonaccorsi and Vargas, 2010; Sabatier *et al.*, 2012). Therefore, the existing dominant R&D logic of pharmaceutical firms following a single technology development pathway becomes insufficient (Sabatier *et al.*, 2012; Tierney *et al.*, 2013), because the latest advancement of biopharma innovations is often generated at the interface between multiple root biopharma research areas (Allhoff, 2009; Styhre, 2011). In this sense, innovations led by practitioners in DIY laboratories may push forward the frontier of biopharma research from a new angle (Fox, 2014, Seyfried *et al.*, 2014; Hecker *et al.*, 2018).

2.2 Biopharma research in Do-It-Yourself (DIY) laboratories as an inclusive innovation

Traditionally, biopharma research is mainly carried out in officially recognized organizations, such as universities, research institutes, or R&D departments of large pharmaceutical firms. Since early 1990s, the emergence of the DIY laboratories movement encouraged independent scientists and even science enthusiasts to participate in and contribute to the advancement of biopharma research and innovation (Landrain *et al.*, 2013; Sleator, 2016). Biopharma research in DIY laboratories varies greatly in terms of people involved, types of innovation activities, and ranges of projected outcomes (e.g. Schillo and Robinson, 2017; De Beer and Jain, 2018). On the one hand, DIY laboratories can be used by amateurs to just play and tinker with biotechnology (Landrain *et al.*, 2013). On the other hand, more serious research is carried out in DIY laboratories by independent scientists, with the aim to prototype and transform their biotechnology-based ideas into real scientific breakthroughs to generate economic returns (De Beer and Jain, 2018). For the purpose of this study, we only concentrate on the latter type of DIY laboratories.

Because DIY laboratories establish an unconventional setting for biopharma innovation at the “grassroots” level (Downes *et al.*, 2013), this phenomenon is commonly understood through the lens of inclusive innovation (De Beer and Jain, 2018). The overarching aim of the inclusive innovation campaign is to give rights, voices, capabilities and incentives for the previously excluded groups of the society to become active participants in processes of R&D and innovation (Johnson and Anderson, 2012). It is believed that inclusive innovation can develop novel, bottom-up solutions to address specific challenges and opportunities (De Beer and Jain, 2018). If

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

inclusive innovation can be successfully achieved and converted into entrepreneurial ventures, it will not only benefit the public, but also generate returns to innovators as well as other stakeholders (Hossain, 2018; Dana *et al.*, 2019).

However, inclusive innovation activities in DIY laboratories face several major challenges. Firstly, DIY laboratory research is often questioned by the public in term of its potential negative ethical implications (Wexler, 2016), its ambivalences in fostering responsible science (Tanenbaum, *et al.*, 2013; Stilgoe *et al.*, 2013), and its potential security threat to public health and environmental safety (Gorman, 2011). Secondly, as “grassroots” innovation, the research performed in DIY laboratories may lack sufficient funding supports. For example, one of the most important constraints of DIY laboratory research is the scarcity of financial resources to access advanced lab equipments (Landrain *et al.*, 2013). Thirdly, research performed in DIY laboratories may also lack regulative guidelines. The quasi-regulated experiments conducted in these rudimentary, DIY-based premises often fail to follow standard laboratory protocols (Wolinsky, 2005; Gorman, 2011; Revill and Jefferson, 2013). Thus the question is whether results of these experiments can be officially approved by withstanding further tests in a fully regulated setting. Fourthly, when an innovative finding generated from a DIY laboratory has been initially justified, the following commercialisation process requires that the value of this inclusive innovation can be effectively transferred in the social network and eventually accepted by relevant stakeholders (Schillo and Robinson, 2017). In this regard, unlike the mainstream research performed in official institutes in which innovation outcomes are easily published, patented and recognized by the public, the marginalised research in DIY laboratories lacks an established social-technical institutional system by which its innovation can be quickly received and adopted in the society (Dana *et al.*, 2019).

To address the challenges in both early development and later commercialisation process of the DIY laboratory-based innovation, some recent studies began to explore the possible connections between DIY laboratories and mainstream pharmaceutical networks (e.g., Schillo and Robinson, 2017; De Beer and Jain, 2018). For instance, to scale up their research projects with high growth potentials, innovators in DIY laboratories are suggested to proactively search for funding opportunities from either public agencies or venture capitals (De Beer and Jain, 2018). On the other hand, research collaborations with academics and industrial institutes, if possible, can harness innovation activities in DIY laboratories (Buys and Bursnall, 2007). Furthermore, early involvement of relevant stakeholders, such as financial sponsors and potential customers, can ensure that the innovation pathway of DIY laboratories is in line with current commercial expectations and needs (Fressoli *et al.*, 2014; Schillo and Robinson, 2017). In short, to realize its full commercial potential, DIY laboratory research needs to be integrated into an effective biopharma innovation ecosystem (De Beer and Jain, 2018).

2.3 Integrating DIY laboratories into pharmaceutical R&D networks: a conceptual framework

In order to fully capitalise on the recent advancement in biopharma research, various R&D models, such as biopharma consortium and collaborative discovery platform, are proposed and tested (Allarakhia and Walsh, 2012; Sabatier *et al.*, 2012; Tierney *et al.*, 2013; Lauto and Valentin, 2016). These new models aim to introduce multiple stakeholders into the biopharma business ecosystem (Lauto and Valentin, 2016), by which firms, research institutes, and others

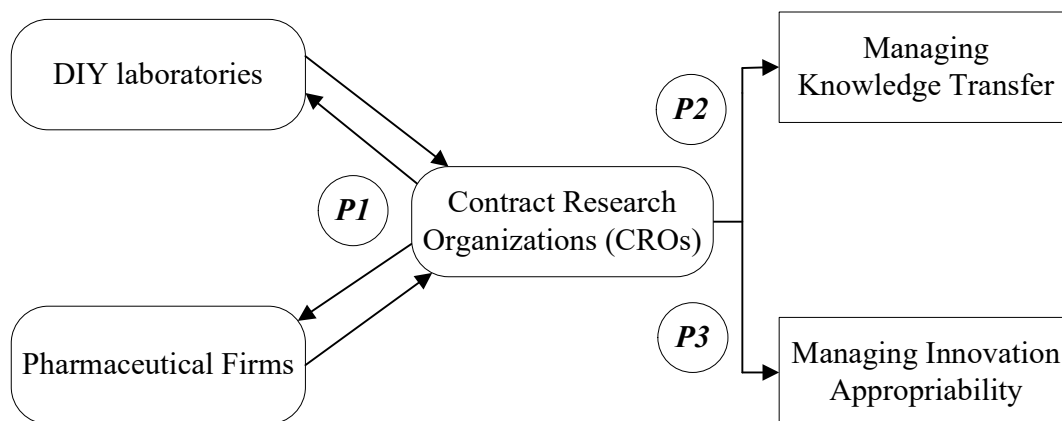
Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

can share their respective knowledge bases, resources and technical competencies in search for specific biopharma innovations (Tierney *et al.*, 2013; Lauto and Valentin, 2016).

As a new type of economic relationship, business ecosystem is defined as “the alignment structure of the multilateral set of partners that need to interact in order for a focal value proposition to materialize” (Adner, 2017: p. 42). The arrangement of a business ecosystem considers what players involved and their respective activities, as well as their interdependent positions and links (Adner, 2017). Moreover, different from other business constellations, such as strategic alliances and supply chains, business ecosystem is a loose alignment of interdependent entities, and lacks full hierarchical control and management (Adner, 2017; Jacobides *et al.*, 2018). It is thus broadly agreed that a hub firm is required in a business ecosystem to coordinate interrelated organizations that have significant autonomy (Iansiti and Levien, 2004; Williamson and De Meyer, 2012; Gulati *et al.*, 2012).

In line with the argument to create a business innovation ecosystem for pharmaceutical R&D (e.g. Allarakhia and Walsh, 2012; Lauto and Valentin, 2016), we propose a conceptual framework to integrate a new entity which has been largely ignored before, namely DIY laboratories, into pharmaceutical R&D networks (see Figure 1). According to this framework, DIY laboratories and pharmaceutical firms reside at the two ends of this business innovation ecosystem. At one end, DIY laboratories used to be excluded from pharmaceutical R&D networks. But based on the open-source science development principle (Landrain *et al.*, 2013), they have the potential to grow novel ideas for disruptive biopharma innovations (Seyfried *et al.*, 2014; Hecker *et al.*, 2018). At the other end, pharmaceutical firms are more interested in projects with high commercial potentials (Lauto and Valentin, 2016; De Beer and Jain, 2018). However, this narrow commercial focus may ignore new findings in relevant biopharma fields (Allhoff, 2009; Styhre, 2011). By linking these two entities and align their interests, CROs arguably can act as an important hub in this innovation ecosystem to transform the inclusive biopharma innovations originated from DIY laboratories into real economic returns and societal benefits. The reasons are threefold which pave the way for our research propositions.

<Insert Figure 1 about here>



Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

Figure 1 – Integrating DIY laboratories into pharmaceutical R&D networks: a conceptual framework

First, when independent innovators initiate biopharma innovation activities in DIY laboratories, their research can be facilitated by CROs via various means, such as financial supports, lab regulation guidance and lab equipment leasing. This ensures the early research in DIY laboratories having access to necessary tangible and intangible resources. Moreover, if proved successful in early tests, findings of DIY laboratory research can be introduced by CROs to large pharmaceutical firms with the aim to obtain further commercial investments (Fressoli *et al.*, 2014; De Beer and Jain, 2018). Therefore, we propose that:

Proposition 1: CROs can be important facilitators to bridge resource utilization between DIY laboratories and pharmaceutical firms.

Second, the literature suggests that one of the primary goals of business ecosystems is to encourage innovation through knowledge exchange among existing but previously widely dispersed, isolated parties (Dhanaraj and Parkhe; 2006; Pellinen *et al.*, 2012; Azzam *et al.*, 2017). For this purpose, CROs, acting as knowledge brokers, make it possible that ideas generated from DIY laboratories can be accessed and applied by pharmaceutical firms to the development of new drugs. Therefore, we propose that:

Proposition 2: CROs can play the hub role through managing and ensuring knowledge transfer between DIY laboratories and pharmaceutical firms.

Third, another primary goal of a business ecosystem is the management of the so-called innovation appropriability, i.e. the control of free riding behaviours to unfairly take away new ideas of other network members for commercialisation (Teece, 2000, Dhanaraj and Parkhe; 2006; Azzam *et al.*, 2017). Stated differently, value creations and equitable distributions among business ecosystem entities depend on the proper management of their intellectual property (IP) rights, especially patents (Leten *et al.*, 2013; Azzam *et al.*, 2017). In this regard, various IP arrangement models, such as co-ownership, cross-licensing and sub-licensing, have already been established between CROs and pharmaceutical firms in long-term R&D collaborations (Mirowski and Van Horn, 2005, Azzam *et al.*, 2017). Using or even renovating these IP models, CROs can encourage innovators in DIY laboratories to share knowledge with pharmaceutical firms through securing their technological collaborations (Azzam *et al.*, 2017). Therefore, we propose that:

Proposition 3: CROs can play the hub role through managing innovation appropriability between DIY laboratories and pharmaceutical firms.

3. Methodology

3.1 Research rationale and logic

All research is based on some underlying assumptions about what constitutes valid research and which research methods are appropriate (Morgan and Smircich, 1980). Making explicit the hidden assumptions and philosophical perspectives of the researcher is thus important because

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

they shape the logistics of the reasoning by which the researcher conducts/or evaluates the research (Easterby-Smith *et al.*, 2008). In this study, a new type of social/economic phenomenon is explored, namely an emergent business ecosystem mainly composed of CROs, DIY laboratories and pharmaceutical firms. We thus adopt a critical realism stance because such a research perspective allows us to explore the nature of a complex social phenomenon through various interpretations (Bhaskar, 1989; Blaikie, 2007).

This study is exploratory in nature. We follow a retrodution logic according to the critical realism perspective (Ragin, 1994; Harrison 2012), to enable the interplay between the relevant deduction and induction processes (see Figure 2). The pre-developed conceptual framework and research propositions are used to deductively navigate the research. However, we also intend to extend the initial conceptual framework based on emerging evidences from empirical studies.

<Insert Figure 2 about here>

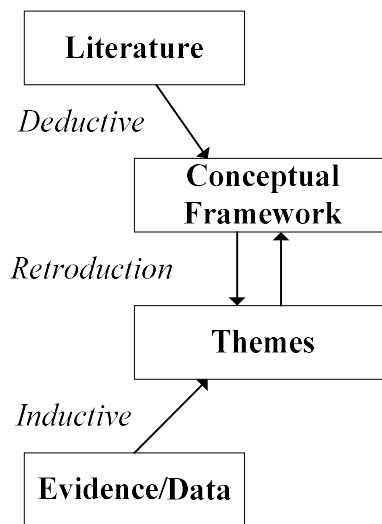


Figure 2 – The retrodution logic

Specifically, based on the relevant literature a conceptual framework is deduced. This conceptual framework and the related research propositions help to focus our study on two analytical categories: (1) interdependent positions and linkages between CROs, DIY laboratories and pharmaceutical firms as three key entities in a business innovation ecosystem; and (2) the hub role of CROs in coordinating the knowledge flow between DIY laboratories and pharmaceutical firms through resource utilization and innovation appropriability management. On the other hand, emerging themes are inductively generated from the evidence/data collected by the embedded case study. These induced themes are then iteratively compared and synthesized into the analysis, until a refined analytical framework is finally constructed through a retrodution reasoning process (Ragin, 1994).

Because what we are going to investigate is an emerging and complex social phenomenon (Eisenhardt and Graebner, 2007), we conduct an embedded case study and use three identified sub-units, namely CROs, DIY laboratories and pharmaceutical firms to gain multiple sources of evidence for better certainty in results (Scholz and Tietje, 2002; Yin, 2003). In addition, as

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

explained in Section 3.2 and 3.3, we use various means to ensure the external validity and reliability of our case study.

3.2 The sample cases in the Chinese pharmaceutical industry

In this case study we focus on the Chinese pharmaceutical industry. First, the Chinese pharmaceutical industry is now a major destination of R&D related foreign direct investment (FDI) of world-leading pharmaceutical firms (Zhao *et al.*, 2020). Second, top Chinese CROs, such as WuXi AppTec, are capable of providing end-to-end CRO services, and have built strong partnerships with leading pharmaceutical firms (Xia and Gautam, 2015). Third, as mentioned in Section 2.1, in the last decade large pharmaceutical firms gradually reconfigured their internal R&D base and downsized existing R&D teams (Masri *et al.*, 2012). During this wave many Chinese scientists who used to work in international pharmaceutical firms returned to China, and established their DIY laboratories to carry out independent biopharma research. In short, the Chinese pharmaceutical industry is a suitable research context because it has now become highly globalized and an indispensable part of the global pharmaceutical industry, in which the three key players in our case study, i.e. CROs, DIY laboratories and pharmaceutical firms can be identified.

A world-leading CRO, a multinational pharmaceutical firm and two DIY biotech laboratories which fit for our sampling criteria were selected (see Table 1). The selected CRO (CRO Co) is one of the top 10 CROs in the world. Established in 2000, it has now become a full-service CRO providing a broad portfolio of R&D and manufacturing services to pharmaceutical, biotech and medical device industries worldwide. We chose this CRO because one of its strategic objectives is to pioneer an open-access R&D platform on which worldwide scientists, technologists, and entrepreneurs can work together for biopharma innovations. This open R&D platform was initiated in 2011. By 2015, it has invested more than 350 million US dollars in over 40 bioscience start-ups, many of which are based in DIY laboratories.

The selected pharmaceutical firm (PHARM Co) was established in 1973. As one of the top 5 in the world, it entered China as early as 1982 and has built close collaborations with CRO Co. The selected DIY biotech laboratories (DIY A and DIY B), are the newly established start-ups which concentrate on tumour drug development, and have contractual relationships with CRO Co.

<Insert Table 1 about here>

Table 1 – Background of case companies

Company Type	Year of Foundation	Number of employees
The full-service CRO (CRO Co)	2000	c. 18,000
The pharmaceutical firm (PHARM Co)	1973	c. 9,000 in Great China
DIY biotech laboratory (DIY A)	2015	18
DIY biotech laboratory (DIY B)	2017	1.5 (one full-time employed and one part-time employed)

This embedded case study includes multiple sub-cases in a biopharma innovation ecosystem. This allows us to form a chain of evidence (Yin, 2003) to examine and compare perspectives of

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

the three different players involved regarding: (1) to what extent CROs can facilitate the development and transfer of innovative findings of the DIY laboratories in pharmaceutical R&D networks, so as to create both economic returns and societal benefits; (2) in what ways such a facilitating role can be achieved.

3.3 Data collection and data analysis

Using the CRO Co as the proxy, a snowball sampling was applied for data collection. First, we approached senior managers of the target CRO for initial data collection. Then through the introduction of the senior managers of the CRO Co, we approached and conducted interviews with a pharmaceutical firm and two DIY laboratories. The data collection was undertaken in two rounds (see Table 2). In the first round, we conducted a face-to-face interview with the executive vice president of the CRO Co and gained access to the company’s relevant documents, such as business plans and auditing reports. We then interviewed the general manager of the CRO Co, with the aim to both verify findings of the first interview and gain more enriched information. In the second round, we interviewed the Vice President of the Chinese subsidiary of the PHARM Co (the pharmaceutical firm) which was a main client of the CRO Co, and two DIY biotech laboratory founders whose innovations were fully supported by the CRO Co. The entire interview process was completed over a period of 13 months, with each interview lasted between approximately 40 minutes to 2 hours.

<Insert Table 2 about here>

Table 2 – In-depth interviews

Interviewee		Date (Duration)	Job Title	Company
First-round	Interviewee 1 (I1) <i>(face-to-face discussion)</i>	April 2018 (112 minutes)	Executive Vice President	CRO Co
	Interviewee 2 (I2) <i>(face-to-face discussion)</i>	April 2018 (56 minutes)	General Manager of SMO service	CRO Co
Second-round	Interviewee 3 (I3) <i>(face-to-face discussion)</i>	April 2019 (60 minutes)	Vice President in Great China	PHARM Co
	Interviewee 4 (I4) <i>(Skype meeting)</i>	April 2019 (44 minutes)	Founder	DIY-A
	Interviewee 5 (I5) <i>(Skype meeting)</i>	May 2019 (48 minutes)	Founder	DIY-B
<i>Note: Interviewee 1 to interviewee 5 are abbreviated as I1 to I5 hereafter.</i>				

For the purpose of data collection, a general interview guide was prepared based on the reviewed literature, and our conceptual framework and research propositions. With the aim to ensure that the following interviews are within the research boundary of our study, this guide supported the development of a semi-structured interview with several open-ended questions to encourage the interviewees to freely express their opinions. The guide was firstly used to conduct interviews with two senior managers of the CRO Co. It was then slightly modified in the following interviews with the PHARM Co and DIY laboratories, in order to fit their specific business contexts.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

In the progress of interviews and the ongoing analysis, the interviewees were classified into three case groups, namely the CRO, the pharmaceutical firm and the DIY laboratories. Facilitated by NVivo 10, we conducted both within-case analysis and cross-case analysis. First, the interview responses in each case group were classified and directed toward emergent themes and concepts through a code interpretation procedure (Strauss and Corbin, 1998). Then guided by the conceptual framework and the literature, these themes and concepts were continuously synthesized and refined within the two preset analytical categories which were explained in Section 3.1. Using a retroduction logic (see Figure 2), where necessary, new themes were constructed from the data to replace the old ones. Alternatively, the former deduction-based analytical framework was revised to reflect the emerging findings from the case data analysis. Second, the codification groups finalized by the within case study were synthesized through an interpretive, cross-case analysis (Yin, 2003) to derive two knowledge transfer models among the case study entities.

To ensure data quality, we performed a cross-comparison of findings between the first and second-round interviews, as well as the relevant document analysis (Yin, 2003). Moreover, two researchers have each independently checked the transcripts and the codifications to reach an inter-rater reliability of 71% (Gwet, 2014). Any disagreements were discussed, and final agreement reached between the two researchers.

4. Findings

The findings of this case study are twofold. First, the positioning and linkages of DIY laboratories, the CRO and pharmaceutical firms, as three key pharmaceutical R&D members identified in a business ecosystem, are delineated along the new drug development pipeline. Second, two knowledge transfer models are revealed by which the inclusive biopharma innovations developed in DIY laboratories can be converted into real economic returns. In these two models the facilitating role of the CRO is especially recognized in connecting DIY laboratories to the R&D platform of the pharmaceutical firm. These findings have important general implications to the business ecosystem formed by DIY laboratories, the CRO and pharmaceutical firms.

4.1 The alignment structure of DIY laboratories, the CRO and pharmaceutical firms in the business ecosystem for new drug development

According to the literature review and interview responses, the pipeline of new drug development is generally composed of four stages (see Figure 3): (1) at the drug discovery stage, initially, a gene or protein (therapeutic agent) that has a significant role in disease is identified and verified, which is called a biological target. Then an active pharmaceutical compound is developed and screened out to be the drug candidate, which is proved to have therapeutic effect on the biological target; (2) at the preclinical research stage, non-human metabolism and side-effect tests are performed on this candidate drug to verify its mechanisms of action, potential benefits, efficacy and safety; (3) at the clinical study stage, three phases of both small-scale and large-scale human safety tests of this new drug are carried out; (4) at the final regulatory review stage, once the new drug has been formulated for its best efficacy and safety, and results from clinical trials become

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

available, the new drug is submitted for regulatory approval for market entry. After that the long-term effect of the new drug will be continuously monitored.

<Insert Figure 3 about here>

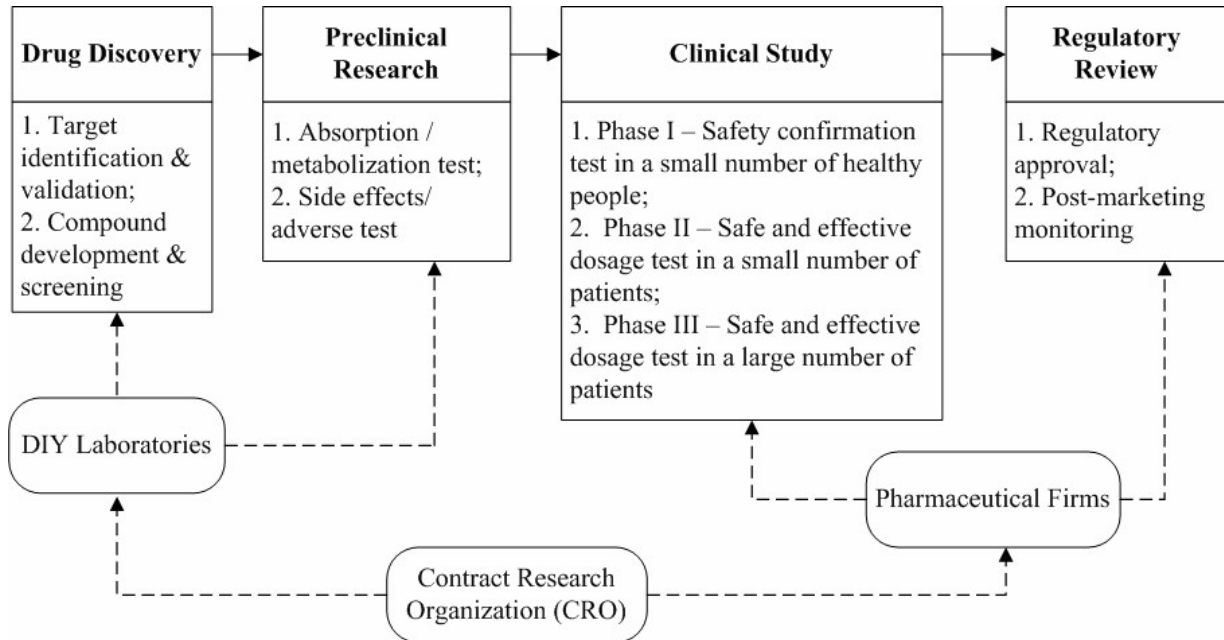


Figure 3 – The positioning and linkage of DIY laboratories, the CRO and pharmaceutical firms in the drug development pipeline

4.1.1 The positioning and linkages between DIY laboratories and the CRO in the new drug development pipeline

In this new drug development pipeline, DIY laboratories are positioned at the early discovery and the preclinical research stages (see Figure 3) for two main reasons. First, organised in small teams and following an open-source principle, research in DIY laboratories, to some extent, is more likely to raise novel, creative scientific assumptions in terms of new biological target identification. Second, unlike the large-scale, official drug development projects which are sponsored and tightly controlled by pharmaceutical firms or governmental bodies, DIY laboratory research does not need to follow conventional and stringent approval procedures, as well as detailed sometimes unnecessary planning and reporting processes. It is believed that such an open innovation environment positively impacts on the disruptive innovation capability of DIY laboratories.

“The research team in my DIY lab is no more than 20 people. But this is exactly our advantage. A small-sized team means that we do not need to be managed as an army. Rather, each of our team members, based on their own talents, can bring with unexpected ideas from new perspectives.” [14]

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

“I used to be a drug scientist working in a leading pharmaceutical company. I chose to be the founder of this DIY laboratory start-up because I found that the company I used to work for concentrated too much on the so-called reliable, but narrow-minded research fields. However, here I have the opportunity to test my genuine ideas without too much concern about short-term, foreseeable goals.” [I5]

Meanwhile, founders of the two DIY laboratories also admit that, in their innovation activities, they lacked sufficient financial, technical and procedural supports in both lab research and the following commercialisation process. To this end the CRO can contribute. On the one hand, the CRO can support DIY laboratories in terms of research funding and laboratory services. On the other hand, at the preclinical research stage, based on its long-term experience in both pre-clinical and clinical trials, the CRO can provide the relevant protocol guidance (see Figure 3).

“Of course the broad aim of my DIY lab is drug innovation. But at present with my limited budget, it is not realistic to invest heavily in laboratory, equipments and plant. So I choose to cooperate with the CRO as a supportive platform for our new drug development.” [I5]

“As a senior manager of the CRO, I contacted many DIY laboratory start-ups and found a big gap. That is, the founders of these start-ups are scientists or professors. Their mind frame in drug development is not what the market needs. Instead, they focus only on what they can do, or what they happen to find. In addition, these DIY innovators know quite well about early drug development. However, they are not familiar with the requirements and processes involved in the following clinical trial and regulatory approval. We can use our resource and expertise to meet the above-mentioned gap.” [I1]

4.1.2 The positioning and linkages between pharmaceutical firms and the CRO in the new drug development pipeline

Pharmaceutical firms dominate the latter clinical study and regulatory review stages (see Figure 3). One reason is that the costly and time-consuming research and trial activities in later stages of new drug development involve huge financial investments, which can only be afforded by leading pharmaceutical firms. More recently, the limited success rate of new drug development projects forces these pharmaceutical firms to focus only on those that can be more realistically implemented to generate foreseeable commercial returns. In this regard, the CRO can help pharmaceutical firms to not only suitably manage their drug development projects, but also reduce the relevant operational cost (see Figure 3).

“Broadly speaking, to cope with the surge in drug development spending, all major pharmaceutical firms begin to cut off their ongoing investigation projects which showed little promising future. For example, our pharmaceutical company now only focuses on the tumour and diabetic drug development fields which have the potential to generate more than 1 billion US dollars market return per year in the future. We work closely with our CRO partner to achieve our R&D goals.” [I3]

“As a CRO, our company actively collaborates with global pharmaceutical firms in new drug development. Last year FDA approved 43 new drugs. Our company participated in the R&D

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

processes of 34 out of them. In fact, right now our business portfolio covers the entire R&D pipeline of the global pharmaceutical industry. Therefore, we can offer end-to-end services to pharmaceutical firms' drug development." [I2]

4.2 Integrating DIY biopharma research into R&D platforms of pharmaceutical firms: the two knowledge transfer models

After clarifying the positions and linkages between DIY laboratories, the CRO and the pharmaceutical firm in a business ecosystem for pharmaceutical R&D, our study further investigates possible mechanisms to integrate DIY laboratories into mainstream pharmaceutical networks. To this end our research findings reveal two knowledge transfer models by which novel DIY research findings can be effectively identified, verified and applied to new drug development. It is worth noting that the development of these two knowledge transfer models follows an incremental process, in which venture capitals (VC) are introduced as new investors (a new entity) at the later stage.

4.2.1 The IP + CRO model

When the CRO initially collaborates with DIY laboratories in new drug development projects, a so-called IP + CRO model is followed (see Figure 4). Here the intellectual property (IP) represents the core patent rights obtained by DIY laboratory research teams who focus on the early stage of new drug development.

<Insert Figure 4 about here>

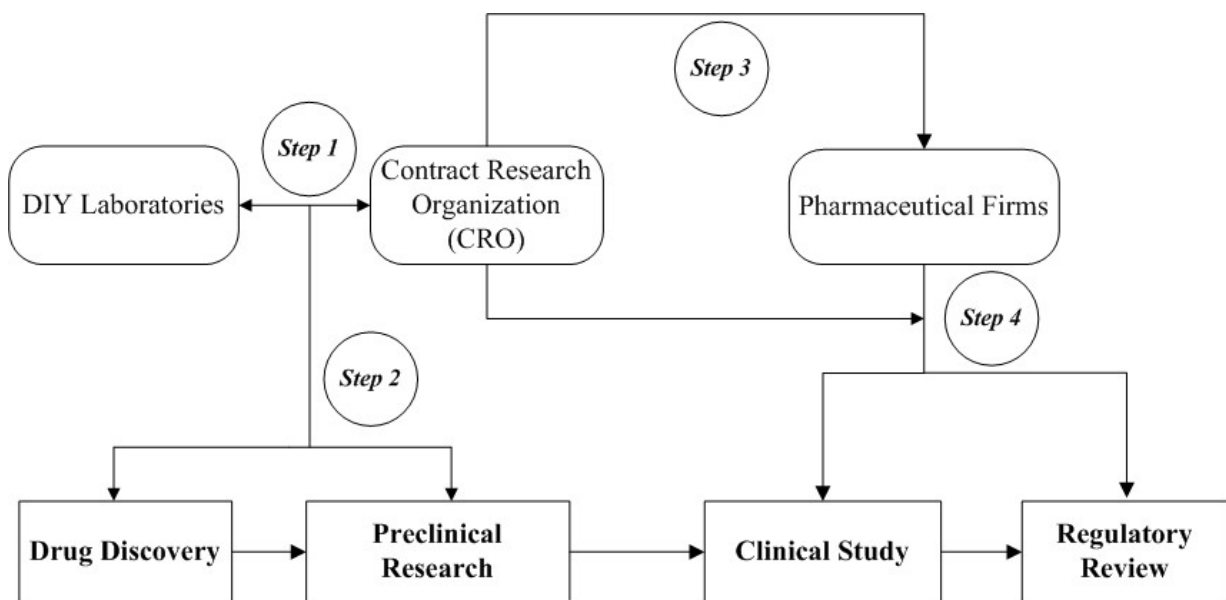


Figure 4 – The IP + CRO model

This IP + CRO model represents the initial structure of a business ecosystem formed by DIY laboratories, the CRO and pharmaceutical firms. As showed in Figure 4, because DIY

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

laboratories and pharmaceutical firms are previously isolated, the CRO plays a pivotal role to bridge these two entities along the new drug development pipeline. On the one hand, in the layer of relationship between DIY laboratories and the CRO, initial drug discovery and preclinical research are carried out. On the other hand, in the layer of relationship between pharmaceutical firms and the CRO, the subsequent clinical study and regulatory review are performed. The major four steps involved in this collaborative R&D process are illustrated as below.

Step 1: the CRO uses its online portal to welcome DIY laboratories to submit their drug development proposals. Once the proposal of a DIY laboratory passes the test of its internal incubation platform, the CRO initiates an exclusive collaboration contract with this DIY laboratory. This contract delineates both parties' responsibilities, liabilities and commercial rights at different drug development stages. The contract also states a shared IP ownership structure if the project will be successful in the future, and an exit mechanism in case of the project failure.

Step 2: based on this exclusive collaboration contract, both parties begin the early drug development. In this step, the DIY laboratory concentrates more on biological target identification and molecule design, while the CRO is mainly responsible for the drug tests of efficacy, toxicity and pharmacokinetics. Such a division of labour proves to be an effective way to reduce costs and time and to increase efficiency and success rate.

“As a DIY lab, we know our unique advantage, which is drug molecule design. So why not we let our collaborator, the CRO help us finish the following lab tests? They are better in this part.” [I4]

“When a DIY lab is chosen to work with our CRO company, what we value is whether this DIY lab has its unique technology advantage..... But we also have our own advantage. For example, all the preclinical drug tests can be done faster and cheaper in our company's lab platform. More importantly, our lab platform receives the accreditation of College of American Pathologists (CAP). This means our drug test results will be accepted worldwide. So what I can say is that DIY lab plus CRO is a win-win solution.” [I1]

Step 3: when early development process of a new drug is successfully accomplished, the CRO seeks to transfer this new drug technology (together with the related patent rights) to pharmaceutical firms. Through its long-term R&D collaboration with world-leading pharmaceutical firms, the CRO has already obtained deep insight into the emerging trend of new drug development in the global pharmaceutical industry. Therefore, before the CRO prepares to sponsor a DIY-based drug development project, its potential market value has been systemically evaluated. Meanwhile, after a new drug project is initiated, the CRO periodically shares its investigation progress and research data with potential buyers, in order to maximize the transfer success rate.

“As a CRO, we work not only with biopharma start-ups such as DIY laboratories, but also pharmaceutical firms. We know their individual expertise and respective needs. So we can act as a bridge to link them together to develop new drugs in an effective and cost-efficient way.” [I2]

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

Step 4: after a new drug technology has been successfully transferred to pharmaceutical firms, based on its R&D service expertise, the CRO can still contribute to the relevant trial and approval tests for the following clinical study and regulatory review.

“In addition to introducing suitable start-up drug projects to pharmaceutical firms, our CRO company also helps them to perform the subsequent clinical trials monitoring, medical and safety reviews, as well as data and statistical analysis. [12]

Using the IP + CRO model, the CRO aligns the interests between DIY laboratories and pharmaceutical firms and orchestrates their individual resources and expertises for new drug development. Moreover, the patent ownership and transfer agreements between DIY laboratories, the CRO, and pharmaceutical firms ensure that their IP rights can be protected. The IP + CRO model is thus proved to be a viable mechanism for the knowledge transfer between DIY laboratories and pharmaceutical firms.

4.2.2 The VC + IP + CRO model

In the above-mentioned IP + CRO model, by transferring early-stage drug technologies to pharmaceutical firms, innovators in DIY laboratories and the CRO receive their respective commercial returns. Meanwhile, pharmaceutical firms obtain valuable pharmaceutical projects to invest. As the value of DIY laboratories has been increasingly recognized by not only the CRO, but also pharmaceutical firms, a VC + IP + CRO model emerges which intensifies such a technology transfer in both speed and scale (see Figure 5).

<Insert Figure 5 about here>

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

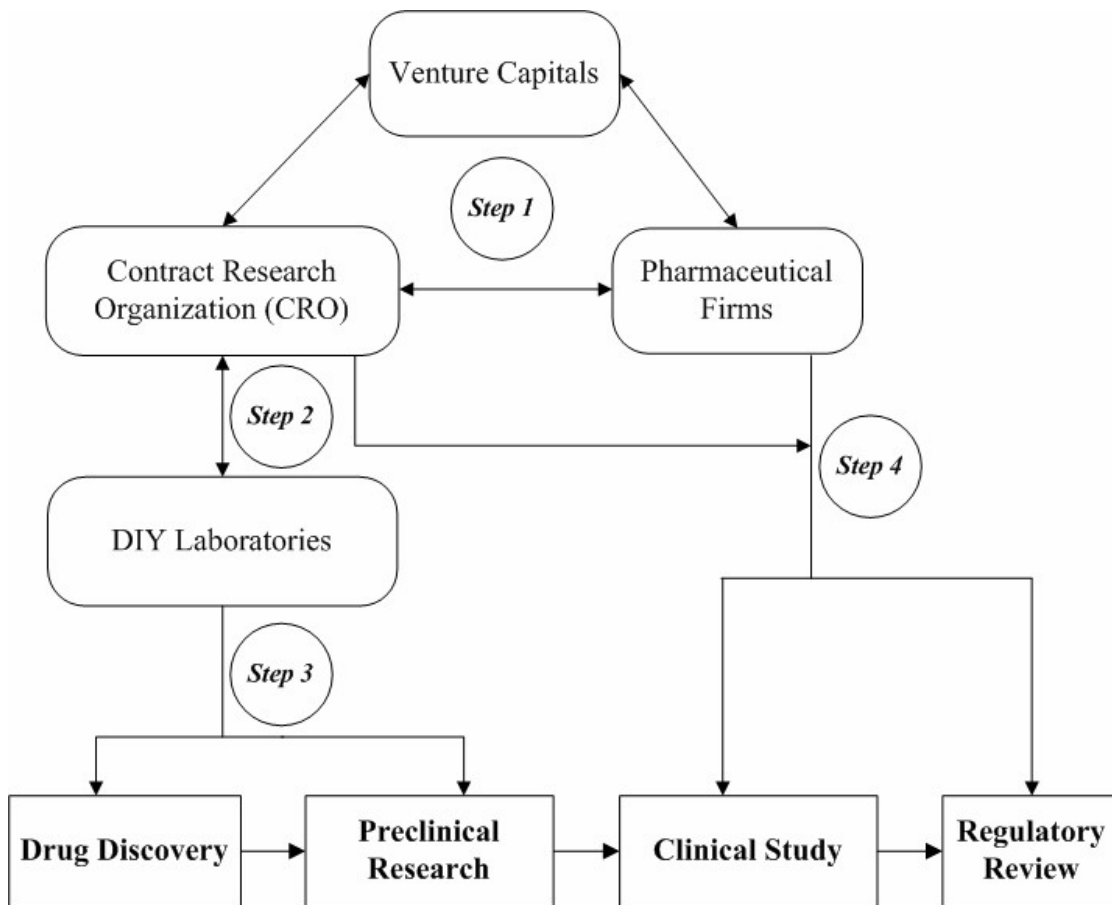


Figure 5 – The VC + IP + CRO model

In this VC + IP + CRO model, pharmaceutical firms become active players to work with the CRO in search of innovative biopharma findings in DIY laboratories. Venture capitals are also introduced as investors in new drug development. As explained in the following steps, based on the mutual investment fund with pharmaceutical firms and venture capitals, the CRO is able to systematically introduce the previously ignored research by DIY laboratories into existing pharmaceutical R&D networks.

In Step 1, the operation of the VC + IP + CRO model begins with a framework agreement between the CRO and pharmaceutical firms. This agreement sets up a timeframe under which a pharmaceutical firm authorizes the CRO to offer comprehensive R&D services in one or more new drug development fields. Based on this framework agreement, normally both parties seek the participation of external venture capitals to establish a mutual investment fund for early drug development, so as to alleviate their own investment burdens and financial risks. As such, three parties are introduced into this mutual investment fund, namely the CRO, pharmaceutical firms and venture capitals.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

“As a pharmaceutical firm, we already noticed that a number of start-ups, such as DIY labs, have emerged which specialize in various biopharma research fields. We hope to work with them if possible.” [I3]

“Our pharmaceutical firm values this VC + IP + CRO model not only because it improves industry-wide R&D efficiency, but also because it has the potential to push forward the frontier of biopharma research by introducing DIY labs as a new player.” [I3]

In Step 2, supported by the mutual investment fund, the CRO globally searches for pioneering research ideas in targeted drug development fields.

“As a CRO, we aim to be a facilitator for new drug development worldwide. The open-access technology service platform we are currently establishing is to connect all the players into a biopharma innovation ecosystem.” [I1]

Similar to the above-mentioned IP + CRO model, in Step 3 the CRO collaborates with identified DIY laboratories to perform early drug development. After that newly developed drug technologies can be passed to pharmaceutical firms for following tests and approval in Step 4.

“Based on this VC + IP + CRO model, our CRO company can transform an idea from scratch into a new drug between DIY labs and pharmaceutical firms. On the one hand, for DIY innovators we provide both financial and technological supports. On the other hand, for pharmaceutical firms we not only introduce new projects worthwhile to invest, but also deliver the following R&D services.” [I1]

The VC + IP + CRO model enhances the interrelationship between multiple stakeholders in a biopharma innovation ecosystem in two aspects. First, the involvement of pharmaceutical firms and venture capitals in early drug development brings sufficient financial and managerial resources for the CRO to establish an open platform for biopharma innovations. Second, the CRO can use this platform to approach and select worldwide biopharma DIY laboratories as its potential investment targets. Therefore, through a closer collaboration between pharmaceutical firms, venture capitals, the CRO and DIY laboratories, new biopharma inventions originated from DIY laboratories can be more effectively transformed to generate economic returns.

“Via the channel provided by our CRO partner, the biopharma findings in our DIY lab can be quickly recognized and evaluated by main pharmaceutical firms.” [I4]

“Facilitated by our CRO company, there are a number of successful transfer cases between DIY laboratories and pharmaceutical firms. For example, in 2015 we collaborated with a DIY lab which was specialized in a rare disease drug. At the moment there were only two full-time members in that lab. But based on the funding and the mature R&D platform provided by us, the pharmacokinetics test of this drug proved to be positive only after 18 months. This project was valued at 250 million US dollars and quickly sold to a big pharmaceutical firm.” [I1]

5. Discussion

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

As an emerging type of inclusive innovation, biopharma research in DIY laboratories has received increasing attention from both industry and academia. One key question is how this grassroots research can be aligned with and integrated into mainstream pharmaceutical R&D activities, so as to generate both economic returns and societal benefits (Schillo and Robinson, 2017; De Beer and Jain, 2018). From an innovation ecosystem perspective (Adner, 2017; Jacobides *et al*, 2018), we conducted an embedded case study to address this issue.

Our empirical findings suggest that potential economic returns and societal benefits of DIY biopharma research can be achieved through two knowledge transfer models. In the IP + CRO model, because the previously isolated DIY laboratories and pharmaceutical firms are connected by the CRO, the knowledge transfer between these two entities becomes possible. The inclusive DIY innovations in various biopharma research areas can thus be accessed and used by pharmaceutical firms. As showed in the knowledge transfer activities identified by our study, new drug projects successfully developed based on the IP + CRO model not only bring economic returns, but also contribute to societal benefits such as the improvement of public health.

Upgraded from the IP + CRO model, the VC + IP + CRO model further enhances the above-mentioned knowledge transfer process. The inclusion of venture capitals in the VC + IP + CRO model leads to an innovative “interest-sharing and risk-sharing” business model for new drug development by establishing a mutual investment fund between venture capitals, pharmaceutical firms and the CRO. As a result, sufficient investments enable the CRO to establish an open-access technology service platform on which all the players involved can work collectively for biopharma innovation. The creativeness of this open-access technology service platform is manifested in two aspects (see Figure 6). On the one hand, the input from pharmaceutical firms and venture capitals includes not only financial supports, but also relevant knowledge and managerial resources which ensure that the new drug projects carried out on the platform are guided by real market needs. On the other hand, instead of contacting and collaborating with DIY laboratories on a case-by-case basis, the CRO uses the platform to provide a uniform technology support structure by which multiple DIY biopharma research projects can be performed simultaneously.

<Insert Figure 6 about here>

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

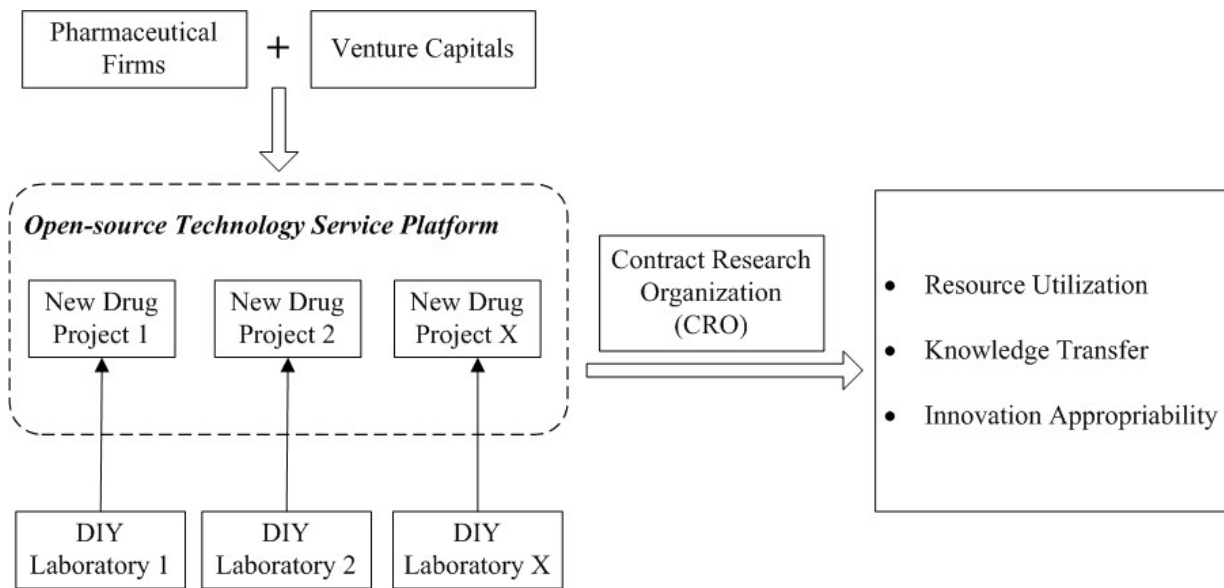


Figure 6 – The hub role of the CRO in the biopharma innovation ecosystem

Existing literature argues that, because the interdependent entities involved in a business innovation ecosystem lack hierarchical control and management, a hub firm is needed to play a coordination role (Williamson and De Meyer, 2012; Adner, 2017). In this regard, to integrate DIY laboratories into mainstream pharmaceutical R&D networks, the CRO acts such a hub role through the management of resource utilization, knowledge transfer and innovation appropriability among DIY laboratories, pharmaceutical firms and venture capitals (See Figure 6).

To form an innovation ecosystem participated by DIY laboratories and pharmaceutical firms, one challenge is how to coordinate their different priorities and expectations. Researchers based in DIY laboratories focus more on the originality of their findings, but often lack the understanding of how these findings can meet future market needs (Fressoli *et al.*, 2014; Schillo and Robinson, 2017). On the contrary, although pharmaceutical firms are eager to invest in new drug projects with high commercial potential (Lauto and Valentin, 2016; De Beer and Jain, 2018), they do not have direct channels to access and evaluate the true value of biopharma initiatives originated from DIY laboratories. The information asymmetry between DIY laboratories as innovators, and pharmaceutical firms as potential investors, is the major barrier to connecting and collectively utilizing these two parties' respective resources.

To this end, the CRO can align the interests of DIY laboratories and pharmaceutical firms in two aspects. On the one hand, through its long-term R&D collaboration with a number of pharmaceutical firms, the CRO is familiar with every major step in drug development. The CRO also understands what R&D resources are valuable to pharmaceutical firms. On the other hand, by stepping into the research works in DIY laboratories, the CRO can gain deep insight into the patent and investment value of these grassroots innovations. By establishing and managing an open-access platform to connect and facilitate both DIY laboratories and pharmaceutical firms, the CRO not only systematically reduces information asymmetry, but also encourages R&D resource combination and synchronization between DIY laboratories and pharmaceutical firms.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

The CRO also performs the knowledge broker role in facilitating the information exchange and knowledge transfer among DIY laboratories, pharmaceutical firms and venture capitals. First, pharmaceutical firms lack reliable methods to verify the experiment results produced in DIY laboratories. Therefore, the CRO, as the knowledge broker, needs to endorse the authenticity of these results. In this sense, our findings suggest that the CRO has measures to ensure that the lab drug tests of their collaborative DIY research projects pass the College of American Pathologists (CAP) accreditation. Second, biopharma drug development is normally featured in a long-term R&D lifecycle. To help pharmaceutical firms continuously monitor and evaluate the ongoing new drug projects in DIY laboratories, the CRO periodically publishes the relevant research progress of these projects. Third, venture capitals participating in new drug development concern more with the initial cost, the project timeframe, the anticipated risk, and the rate of return of their invested projects. The CRO thus cooperates closely with venture capitals to work out and implement a detailed business plan following the pre-agreed investment milestones.

Furthermore, to control the potential innovation appropriability disputes involved in new drug development, the CRO creates a novel IP arrangement, under which the drug development contract between DIY laboratories and the CRO stipulates their IP co-ownership structure based on their respective tangible and intangible inputs, such as patent rights, financial investments and technology supports. Once the new drug technologies are acquired by pharmaceutical firms, the attached patent rights are transferred as well. Then the payback is divided between DIY laboratories and the CRO according to their agreed IP ownership share. Therefore, this IP arrangement secures the individual patent rights of DIY laboratories, the CRO and pharmaceutical firms in the knowledge creation and transfer process.

6. Conclusion

This paper examines and clarifies the basic mechanisms through which the integration of DIY laboratories into R&D networks of the pharmaceutical industry can be possible. Our empirical study based on multiple entities in a pharmaceutical R&D network demonstrates clear knowledge transfer processes between DIY laboratories, CROs and pharmaceutical firms.

As an early attempt to extend the perspective of business innovation ecosystem (Adner, 2017; Jacobides *et al*, 2018) into the study of DIY laboratories, this paper explains the interdependent relationship between DIY laboratories, CROs, pharmaceutical firms and venture capitals in an innovation ecosystem. The important hub and knowledge broker roles of CROs are also clarified in aligning different priorities and expectations of multiple entities in this innovation ecosystem.

This paper depicts a clearer picture of relationships between different entities in the biopharma ecosystem, in which different players are less bounded by loose hierarchical or market controls but more by layers of mutually beneficiary relationship models. Moreover, this paper provides important evidence of how economic returns and societal benefits are generated by inclusive innovation models (Schillo and Robinson, 2017). It also answers previous calls for research on how business ecosystems will benefit the industry and the society (Schillo and Robinson, 2017; De Beer and Jain, 2018). This paper thus paves the way for larger scale research of the dynamics of emerging innovation ecosystems in general.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

This paper provides an important practical guidance by mapping two knowledge transfer models (IP + CRO and VC + IP + CRO) through which grassroots knowledge from DIY laboratories can be converted into commercialisable products. These models will enable managers and policy makers to better understand and choose the optimized approach to engage the vast number of DIY laboratories into R&D networks of the contemporary pharmaceutical industry and to generate both commercial and social returns from more effective R&D activities. In particular, the important hub role played by CROs will also call for further attention from investors and policy makers to better regulate and improve services of CROs, which can be a centre element in the contemporary biopharma innovation ecosystem.

This study has some limitations which deserve future research. First, an embedded case study was conducted, such that all the sample cases are from the same innovation ecosystem. Future research could examine multiple different innovation ecosystems to generate more diversified evidence of the composition of biopharma innovation ecosystems. Second, because there is limited research clarifying mechanisms of biopharma innovation ecosystems involving DIY laboratories, this study is rather exploratory in nature. Future researchers could develop explanatory studies to examine the substantive underlying relationships between barriers/enablers and the innovation contribution of DIY laboratories in pharmaceutical R&D networks. Third, this study focuses on the pharmaceutical industry. Although in-depth results are provided in a contextualized manner, future researchers could extend this study into other industries, such as ICT and bioengineering, to gain more comprehensive understanding of roles of DIY laboratories in innovation ecosystems of various industry sectors.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

References

Adner, R., 2017. Ecosystem as structure: an actionable construct for strategy. *Journal of Management*, 43(1), 39-58.

Allarakhia, M. and Walsh, S., 2012. Analyzing and organizing nanotechnology development: Application of the institutional analysis development framework to nanotechnology consortia. *Technovation*, 32(3-4), 216-226.

Allhoff, F., 2009. The coming era of nanomedicine. *The American Journal of Bioethics*, 9(10), 3-11.

Azzam, J. E., Ayerbe, C. and Dang, R. J., 2017. Using patents to orchestrate ecosystem stability: The case of a French aerospace company. *International Journal of Technology Management*, 75(1-4), 97-120.

Bhaskar, R., 1989. *Reclaiming Reality: A Critical Introduction to Contemporary Philosophy*, Verso, London.

Blaikie, N., 2007. *Approaches to social enquiry: Advancing Knowledge*. Polity Press, Cambridge, UK.

Bonaccorsi, A. and Vargas, J., 2010. Proliferation dynamics in new sciences. *Research Policy*, 39(8), 1034-1050.

Buys, N. and Bursnall, S., 2007. Establishing university–community partnerships: Processes and benefits. *Journal of Higher Education Policy and Management*, 29(1), 73-86.

Coccia, M. and Wang, L., 2015. Path-breaking directions of nanotechnology-based chemotherapy and molecular cancer therapy. *Technological Forecasting and Social Change*, 94, 155-169.

Dana, L.P., Gurău, C., Hoy, F., Ramadani, V. and Alexander, T., 2019. Success factors and challenges of grassroots innovations: Learning from failure. *Technological Forecasting and Social Change* (in press).

De Alcantara, D.P. and Martens, M.L., 2019. Technology Roadmapping (TRM): a systematic review of the literature focusing on models. *Technological Forecasting and Social Change*, 138, 127-138.

De Beer, J. and Jain, V., 2018. Inclusive Innovation in Biohacker Spaces: The Role of Systems and Networks. *Technology Innovation Management Review*, 8(2), 27-37.

Deloitte, 2018. *Unlocking R&D productivity: measuring the return from pharmaceutical innovation 2018*. GlobalData, UK

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

Dhanaraj, C. and Parkhe, A., 2006. Orchestrating innovation networks. *Academy of Management review*, 31(3), 659-669.

DiMasi, J.A. and Grabowski, H.G., 2007. The cost of biopharmaceutical R&D: is biotech different? *Managerial and Decision Economics*, 28(4-5), 469-479.

Downes, J., Breeze, M. and Griffin, N., 2013. Researching DIY cultures: towards a situated ethical practice for activist-academia. *Graduate Journal of Social Science*, 10(3), 100-124.

Easterby-Smith, M., Thorpe, R., Jackson, P. and Lowe, A., 2008. *Management Research: Theory and Practice*. Sage Publications, UK.

Eisenhardt, K.M. and Graebner, M.E., 2007. Theory building from cases: Opportunities and challenges. *Academy of Management Journal*, 50(1), 25-32.

Ferretti, F., 2019. Mapping do-it-yourself science. *Life Sciences, Society and Policy*, 15(1), 1-23.

Fox, S., 2014. Third Wave Do-It-Yourself (DIY): Potential for prosumption, innovation, and entrepreneurship by local populations in regions without industrial manufacturing infrastructure. *Technology in Society*, 39, 18-30.

Fressoli, M., Arond, E., Abrol, D., Smith, A., Ely, A. and Dias, R., 2014. When grassroots innovation movements encounter mainstream institutions: implications for models of inclusive innovation. *Innovation and Development*, 4(2), 277-292.

Gassmann, O., Reepmeyer, G. and Von Zedtwitz, M., 2008. *Leading Pharmaceutical Innovation: Trends and Drivers for Growth in the Pharmaceutical Industry*. Springer, Berlin/Heidelberg.

Gorman, B., 2011. Patent office as biosecurity gatekeeper: Fostering responsible science and building public trust in DIY science. *Marshall Review of Intellectual Property Law*, 3(10), 423-449.

Gulati, R., Puranam, P. and Tushman, M., 2012. Meta-organization design: Rethinking design in interorganizational and community contexts. *Strategic Management Journal*, 33(6), 571-586.

Gwet, K.L., 2014. *Handbook of inter-rater reliability: The definitive guide to measuring the extent of agreement among raters*. Advanced Analytics, LLC, Gaithersburg, MD.

Harrison, A., 2002. Case study research. In: David P. (Ed.), *Essential Skills for Management Research*. Sage Publications, London.

Hassanzadeh, F., Modarres, M., Nemati, H.R. and Amoako-Gyampah, K., 2014. A robust R&D project portfolio optimization model for pharmaceutical contract research organizations. *International Journal of Production Economics*, 158, 18-27.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

Hecker, S., Haklay, M., Bowser, A., Makuch, Z., Vogel, J. and Bonn, A., 2018. Innovation in open science, society and policy-setting the agenda for citizen science. In Hecker, S., Haklay, M., Bowser, A., Makuch, Z., Vogel, J. and Bonn, A. (Ed.), *Citizen Science: Innovation in Open Science, Society and Policy*. UCL Press, London, UK.

Hossain, M., 2018. Grassroots innovation: The state of the art and future perspectives. *Technology in Society*, 55, 63-69.

Hu, Y., Scherngell, T., Qiu, L. and Wang, Y., 2015. R&D internationalisation patterns in the global pharmaceutical industry: evidence from a network analytic perspective. *Technology Analysis & Strategic Management*, 27(5), 532-549.

Iansiti, M. and Levien, R., 2004. *The keystone advantage: What the new dynamics of business ecosystems mean for strategy, innovation, and sustainability*. Harvard Business School Press, Boston, MA.

Industry Standard Research (ISR), 2017, CRO Market Size Projections 2016-2021. URL: <https://isrreports.com/reports/2017-edition-of-the-cro-market-size-projections-2016-2021/>.

Jacobides, M.G., Cennamo, C. and Gawer, A., 2018. Towards a theory of ecosystems. *Strategic Management Journal*, 39(8), 2255-2276.

Johnson, B. and Andersen, A.D., 2012. *Learning, Innovation and Inclusive Development*. Aalborg University Press, Aalborg, Denmark.

Landrain, T., Meyer, M., Perez, A.M. and Sussan, R., 2013. Do-it-yourself biology: Challenges and promises for an open science and technology movement. *Systems and Synthetic Biology*, 7(3), 115-126.

Lauto, G. and Valentin, F., 2016. The knowledge production model of the New Sciences: The case of Translational Medicine. *Technological Forecasting and Social Change*, 111, 12-21.

Leten, B., Vanhaverbeke, W., Roijackers, N., Clerix, A. and Van Helleputte, J., 2013. IP models to orchestrate innovation ecosystems: IMEC, a public research institute in nano-electronics. *California Management Review*, 55(4), 51-64.

Lowman, M., Trott, P., Hoecht, A. and Sellam, Z., 2012. Innovation risks of outsourcing in pharmaceutical new product development. *Technovation*, 32(2), 99-109.

Malerba, F. and Orsenigo, L., 2015. The evolution of the pharmaceutical industry. *Business History*, 57(5), 664-687.

Marques, C.M., Moniz, S. and de Sousa, J.P., 2019. Challenges in Decision-Making Modelling for New Product Development in the Pharmaceutical Industry. *Computer Aided Chemical Engineering*, 46, 1411-1416.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

Masri, D.M., Ramirez, B., Popescu, C. and Reggie, E.M., 2012. Contract research organizations: an industry analysis. *International Journal of Pharmaceutical and Healthcare Marketing*, 6(4), 336-350.

Meyer, M., 2013. Domesticating and democratizing science: A geography of do-it yourself biology. *Journal of Material Culture*, 18(2), 117-134.

Mirowski, P. and Van Horn, R., 2005. The contract research organization and the commercialization of scientific research. *Social Studies of Science*, 35(4), 503-548.

Morgan, G. and Smircich, L., 1980. The Case for Qualitative Research. *Academy of Management Review*, 5, 491-500.

Pellinen, A., Ritala, P., Järvi, K. and Sainio, L. M., 2012. Taking initiative in market creation—a business ecosystem actor perspective. *International Journal of Business Environment*, 5(2), 140-158.

Ramirez, P., 2006. The globalisation of research in the pharmaceutical industry: A case of uneven development. *Technology Analysis & Strategic Management*, 18(2), 143-167.

Ragin, C.C., 1994. *Constructing Social Research: The Unity and Diversity of Method*. Pine Forge Press, USA.

Revill, J. and Jefferson, C., 2013. Tacit knowledge and the biological weapons regime. *Science and Public Policy*, 41(5), 597-610.

Sabatier, V., Craig-Kennard, A. and Mangematin, V., 2012. When technological discontinuities and disruptive business models challenge dominant industry logics: Insights from the drugs industry. *Technological Forecasting and Social Change*, 79(5), 949-962.

Sarpong, D., Ofosu, G., Botchie, D. and Clear, F., 2020. Do-it-Yourself (DiY) Science: The proliferation, relevance and concerns, *Technological Forecasting and Social Change*, 158 (2020) 120127.

Sarpong, D. and Rawal, A., 2020. From the open to DiY laboratories: managing innovation within and outside the firm, In Fritzsche A (Eds.), *Innovating in the Open Lab: The New Potential for Interactive Value Creation across Organizational Boundaries*. ISPIM.

Schillo, R.S. and Robinson, R.M., 2017. Inclusive innovation in developed countries: The who, what, why, and how. *Technology Innovation Management Review*, 7(7).

Scholz, R. W. and Tietje, O., 2002. *Embedded Case Study Methods: Integrating Quantitative and Qualitative Knowledge*. Sage Publications, London.

Seyfried, G., Pei, L. and Schmidt, M., 2014. European Do-it-yourself (DIY) Biology: Beyond the hope, hype and horror. *Bioessays*, 36(6), 548-551.

Citation: Wu, Q. and He, Q. (2020) "DIY Laboratories and Business Innovation Ecosystems: The Case of Pharmaceutical Industry", *Technological Forecasting & Social Change*, In press.

Shtilman, Y., 2009. Pharmaceutical drug testing in the former Soviet Union: contract research organizations as broker-dealers in an emerging testing ground for America's big pharma. *Boston College Third World Law Journal*, 29(2), 425-454.

Sleator, R.D., 2016. DiY biology-hacking goes viral. *Science Progress*, 99(3), 278-281.

Stilgoe, J., Owen, R. and Macnaghten, P., 2013. Developing a framework for responsible innovation. *Research Policy*, 42(9), 1568-1580.

Strauss, A. and Corbin, J., 1998. *Basics of qualitative research*. Sage Publications, Newbury Park, CT.

Styhre, A., 2011. Institutionalizing technoscience: Post-genomic technologies and the case of systems biology. *Scandinavian Journal of Management*, 27(4), 375-388.

Tanenbaum, J., Williams, A. Desjardins, A. and Tanenbaum, K., 2013. Democratizing technology: pleasure, utility and expressiveness in DIY and maker practice. *In Proceedings of the SIGCHI Conference on Human Factors in Computing Systems (2603-2612)*, ACM.

Teece, D. J. 2000. *Managing Intellectual Capital: Organizational, Strategic, and Policy Dimensions*. Oxford University Press, London, UK.

Tierney, R., Hermina, W. and Walsh, S., 2013. The pharmaceutical technology landscape: A new form of technology roadmapping. *Technological Forecasting and Social Change*, 80(2), 194-211.

Wexler, A., 2016. The practices of do-it-yourself brain stimulation: implications for ethical considerations and regulatory proposals. *Journal of Medical Ethics*, 42(4), 211-215.

Williamson, P.J. and De Meyer, A., 2012. Ecosystem advantage: How to successfully harness the power of partners. *California Management Review*, 55(1), 24-46.

Wolinsky, H., 2005. Do-it-yourself diagnosis: Despite apprehension and controversy, direct-to-consumer genetic tests are becoming more popular, *EMBO Reports*, 6(9), 805-807.

Xia, C. and Gautam, A., 2015. Biopharma CRO industry in China: landscape and opportunities. *Drug Discovery Today*, 20(7), 794-798.

Yin, R. K. 2003. *Case study research: design and methods*. Sage Publications, Newbury Park.

Zhao, S., Tan, H., Papanastassiou, M. and Harzing, A.W., 2020. The internationalization of innovation towards the South: A historical case study of a global pharmaceutical corporation in China (1993–2017). *Asia Pacific Journal of Management*, 37(2), 553-585.