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Reinventing the clinical trials process: The SCIO concept meets personalized medicine needs

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Precision medicine identifies the evolving field holding the promise to transform our health care system which consumes almost $3 trillion a year. Clinical trials are at the heart of the drug development process. They represent a significant proportion of the total cost and effectively define the critical path to a regulatory submission. Even the most-simple study costs over $1 million and in the later stages of the development phase they can cost hundreds of millions of dollars and take several years to complete. Historically, the clinical trial process had been designed to develop therapeutics for the average patient. This one-size-fits-all approach has demonstrated not effective as demonstrated by the rising cost and low success rate of clinical trials as well as the percentage of non-responder patients in clinical trials. Precision medicine is the tailoring of medical treatments to the individual characteristics of each patient and the ability to classify individuals into subpopulations based on their susceptibility to a particular disease or their responses to a specific treatment. The development of precision therapies is closely associated with subpopulations defined by biomarkers. The design of clinical trials for these subpopulations represents a challenge from the perspective of population size, determination of response thresholds and co-development of diagnostic assays to support novel therapies. A fundamental shift in perspective and a willingness to challenge the clinical trial process is required. The SCIO concept solution provides innovation to the trial process in which new technologies find the ideal background to be developed and applied.

Biography

Candida Fratazzi has devised the concept of SCIO and founded the first SCIO-BBCR Consulting in 2009 with the objective of actively contributing to innovation in the clinical process. She acts as a Consultant to drug and device companies and investors. She is a renowned Immunologist; contributed to the registration of 4 drugs. She is the recipient of 2013, 2014 and 2015 Best Pharmaceutical Consultant award and is a Member of Advisory Board and Board of Directors; Invited speakers and Chairman at international conferences. She has received her early training at the Johns Hopkins University and Harvard University in the USA and at Imperial College in London.

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