"LITTLE" STUDIES ARE GROWING-UP: THE ITALIAN REGULATION AND EXPERIENCE ON PHASE I CLINICAL TRIAL AUTHORIZATION

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Phase I clinical trials include a series of studies to be conducted on volunteers (healthy individuals or patients), to determine the tolerability profile of a new drug, its pharmacokinetic/metabolic characteristics and, in case of patients, some efficacy parameters. In Italy, the Istituto Superiore di Sanità (ISS, *i.e. the Italian National Health Institute*).is the competent authority for the authorization of phase I studies. This authorization is based on the ascertainment of the quality of the product and on the evaluation of the ratio between the expected risks and the foreseen benefits, as revealed by preclinical studies. The Committee for the evaluation of new pharmaceutical products, established in the frame of the ISS, is responsible for the approval of phase I studies . Since the authorization of a phase I study allows the passage from the preclinical to the clinical phases, it represents both a cultural challenge and a pivotal step in the development of a new drug.

For these reasons, in the last months the Committee has implemented a series of initiatives to improve/promote phase I trials in Italy. The idea beyond such initiatives is that there is the need for "Education/Training" measures and that, at the same time, approval procedures could be improved and/or facilitated. Specifically, the Committee is considering to implement educational projects together with the University, Scientific Hospitals, AIFA and Industries. As for the issue of improving/facilitating procedures, the goal is not merely to shorten the process, but rather to provide a high-quality expert opinion in a reasonable and, even more importantly, predictable time. As a first measure, some new "fast" procedures (electronic approval, use of teleconferences) have been introduced. The results of these efforts have been an increase (+30%) in the number of applications accompanied by a significant decrease (-57%) in the evaluation time. The absolute number of application however, remains low as compared with other European countries.

In conclusion, the authorization of a phase I study represents a pivotal step in the development of a new drug. Given the complexity of this passage, having it formally authorized by an independent scientific institution does represent a support and a resource. Although several initiatives have been undertaken to support the applicants and to speed up/optimize the evaluation process, further improvements are still needed. The involvement of all the interested parties (ISS, AIFA, University, Hospitals, Industry) is crucial to achieve significant improvements of the whole process.