A Survey on Support to Investigator Sponsored Trials. Trends and Proposals

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Introduction

A relevant part of health solutions to patients' needs depends on the availability of new drugs and new information to define both their place in therapy and optimal use in the clinical setting. Clinical trials are the primary tools to produce such information. Investigator Sponsored Trials are often discussed in terms of opposition to pharmaceutical industry-sponsored clinical trials. It is known that some Investigator Sponsored Trials are supported by pharmaceutical companies, through the provision of funding and/or drugs.

This study aims to evaluate the possible size of the support provided by the pharmaceutical companied to Investigator Sponsored Trials in Italy and to provide some guidance to support the development of these trials in a competitive and global environment to meet patients' needs.

Methods

The study was performed using the following data sources: (a) qualitative survey among 12 of the top 20 pharma companies in Italy to acquire information on the Investigator Sponsored Trials supported in 2013 in terms of number, distribution in phases clinical development, dedicated staff, use of website, type of contract used; (b) analysis of websites developed by pharma companies to support investigator sponsored trial among the top 15 pharma companies in Italy, in order to verify the methodology and characteristics of the support.

Results

Data provided by nine of the 12 companies were assessed. In 2013, between 132 and 195 clinical trials were supported. Phase 1 trials accounted for 9% of supported studies, Phase 2 for 39%, Phase 3 for 19% and Phase 4 for 32%. Up to 75% of the studies were carried out according to paragraph a, Article 1 of DM 17.12.2004.On average 2 full time employees for the management of the support to such studies.

Six of the 11 pharmaceutical companies described in the company website how to submit an investigator sponsored trial request. Support to investigator sponsored trials is defined in different ways (Investigator-Initiated Research, Investigator Supported Studies, Investigator Initiated Trials and more). In 5 cases, the website was the only way to get information and submit proposals, while in 4 cases information about the research areas of interest to the company for the evaluation of proposals were provided.

Discussion

The binary dichotomy between pharmaceutical clinical trials and investigator sponsored trials has gradually evolved in the last years with the development of a new ecosystem based on a collaborative models between pharma with, academic research and new research players, like Charities and Patient Networks. The new role of non-profit organizations in the drug discovery and development process with the purpose to make new discovered compounds more readily available to patients with rare or neglected diseases has emphasized the need for a revision of the concept of "industrial drug development".

In Italy, as in other countries, a significant portion of the clinical trial for industrial purposes is supported by the pharmaceutical industry. The recognition of the value of investigator sponsored trials and complementarity of the non-profit research with its clinical development programs led many pharmaceutical companies to develop and infrastructure to support clinical trials and to progressively increase the human and economic resources allocated to the support of such research, websites included.

As a result of the evolution of such support, in order to ensure the best development of this cooperation in alignment to the best patients' interest, we believed that it is necessary to provide physicians with more information and training on investigator sponsored trials and to define with clarity and transparency the limits and characteristics of the support of pharma company and the possibility that the results of the study may be used for to approve new drug indications.