other validated QL measures to ensure that improvement in the primary endpoint (e.g. pain) is not obtained at the cost of deterioration in other aspects of QL. A double-blind fomat, and supportive data on biological response (e.g. PSA response for prostate cancer) are desirable to rule out placebo or non-specific effects, although we have found placebo effects to be rare in oncology if rigorous patient-recorded QL or symptom scales are used. These methods have been applied in randomised controlled trials to establish the palliative value for patients with HRPC of (i) bone-seeking isotopes such as strontium-89, and (ii) chemotherapy with mitoxantrone plus prednisone. Similar methods are appropriate for any trial of advanced disease where the probability of improvement in survival is low, and where the goal of treatment is palliation.

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Conflict of interest

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Modern medicine is increasingly dependent on research activities and effective communication of scientific information. Research results are often made public very quickly, thus rapidly incorporating ethical, sociological and political perspectives into the research process. The many different types of interests invested in science have from time to time threatened a public trust in its reliability.

Conflict of interest has mostly been discussed in economical terms. There are examples that economic dependence may have clouded investigators' judgement. Although most actors have taken such examples very seriously, the suggestions for remedies have varied widely from detailed check lists of conflict of interest to leaving everything to the scientist's conscience. Discussing actions to be taken, there are important points to consider: All science is theory impregnated and all scientists have some kind of expectations and interests. Editors and publishers also have different types of interest invested in their product. Conflict of interest can thus be of *academic, political, religious, etc. type. A discussion narrowly focused on* conflict of interest will tend to disregard issues of scientific content of the published results. Always allowing dissenting views, rational criticism and an open debate may be the best way to fight uncritical thinking.

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Collaboration between large intergroups and the pharmaceutical industry

Martine J. Piccart. *On behalf of BIG, Jules Bordet Institute, Brussels, Belgium*

The coming years are going to see the emergence of numerous new compounds with new and original targets in the cancer cell or its stroma. This accelerated drug development demands fundamental changes in the way we conduct clinical trials, in general, and clinical trials of adjuvant therapy in particular, since the latter often require more than 2000 patients to answer 1 or 2 questions with adequate statistical power.

In 1996 the "Breast International Group" or "BIG" has been established with the hope to respond to this need and to accelerate as well as coordinate *clinical research in the adjuvant treatment of breast cancer in Europe* – Australia – New Zealand, South America and South Africa.

Among 4 "BIG" adjuvant trials currently open to accrual and involving the participation of not less than 12 research groups around the world (the EORTC-BCCG, the IBCSG, the ICCG, the NCI-C-CTG, the Scandinavian/Danish Breast Cancer Groups, the FNCLCC, the GOIRC, the ANZ-BCTG, the Austrian BCG, the "BREAST", the GEICAM, ...), 3 are pivotal registration trials run in close collaboration with the pharmaceutical Industry.

The learning curve for conducting these difficult trials in a timely and coherent manner will be presented ...

There is however little doubts that we are witnessing a profound mutation in cancer clinical research at the turn of this century.

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Abstract not received.

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The coordinating role of the EORTC

Meunier Françoise. *EORTC, Belgium*

The EORTC is an international organization coordinating multi-disciplinary cancer research, with the aim of improving treatment of cancer through high quality clinical trials conducted by a Pan-European network of about 2,500 scientists and clinical investigators in more than 300 hospitals and research institutions (31 countries). Overall, more than 6.500 patients are treated according to EORTC protocols on a yearly basis. The ultimate goal of the EORTC is to raise the standard of cancer treatment to improve and save the life of cancer patients and to facilitate the transition from experimental discovery to state-of-the-art treatment.

The EORTC is involved in new drug development (from preclinical evaluation up to pivotal registration Phase III trials conducted in cooperation with the pharmaceutical industry), as well as in strategy trials dealing with combined therapeutic modalities (surgery, radiotherapy, chemotherapy, immunotherapy...), but also quality of life evaluation and health economics assessment.

Strategy trials testing agents already available on the market alone or in combination with other therapeutic modalities (surgery, radiotherapy) are usually not supported by the pharmaceutical industry.

The EORTC headquarters are based in Brussels. The staff of the EORTC Data Center consists of more than 80 scientists involved in statistical design *and analysis, data management, quality assurance programs, medical* monitoring, safety desk and regulatory affairs issues, quality of life and health Economics issues, etc.

The EORTC provides a comprehensive cancer research program cooperating on a transatlantic basis, as well as with national research groups throughout Europe. The EORTC standard operating procedures have been filed at the US FDA (DMF N° 13059). In addition, the Office of the Protection from Research Risks (OPRR) of the US NIH has also awarded the EORTC with an International Cooperative Project Assurance agreement, that allows the EORTC to improve and speed up transatlantic cancer clinical research. These goals and achievements allow the EORTC to bring a significant contribution to promote high quality cancer clinical research for the benefit of all cancer patients.

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The view from the pharmaceutical industry

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The development of new anti-cancer agents has assumed increasing importance to the pharmaceutical industry as more is known about the biology of cancer and therefore specific mechanisms can be targeted by new approaches. Whilst a primary aim of a pharmaceutical company is to return value to its shareholders, it is also important from the point of view of satisfying potential customers, that useful effective new agents are developed which have a perceived clinical benefit. Three factors are key in the development of new agents. The first is that the clinical trials that are performed should demonstrate, in as unequivocal a way as possible, the benefits of a new agent. The second is that this should be done as quickly as possible so that the new agent can be made available to the widest number of people and the company benefits from this, and the third is that expenditure is minimised.

Issues can arise when determining clinical trial design. With new agents, a pharmaceutical company must ensure that the trial design will be acceptable, both to regulatory agencies in different countries, as well as to *clinicians. Post-registration, clinical trial design is likely to attempt to fulfil the* interests and needs of clinicians opposite their patients in the environment within which they are working. Whilst good clinical trial design and credible science are important, the strictures of the regulatory process can often cause frustration amongst academic clinicians with creative trial protocols.

Given good will and a mutual understanding of objectives, it is possible for individual clinicians, co-operative groups and organisations such as the EORTC to work with industry in a constructive and mutually satisfactory way.