

**Open Innovation and Entrepreneurship: The Contract Research
Organization (CRO) as a response to the biopharmaceutical industry**

Entrepreneurship’s development – and the emergence of new companies that it involves – is the condition to promote technological and product’s innovations as well as economic development. Consequently, at the basis of innovation, innovative entrepreneurship is found out, as it is provided with top management and able to create value for clients, stockholders and the whole territory itself. Entrepreneurship’s scholars focus their attention on cognitive aspects which due individual to identify business opportunities for the creation of new companies. The theories about entrepreneurial opportunities state that the entrepreneurship is influenced by external framework and by the way according to which the companies use to relate with it.

In this perspective, the so-called Closed Innovation Model – all originates from the firm - is replaced by the Open Innovation Model, according to which companies can both obtain the no-owned ideas, knowledge, technologies from the external and transfer owned ideas, knowledge and technologies to other companies. The Open Innovation Model finally supports innovative entrepreneurial development, so allowing careful businessman to seize business opportunity. Surely, the main risk that the Open Innovation Model involves is to manage Intellectual Property, since “the opening” provides greater transparency in communication and represents, for this reason, a source of potential opportunistic behaviors.

Therefore innovative entrepreneur has to select the best strategy to manage the new knowledge that he has produced. Furthermore, the Open Innovation Model promotes partnerships and “de-verticalization” process as in the outsourcing case. While many businessmen consider the

outsourcing as a business strategy, others regard it as an entrepreneurial opportunity. The above mentioned theoretical conclusion finds evidence in biotech and pharmaceutical sectors.

Due to the own internal crisis, both biotech and pharmaceutical companies had to change their traditional business models, restructuring the industry in a way able to stimulate the creation/discovery of new opportunities. Biopharmaceutical sector development has involved new technologies and new approaches related to the scientific progress in different areas. In this framework, the Open Innovation Model contributes to generate new partnerships and more or less integrated relationships, as the outsourcing. According to these paradigms, in the biopharmaceutical sector, CROs (Contract Research Organizations) are increasing their role and their influence. CRO are companies provided with pharmaceutical know how and that supply services, especially, in outsourcing. The main Contract Research Organizations are Quintiles, Covance, Pharmaceutical Product Development (PPD), Parexel, Icon Clinical (ICON), Charles River Laboratories (CRL), MDS, Kendle, PRA International, InVentiv Health Clinical, which dominate the global market and constantly increase in their turnover.

The analysis of CRO's investments and market behavior discloses their increasing interest in offshoring their activities, above all in BRICS countries, due to the regulatory and fiscal advantages that they find here. In the BRICS Areas, in fact, CROs are progressively moving not only their production but also the clinical trial of drug and the main phases of the biopharmaceutical product development.

In the course of time, CROs have changed their business model in order to guarantee growing flexibility and quality in providing services for clients, as well as in finding solutions related to the diversified needs of the biopharmaceutical sector.

According to this trend, CRO 2.0 and virtual outsourcing are going to identify the future model of CRO's new generation.

While the international framework in which CROs use to act is adequately described by scholars, the same doesn't occur as regards as the Italian framework. In this perspective, our work aspires to

investigate and analyze the CRO's sector in Italy. In order to achieve this result, a survey to fifty CROs has been sent, using the 11th *Rapporto Nazionale della sperimentazione* as source to find their details. The available data on which the analysis has focused its attention show clearly a growing trend of CROs in the Italian market. This statement is true and valid both for the Italian CROs generated by Italian entrepreneurs and for the Italian branch of multinational CROs. The Italian native CROs, however, basically - but slowly - tend to imitate the international models, although they prefer to select different strategies also in their *offshoring policies*, according to the different entrepreneurial culture and approach. Nonetheless, in Italy, both CROs' types development encounters regulatory, bureaucratic and financial obstacles - that the work underlines - which constitute the real limit to the growing process of the Italian CRO experience in respect to the international competitors.