Section introduction

Introduction to clinical research sessions

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The two clinical research sessions considered the status of previous trials, as examined in the Oxford Overview (Professsor Ingle) [1], as a background for the discussion of the current generation of clinical trials employing endocrine therapy and other targeted therapies (Professor Hudis) [2]. Clinical outcomes were considered within the context of the spectrum of clinical trials (Professor Cameron) [3], and the concluding presentation addressed a novel paradigm for future research (Professor Howell) [4].

Professor James Ingle [1] addressed the findings of the most recent main meeting of the Early Breast Cancer Trialists' Collaborative Group (EBCTCG) from September 2006. Updated information from this Oxford Overview addresses the value of systemic therapy (tamoxifen, ovarian oblation/suppression, polychemotherapy, anthracyclines, aromatase inhibitors, taxanes and high-dose chemotherapy) and local therapy (postmastectomy radiation therapy). All of these analyses will be the subject of reports in the near future from the EBCTCG. The Oxford Overview process was initiated in the era of relatively small and underpowered clinical trials, and the resulting meta-analyses revealed robust information that would otherwise not have been available. The meeting attendees addressed the question of the relevance of the Oxford Overview process in the era of very large clinical trials as are being conducted today. The conclusion was that the Oxford Overview remains highly relevant and is a mechanism to gain knowledge relating to end-points, such as survival and adverse events, which cannot readily be obtained from individual trials despite their large size.

Professor Cliff Hudis [2] addressed the very important area of combined endocrine therapy and other targeted therapies. The primary goal of this research is to address endocrine therapy resistance in the cancer cell. The crosstalk between the oestrogen receptor pathway and growth factor pathways, such as the HER pathways, is a prime example of ongoing research. Numerous potential targets exist, including downstream signalling mediators, angiogenesis and cyclo-oxygenase-2. Of great importance and opportunity in targeted therapy research is the availability of the specific targets for interrogation in clinical trials. The acquisition of biological information in clinical research is an important goal of current and future research.

Professor David Cameron [3] addressed the important questions of surrogate end-points in clinical trials. Whereas overall survival is the ultimate end-point, the case is made for utilizing other end-points according to the stage of disease and needs of the patient, for example utilizing disease-free survival as the first end-point in the adjuvant trial because of its relationship to overall survival. Important consideration in surrogate end-points is the use of biological factors that can be examined in short-term therapy studies and thus related to long-term outcome of patients. This will remain a crucial area of future research.

Professor Anthony Howell considered metabolic approaches to breast cancer therapy and prevention as a paradigm for future research. This provocative discussion provided evidence of and support for targeting metabolic pathways either alone or in combination with standard therapies. Of particular interest are the data on new agents that mimic caloric restriction, called caloric restriction mimetics. This novel approach provides a new area of investigation based on our increasing understanding of metabolic pathways in tumours.

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