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Personalized Medicine and Clinical Trials on "Target Therapy" in Oncology, Research or Business?

Andrea Nicolini*

Department of Oncology, University of Pisa, Italy

***Corresponding author:** Andrea Nicolini, Retired, Clinical Researcher and Professor, Department of Oncology, University of Pisa, Italy, E-mail: andrea.nicolini@med.unipi.it

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Introduction

In the last decades personalized medicine and the so called "target therapy" became the new paradigm in oncology and an increasing number of "target drugs" have been built-up by the industry for treatment of advanced cancer disease. Likely frustration due to incurability in most instances and some advances has favored the arising of the new paradigm. In spite many target drugs so far have entered into clinical practice and take part of the guidelines recommended by many international scientific societies, median survival in the most common types of advanced cancer and fatal outcome of these patients did not substantially change[1-3]. Only small subsets in different types of advanced cancers have shown to significantly benefit from some of these new drugs.

It is then noteworthy that after receiving approval by the National Health Service (NHS), any new drug usually enters into clinical practice at high cost . It has been recently reported that the cost of many of these drugs is more than 10,000 USD per month of therapy against improvement in survival of few weeks or months and sometimes heavy toxicity[4]. Moreover the annual average cost of the 51 new oncological drugs approved from 2009 to 2013 in USA has been computed to be 116,000 USD[4].

In most trials on these new drugs, the use of time to progression (TTP) or progression-free-survival (PFS) as surrogate markers of overall survival and the large number of the recruited patients permit to achieve statistical significance and magnify an actual relatively small benefit. On the other hand another principal aspect of the new paradigm is that currently some of these new drugs are included in the recommendations by the guidelines at the different lines of salvage treatment. Therefore, for clinical oncologists therapy of patients with advanced disease is a pre-established route "paved" with these new drugs. Indeed it is now clear that cancer is a systemic very complex disease sustained by a network of many not well elucidated and interconnected molecular pathways also changeable over time (biologic plasticity of cancer cell). So it is not surprising that not temporally planned, not appropriately directed and/or not appropriately synergizing targeting of one or few molecular signaling pathways does not importantly impact the outcome of such a disease. Also it is not unlikely[5] to think that most patients could have been treated with the same outcome but in much less expensive way and lower toxicity using the "old pathway" that is the conventional lines of therapy existing before the advent of the "target therapy".

Therefore the following questions must be urgently answered: what of the submitted reports on the many ongoing trials referring to these new drugs any scientific high rank journal must accept for publication ?Is it enough a correctly designed study with small even if statistically significant result of a surrogate marker or rather it must be necessary to provide a relevant contribution to the comprehension and/or the outcome of the disease? Accordingly, for being a tested drug approved to enter into clinical practice and paid with the money from all citizens is it enough a significant but small improvement of a surrogate marker or it should rather improve importantly, that is not weeks or months but years, overall survival? A clear answer to these crucial questions permits to distinguish actual research from business and all the involved professionals (scientists, industries, non-profit research, NHS, clinical oncologists) to play their due role; moreover it should restore more protection of patient's and common people interests.

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