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Editorial Comment

Pharmaceutical industry, investigators and institutions: Partners or tools?

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In recent decades we have witnessed a tremendous increase in interest within the pharmaceutical industry for development of new agents directed against cancer. Prior to this change, development of novel agents was mainly the concern of academic investigators and institutions. In those days, the major challenge was the harmonisation of preclinical and clinical research. Absence of appropriate translational research has led to statements such as the one of the late professor Tom Connors: ''The probability of developing a successful antitumor agent is not directly proportional to the degree of science involved, and certain cynical people even believe that it is inversely related''. Clearly, this lack of mutual understanding has hampered developments.

It was the personal commitment of the involved investigator that was largely responsible for the quality of the research performed. If commitment and devotion were not adequate, the chances of taking the wrong decisions in times of crises during drug development were huge, and they made Professor Dan Von Hoff introduce the term ''pharmacopotosis'' or ''programmed drug death'' during his lecture at the NCI-EORTC symposium on New Drugs for Cancer in 1994. However, with a committed investigator, achievements were great, with in depth assessments of mechanisms, safety and activity. Yet, the time to bring a new anti-cancer drug to registration usually spanned from 10 to 15 years. Obviously the increased interest in pharmaceutical industry also coincided with a pressure to decrease this development time. A decrease that on one hand could benefit patients that would get access to newly registered drugs earlier, but on the other hand also increases the risk of development by the pressure of time involved. Importantly, another event was the implementation of the ICH-''Good Clinical Practice'' guidelines. The administrative burden coinciding with the performance of clinical trials has increased tremendously with the issuing of these guidelines. The recent introduction of the EU-Clinical Trials Directive will add a further dimension to this administrative burden. This seems to be in contradiction with the need to develop drugs more rapidly.

With the mentioned increased interest from industry and the increased bureaucracy, over the last few years we have witnessed a clear change in performance of drug development trials. The demands of pharmaceutical industry are continuously increasing, partly related to apparently different interpretations of the ICH-GCP guidelines and in addition, related to the already indicated time pressures. Due to this we face the threat of a lack of appropriate involvement of potential investigators during the period of study protocol design. So from a ''language barrier'' between laboratory and clinic, we seem to be moving to a ''language barrier'' between pharmaceutical industry and potential clinical investigators.

In the current issue of the European Journal of Cancer Dr. Eric Rowinsky highlights some points of view of the clinical investigator in this process, while Dr. George Blackledge highlights some issues pertaining to the point of view of the pharmaceutical industry in exactly the same process. It may be important to stress that the opinions given are personal. Both papers reflect the content of lectures given by the authors during the EORT-NCI-AACR Symposium Molecular Targets and Cancer

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Therapeutics, held in Geneva in September 2004. These lectures were followed by a very vivid discussion. At the end of the discussion one of the questions raised from the audience was whether investigators should accept protocols offered to them by pharmaceutical industry as "final" without prior discussion, and as "take it, or leave it". Unfortunately this is no longer an uncommon situation. Importantly, the consensus opinion appeared to be that such an approach had to be considered to be undesirable and unacceptable. Investigators accepting to participate in studies without having had the opportunity in being involved in clinical study design may have to be considered as performers rather than investigators. A shared responsibility in true partnership seems to be the best guarantee to move forward quickly and adequately.