# Symposium

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## CHANGING APPROACHES IN CANCER CLINICAL TRIALS: THE NURSING CONTRIBUTION

*D. Batchelor*
*The Netherlands Cancer Institute, Plesmanlaan 121, 1066 CX Amsterdam, The Netherlands*

Trends in the development of new drugs and treatment modalities have had an impact on the traditional standards governing the performance of phase I, II, and II trials. For example, in a phase I study of genetically transduced tumour cell vaccines, patients were randomized to receive 2 different cell doses instead of 3–6 patients being treated at escalating cell dose levels. Why is this? Quality of life studies are also being introduced in some phase I studies. Is this now becoming another way to establish feasibility of new treatments?

Nurses, as members of the multi-disciplinary team are increasingly playing key roles in the performance of clinical trials. Traditional approaches are well integrated in nursing and thinking patterns. Any changes in these practices creates needs for education and a change of attitude. In addition, changing designs/approaches of clinical trials have raised questions in the clinic such as: Do we really need all information, what are we going to do with it? Are the new approaches methodologically and ethically sound? Do they confirm to present guidelines of good clinical practice?

New designs in clinical trials challenge nurses to keep up to date with research developments. Issues that arise should be addressed in the research team, in this way nurses can contribute to the refining of these new designs, while keeping patient's best interests in mind.

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## CHANGING APPROACHES IN CANCER CLINICAL TRIALS: COMPANION STUDIES

*P. Di Giulio*
*Rivista Dell'Infermiere*

Companion studies are challenging instruments for the development of nursing research. Two models of study actually being conducted in Italy are presented anti. Discussed for their specific technical aspects and with respect to their broader implications: a) on quality of life myocardial infarction patients (GISSI-Nursing); b) on the presence and evolution of some problems: pain, leg ulcers, treatments side effects and quality of life for chronic limb ischemia patients (i.c.a.i. Nursing). Wider implications and opportunities for nursing research will be addressed in the presentation.

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## PRACTICAL ISSUES CONCERNING QUALITY OF LIFE FROM DESIGN TO INTERPRETATION

*L. Fallowfield*
*CRC Communication & Counselling Research Centre, University College Hospitals, London, U.K.*

Over the past 10 years there has been an increasing shift of emphasis from survival to quality of life as an endpoint in clinical trials. This is especially true in oncology where treatments may produce quite small survival advantages at the cost of high toxicity and impaired quality of life. Nevertheless, many people remain sceptical about the ability to measure reliably a seemingly conceptually vague parameter such as quality of life. The supposed softness' of the data derived from clinical trials is often due to poorly constructed protocols employing inappropriate measures of quality of life, careless administration of questionnaires and faulty analysis and statistics. Important practical issues concerning choice of instrument and interpretation of data will be discussed in this paper.

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## GOOD CLINICAL PRACTICE (GCP)

*M. de Boer*
*The Rotterdam Cancer Institute, 3075 EA Rotterdam, The Netherlands*

Clinical trials are performed to identify the efficacy and/or safety of investigational products, new treatment combinations or routes of administration. In order to arrange formal protection of patients participating in clinical trials, governmental regulations have been designed and implemented. It is obligatory that trials are performed according to the Declaration of Helsinki, and that patients give written or oral informed consent. In July 1991 the guidelines of Good Clinical Practice (GCP) were issued in Europe. The authorities of the European Union now require that trials are conducted in accordance with GCP defining standards so that the rights, safety, integrity of participants are protected and the data are valid and credible. Patients are in this way protected from unnecessary exposure to new modalities. The current guidelines cover the ethical committee, responsibilities of sponsor, monitor and investigator, data handling, statistics and quality assurance.

To implement GCP in our hospital setting related to new drug development, clinical trial standard operating procedures (SOPs) were written translating the guidelines into practical applications for the team involved. During this process we found that although the role of the nurse in clinical trials has been well established the GCP guidelines do not include this expertise. Clearly implications on nursing practice can be derived and in the SOPs the responsibilities of all team members, including the research nurses and the ward nurses are detailed. As for the nursing practice several adaptations were made and emphasized on patient safety procedures and data documentation. Major changes were: achieving the nursing records and keeping them for 15 years, limiting the admission of clinical trial patients to prevent workload interference with quality and starting a GCP training for phycisians and nurses.

Of additional benefit: the SOPs clarified already existing procedures not known in detail by all team members.

An overview of this process; the SOPs and the adaptations made to put the recommendations into practice will be presented.

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## A NETWORK OF EDUCATORS FOR CANCER CLINICAL TRIALS

*K. Crosson, EONS(EORTC)*
*National Cancer Institute, Bethesda, Maryland, U.S.A*

Networks of educators are being used in the U.S.A. to promote cancer prevention and treatment clinical trials. These educators are educating the public, patients, and their families about the clinical trials process and what to expect while participating in a trial. Since clinical trials are the most effective tool scientists have to evaluate new approaches to cancer prevention and treatment, the National Cancer Institute has placed a strong emphasis on clinical trials as part of a comprehensive research agenda. Despite the importance of the issues, clinical trials continue to face significant obstacles to producing timely answers. This presentation will describe education and training efforts being coordinated by the National Cancer Institute in collaboration with patient advocates, cancer centers, and professional organizations to increase the number of patients enrolled in clinical trials, nationwide. Special emphasis will be placed on the design and development of a 4-part training program for the target audiences.