Breast Cancer RESEARCH

SHORT COMMUNICATION

Deciding priorities in a clinical studies group

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A Breast Clinical Studies Group seeks to support the initiation, development, recruitment to and reporting of clinical studies and randomised controlled trials. In the United Kingdom, the National Cancer Research Institute (NCRI) Breast Cancer Clinical Studies Group serves these functions (Figure 1).

Trials utilising drugs, radiation and/or surgery are usually conceptualised, discussed and developed or adopted from other (international) trials organisations via the three subgroups: the UK breast intergroup for adjuvant and perioperative studies (usually the development of later phase trials), the advanced disease subgroup or the translational and imaging subgroup. Individuals with good ideas, sometimes with links to industry, will engage with Clinical Trials Units and other external organisations. In addition, there is an adoption panel for early phase drug trials led by Industry.

Industry-trialist interactions include identifying individuals with an interest in the pathway/compound, early discussion with interested parties and an approach to the Breast Clinical Studies Group. The challenges of such interactions include the time taken to go through both the company and legislation required processes, the need for biological samples (which may be particularly problematic for metastatic breast cancer), how to reach 'new' investigators and how to compete with processes in the US and elsewhere.

There is a continuing need for prompt and open communication between all parties, and adherence to the formal processes with properly recorded discussions and decisions. Work behind the scenes may significantly speed the process along, but occasionally can be disruptive. Additional considerations include the potential for competing trials in the UK (for example HER2 therapies in advanced disease) and particularly the delivery of accrual to trials and where trials fail to achieve recruitment targets, termination of the trial.

The success of the Breast Clinical Studies Group is reflected in the 16,108 patients entered into trials/observational studies in 2009/2010, of whom 4,121 patients were entered into randomised controlled trials. These totals represent 30 to 45% of UK cancer patients in trials. Perhaps more importantly, through plenary and poster presentations at international cancer meetings and through peer reviewer publications, significant changes in clinical practice have been achieved.

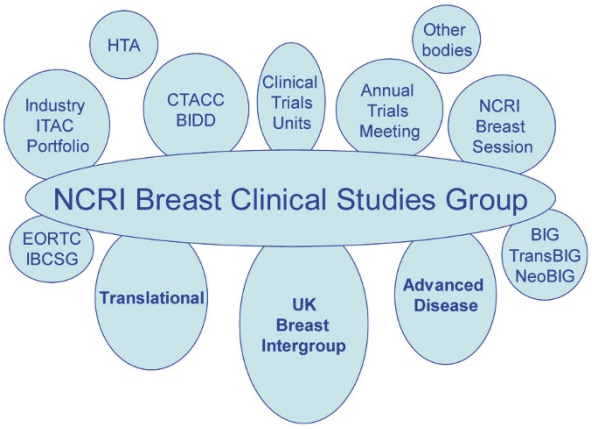

Figure 1. Structure and interaction of the National Cancer Research Institute (NCRI) Breast Clinical Studies Group. BIDD, Biomarkers and Imaging Discovery and Development Committee; CTACC, Clinical Trials Advisory and Awards Committee; EORTC, European Organisation for Research and Treatment of Cancer; HTA, Health Technology Assessment; IBCSG, International Breast Cancer Study Group; ITAC, Industry Trials Adoption Committee.

While the processes of trial development and implementation may be complex, but can successfully involve Industry, the independent NCRI Breast Clinical Studies Group seeks to improve the prevention, diagnosis, treatment and prognosis of patients with breast cancer.

Abbreviations
NCRI, National Cancer Research Institute.

Competing interests
The author has received grant support from: Astrazeneca, Cyclacel, Novartis, Pfizer, Roche, Roche Diagnostics, Sanofi and Wyeth (through the Translational Medical Research Collaboration). There are no other competing interests.

Acknowledgements
This article has been published as part of *Breast Cancer Research* Volume 12 Supplement 4, 2010: Controversies in Breast Cancer 2010. The full contents of the supplement are available online at http://breast-cancer-research.com/supplements/12/S4

Published: 20 December 2010

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doi:10.1186/bcr2751
Cite this article as: Thompson AM: **Deciding priorities in a clinical studies group.** *Breast Cancer Research* 2010, **12(Suppl 4)**:S22.