Clinical Trials In Early Breast Cancer

#early breast cancer clinical trials #breast cancer research studies #adjuvant therapy trials #neoadjuvant breast cancer treatment #innovative breast cancer therapies

Explore the crucial role of clinical trials in advancing early breast cancer treatment, focusing on research into new adjuvant and neoadjuvant therapies. These studies aim to improve patient outcomes, prevent recurrence, and introduce innovative strategies, driving the continuous evolution of care for individuals with early-stage breast cancer.

Clinical Trials in ‘Early’ Breast Cancer

The controlled clinical trial has become an essential part of the clinician's decision-making process. Clinical trials, however, still raise methodological problems that are important and at the same time controversial: subgroup analysis and interactions, meta-analy sis of similar trials, consideration of subjective clinical opinions and those of the public at large, assessment of quality of life, pre vention trials, and so on. In February 1987 we took our third step along the road to evaluating these issues in dialogues between cli nicians, psychologists, legal experts, and statisticians. The talks presented at the meeting were revised by the authors afterwards and have been rearranged by the editors to form a strictly organ 1 2 ized book. The two preceding meetings in 1978 and 1981 focused strongly on adjuvant therapy in primary breast cancer, but this top ic served merely as a nucleus in the third meeting. This meeting, although called the Third Heidelberg Symposium was forced to leave Heidelberg and in fact was held in Freiburg. Without the interest and enthusiasm of Professor Martin Schu macher and his colleagues in Freiburg the meeting would never have taken place. The meeting was generously supported again by the Federal Ministry of Research and Technology (Bundesministe rium flir Forschung und Technologie, BMFT) within the framework of the West German BMFT Breast Cancer Study Group. We are grateful, in particular, to Mr. Hans W. Herzog for his personal in volvement. Juni 1988 H. Scheurlen, R. Kay, M.

Participation in Clinical Trials of the Treatment of Early-stage Breast Cancer at the National Cancer Institute

This book provides an overview of the evidence from nearly 100 clinical trials in early breast cancer and presents conclusions aimed at helping all clinicians who treat women with this disease to select the best available therapy. Early breast cancer is diagnosed in several hundreds of thousands of women each year. If some widely practicable treatment could produce even a moderate reduction in the risk of death from the disease, this might avoid 10,000 deaths in a year and the unique world-wide collaboration of the EBCTCG has shown that this can be achieved.

Clinical Trials in Early Breast Cancer

An ideal health care system relies on efficiently generating timely, accurate evidence to deliver on its promise of diminishing the divide between clinical practice and research. There are growing indications, however, that the current health care system and the clinical research that guides medical decisions in the United States falls far short of this vision. The process of generating medical evidence through clinical trials in the United States is expensive and lengthy, includes a number of regulatory hurdles, and is based on a limited infrastructure. The link between clinical research and medical progress is also frequently misunderstood or unsupported by both patients and providers. The focus of clinical research changes as diseases emerge and new treatments create cures for old conditions. As diseases evolve, the ultimate goal remains to speed new and improved medical treatments to patients throughout the world. To keep pace with rapidly changing health care demands, clinical research resources need to be organized and on hand to address the numerous health care questions that continually emerge. Improving the overall capacity of the clinical research enterprise will depend on ensuring that there is an adequate infrastructure in place to support the investigators who conduct research, the patients with real diseases who volunteer to participate in experimental research, and the institutions that organize and carry out the trials. To address these issues and better understand the current state of clinical research in the United States, the Institute of Medicine's (IOM) Forum on Drug Discovery, Development, and Translation held a 2-day workshop entitled Transforming Clinical Research in the United States. The workshop, summarized in this volume, laid the foundation for a broader initiative of the Forum addressing different aspects of clinical research. Future Forum plans include further examining regulatory, administrative, and structural barriers to the effective conduct of clinical research; developing a vision for a stable, continuously funded clinical research infrastructure in the United States; and considering strategies and collaborative activities to facilitate more robust public engagement in the clinical research enterprise.

Cancer Clinical Trials

This book provides an overview of the evidence from nearly 100 clinical trials in early breast cancer and presents conclusions that will help all clinicians who treat women with this disease to select the best available therapy. If some widely practicable treatment could produce even a moderate reduction in the risk of death from the disease, 10,000 deaths per year might be avoided. The worldwide collaboration of the EBCTCG demonstrates that this assertion can be turned into reality. The trials reviewed in this first report involve about 40,000 women with an average follow-up of three years. The treatment of early breast cancer with tamoxifen, chemotherapy, radiotherapy, and ovarian ablation is investigated and the effect of these therapies on mortality and recurrence is reported. A further self-contained volume reviewing 300 randomized trials with a follow-up of six years will be published early in 1991.

Treatment of Early Breast Cancer: Worldwide evidence 1985-1990

Wherever you are in your career, and whatever involvement you have with caring for women with breast cancer, the fifth edition of 'Fast Facts: Breast Cancer' has something for you. The world-class authors of this popular fact-packed handbook provide practical advice on all the key areas of breast cancer management, from risk factors and diagnosis to treatment of all cancer stages. But what really makes it stand out from the crowd is the authors' awareness of the information you need when you talk to a woman concerned about breast cancer. The chapter dedicated to perception of risk will refresh your knowledge and help you talk to your patients about their individual prospects, while the short chapter on clinical trials will help you discuss potential participation in trials and answer common questions. Improvements in the management of breast cancer have followed three major themes in recent years: greater optimization of individualized local treatment, longer duration of therapies, and the use of biological therapies targeted at specific receptors. This colorful up-to-date handbook addresses all these trends, alongside the disturbing issues of overdiagnosis as a result of screening and overtreatment. Given the explosion in information technology, patients and their families have access to much more information on their condition and as a result assume a more active role in their medical management. Health professionals have an important role in helping patients sort the facts from the fallacies, put the risks and benefits into perspective and balance their treatment choices. For this reason alone, 'Fast Facts: Breast Cancer' is an invaluable evidence-based resource for everyone working in breast cancer care in primary and secondary settings, from medical and nursing students, to GPs, specialist nurses and residents. And one for your patients too … The authors encourage you to make your patients well-informed active partners in their breast cancer care by sharing this highly readable book with them. Contents: • Risk factors • Perception of risk • Pathophysiology • Diagnosis

• Local control of primary tumor • Adjuvant therapy • Follow-up and rehabilitation • Management of advanced cancer • Clinical trials • Future trends • Useful resources

Clinical Trials in Early Breast Cancer

Adjuvant treatment is administered prior to or as follow up to surgical procedures for breast cancer. Proven success in using medical therapies allowing for breast conserving procedures or reducing risk of occurrence. Although there has been much progress towards a cure, including the introduction of new targeted therapies, metastasizing cancer remains highly incurable.

Clinical Trials in Early Breast Cancer

The third edition of the bestselling Clinical Trials in Oncology provides a concise, nontechnical, and thoroughly up-to-date review of methods and issues related to cancer clinical trials. The authors emphasize the importance of proper study design, analysis, and data management and identify the pitfalls inherent in these processes. In addition, the book has been restructured to have separate chapters and expanded discussions on general clinical trials issues, and issues specific to Phases I, II, and III. New sections cover innovations in Phase I designs, randomized Phase II designs, and overcoming the challenges of array data. Although this book focuses on cancer trials, the same issues and concepts are important in any clinical setting. As always, the authors use clear, lucid prose and a multitude of real-world examples to convey the principles of successful trials without the need for a strong statistics or mathematics background. Armed with Clinical Trials in Oncology, Third Edition, clinicians and statisticians can avoid the many hazards that can jeopardize the success of a trial.

Transforming Clinical Research in the United States

The results of randomized trials evaluating the use of early or adjuvant systemic treatment for patients with resectable breast cancer provide an eloquent rebuttal to those who would argue that we have made no progress in the treatment of cancer. Many of the tumors that we have been most successful in curing with chemotherapy and other newer forms of treatment are relatively uncommon. In contrast, breast cancer continues to be the single most common malignancy among women in the western world, is increasingly a cause of death throughout Asia and Third-World countries, and remains one of the most substantial causes of cancer mortality world wide. The use of mammography as a means of early detection has been shown to reduce breast cancer mortality by 25-35% among those popu lations in which it is utilized. The use of adjuvant systemic treatment in appropriate patients provides a similar (and additional) reduction in breast cancer mortality. Few subjects have been so systematically studied in the history of medicine, and it seems fair to conclude that the value to adjuvant systemic therapy in prolonging the lives of women with breast cancer is more firmly supported by empirical evidence than even the more conventional or primary treatments using various combinations ofsurgery and radiotherapy.

Breast Cancer

There were no medical oncologists until a few decades ago. In the early 1960s, not only were there no such specialists, many practitioners regarded the treatment of terminally-ill cancer patients with heroic courses of chemotherapy as highly questionable. Physicians loath to assign patients randomly to competing treatments also expressed their outright opposition to the randomized clinical trials that were then relatively rare. And yet today these trials form the basis of medical oncology. How did such a spectacular change occur? How did medical oncology move from a non-entity and in some regards a reviled practice to the central position it now occupies in modern medicine? Cancer on Trial answers these questions by exploring how practitioners established a new style of practice, at the center of which lies the cancer clinical trial.

Treatment of Early Breast Cancer

The ultimate "consumer" of the data presented at conferences on the primary treatment of operable breast cancer is the patient, and when, as in this disease, the benefits of therapy are relatively mod est, the availability and interpretation of the data from trials be comes an issue of primary importance. The effects of present treat ment are in fact such that more patients relapse despite therapy than are estimated to benefit from it. It is, therefore, extremely dif ficult for the physician to recommend unequivocally one particular adjuvant treatment modality for the vast population of women with breast

cancer. The interpretation of results from clinical research-oriented pro grams is constantly applied, however, in the treatment of breast cancer patients outside of clinical trials. From presented or publish ed data, many physicians extrapolate indications for the use of a given treatment regimen for their patients, perceiving it as the "best available therapy. " It is essential that the "best available therapy" be selected individually for each patient. However, considering the modest effect of treatment upon outcome, it is imperative that those who provide the data - those who are involved in both pa tient care and clinical research - make it known that the best cur rent treatment for the population of breast cancer patients is avail able within the framework of clinical trials. In this way not only present-day patients but also future ones will derive the greatest benefit.

Fast Facts: Breast Cancer

This volume provides an in-depth understanding of the biology of breast cancer, the natural history of the disease, the use of molecular markers, the interpretation of clinical trial data, and the integration of multiple therapeutic modalities. Outcomes of clinical trials and details about commonly used drug regimens, drug dosage, and the expected side effects are summarised.

Adjuvant Therapy for Breast Cancer

With the current advances in chemotherapy and hormonal drugs for breast cancer, as well as in surgical techniques and procedures, a revised edition of this popular textbook has become increasingly necessary. Completely overhauling the existing material, the editors of this important work have provided a full update of the area, focusing in particular upon the topics where there has been most progress and controversy.

Clinical Trials in Oncology, Third Edition

This work provides a thought-provoking account of how medical treatments can be tested with unbiased or 'fair' trials and explains how patients can work with doctors to achieve this vital goal. It spans the gamut of therapy from mastectomy to thalidomide and explores a vast range of case studies.

Adjuvant Therapy of Breast Cancer

This book focuses on innovative treatment options for breast cancer, including surgery, radiotherapy, systemic therapy and of course immunotherapy that is changing outcomes in some aggressive breast cancer histotypes. Subsequent chapters also address the ongoing emerging research in the screening, diagnostics, and management of all subtypes of breast cancers. All current landscapes and future perspectives in each molecular subtype: luminal, HER2-positive, and triple-negative breast cancers are discussed within the different chapters. Breast cancer is still the most common cancer and cause of cancer deaths among women worldwide. The improvement of breast cancer outcome appears to be strictly related to the validation of precise biomarkers that enable us to better select personalized approaches in breast cancer management. The closing chapters deal with the challenges of conducting research in the era of precision medicine for cancer. The book is edited and authored by leading experts in this field and will be of interest for clinicians and scientists alike.

Cancer on Trial

Over the last several decades breast cancer management has made great strides in the improvement of oncologic treatment outcomes, particularly so in patients with early stage disease. While wide-spread access to screening resulting in early detection is undoubtedly to be credited for this trend, at the same time, the management of breast cancer has evolved to be an intricate multidisciplinary collaboration between breast imagers, surgeons, medical oncologists and radiation oncologist. As a result, with better mutual understanding of multidisplinary goals and challenges, the treatment strategies have become more individualized, with a great emphasis being placed on the intrinsic disease biology. Furthermore, the indications for neoadjuvant systemic therapy have significantly broadened, with a substantial number of patients with early stage breast cancer being able to take advantage of this strategy to decrease the extent of breast surgery they would undergo at its completion. As such, the management of the axilla in these patients has presented with new challenges as well as with new opportunities to scale down on the extent of local therapy and, consequently, its toxicity. This text will provide a comprehensive, state-of-the art review of this field, and will serve as a valuable resource for clinicians (surgeons, medical oncologists, radiation oncologists) and researchers with an interest in

breast cancer. The book will review novel and evoling strategies in neoadjuvant systemic therapy forn early stage breast cancer, provide new perspectives about appropriate axillary imaging in anticipation of neoadjuvant systemic therapy, and describe new data on innovative surgical techniques and Radiation Oncology concepts designed to deescalate the extent and toxicity of local therapy while insuring oncologic safety. Several landmark clinical trials have been published in the last few years and will be placed in context with respect to current management. Integration of novel diagnostic and interventional breast imaging, local therapy (surgery and radiation) with contemporary systemic therapy will also be discussed. This text will serve as a very useful resource for physicians and researchers dealing with, and interested in, this challenging field. It will provide a concise yet comprehensive summary of the current status of the field that will help guide patient management and stimulate investigative efforts. All chapters will be written by experts in their fields and will include the most up to date scientific and clinical information.

Adjuvant Therapy of Primary Breast Cancer

Breast cancer is the most common cancer in women in the U.S. and Western Europe. Amplification of the her-2/neu gene occurs in approximately 25% of invasive ductal carcinomas of the breast. The first HER-2/neu-targeted approach to reach the clinic was trastuzumab, a humanized monoclonal antibody directed against the extracellular domain of the HER-2/neu protein. Trastuzumab therapy prolongs the survival of patients with metastatico HER-2/neu-overexpressing breast cancer when combined with chemotherapy and has recently been demonstrated to lead to dramatic improvements in disease-free survival when used in the adjuvant therapy setting in combination with or following chemotherapy. Here, we performed a meta-analysis of completed clinical trials of adjuvant trastuzumab in the adjuvant setting. Survival, recurrence, brain metastases, cardiotoxicity and directions for future research are discussed. The results from this meta-analysis are sufficiently compelling to consider 1 year of adjuvant trastuzumab treatment for women with HER-2-positive EBC based on the risk: benefit ratio demonstrated in these studies. Adequate assessment of HER-2/neu status is critical, and careful cardiac monitoring is warranted because of cardiac toxicity. Clinical trials should be designed to answer unsolved questions."

Breast Cancer

The second, updated edition of Management of Breast Cancer in Older Women offers the reader evidence-based knowledge to support the care of older patients with breast cancer. It presents the most up-to-date research and clinical practice from leading specialists across a range of fields that come into contact with older breast cancer patients. With new chapters on nursing and clinical trials in older women, as well as patient perspectives and the issues of managing patients with cognitive impairment, the book offers a new focus on this increasingly common and important group of patients. Multidisciplinary in its approach, this book covers all the bases for managing breast cancer in older women. The full range of therapeutic options is presented, as well as the epidemiology and specific psychosocial considerations for older patients. Medical, surgical and radiation oncologists, breast nurses, gerontologists and all healthcare professionals involved in the management of older breast cancer patients will benefit from this unique and important work.

Textbook of Breast Cancer

We often hear physicians, health care professionals, poli ticians, and patient advocates that "nothing has happened in the treatment of breast cancer," since patients with breast cancer, the most frequent neoplastic condition in women in industrialized countries, are continuing to suffer relapse and succumb to this dreadful disease! This negativistic attitude does not seem to be justified, but, why is the transmission of clinical trial results into general practice, and with it progress, such a slow process? After many decades of frustrating stagnation of long-term survival expectations, in all stages of early, oper/lble breast cancer treated only by surgery and locoregional radio therapy, adjuvant systemic therapy (chemo- as well as endocrine treatments) clearly showed to significantly benefit in terms of disease-free and overall survival. This evolution has been extensively expounded on by the Worldwide Oxford Overview and the Expert Consensus Panel at the fourth International Conference 'on Adjuvant Therapy of Primary Breast Cancer in St. Gallen (Early Breast Cancer Trialists' Collaborative Group 1992; Glick et al. 1992). What has happened since then? During the past 3-5 years, several new concepts and treatment strategies have emerged and have been studied in various major breast cancer groups and treatment centers worldwide. Some of these can already be considered to assist in the

primary treatment of operable breast cancer today, while others are . still undergoing clini,cal trials for better definition of their practical usefulness.

Testing Treatments

Many new challenges have arisen in the area of oncology clinical trials. New cancer therapies are often based on cytostatic or targeted agents, which pose new challenges in the design and analysis of all phases of trials. The literature on adaptive trial designs and early stopping has been exploding. Inclusion of high-dimensional data and imaging techniques have become common practice, and statistical methods on how to analyse such data have been refined in this area. A compilation of statistical topics relevant to these new advances in cancer research, this third edition of Handbook of Statistics in Clinical Oncology focuses on the design and analysis of oncology clinical trials and translational research. Addressing the many challenges that have arisen since the publication of its predecessor, this third edition covers the newest developments involved in the design and analysis of cancer clinical trials, incorporating updates to all four parts: Phase I trials: Updated recommendations regarding the standard 3 + 3 and continual reassessment approaches, along with new chapters on phase 0 trials and phase I trial design for targeted agents. Phase II trials: Updates to current experience in single-arm and randomized phase II trial designs. New chapters include phase II designs with multiple strata and phase II/III designs. Phase III trials: Many new chapters include interim analyses and early stopping considerations, phase III trial designs for targeted agents and for testing the ability of markers, adaptive trial designs, cure rate survival models, statistical methods of imaging, as well as a thorough review of software for the design and analysis of clinical trials. Exploratory and high-dimensional data analyses: All chapters in this part have been thoroughly updated since the last edition. New chapters address methods for analyzing SNP data and for developing a score based on gene expression data. In addition, chapters on risk calculators and forensic bioinformatics have been added. Accessible to statisticians and oncologists interested in clinical trial methodology, the book is a single-source collection of up-to-date statistical approaches to research in clinical oncology.

Breast Cancer Research and Treatment

Tailoring treatment for individual breast cancers is no longer a dream and is now the main goal for current research. This book gives an overview of the most recent techniques, agents and approaches for breast cancer and the individualization of treatment. Particular attention is given to organ-specific tailored approaches, specific populations, patients' preferences and rehabilitation. Contributions from experts focus on the biomedical research behind the transfer of molecular biology knowledge into the clinical management of patients. This has led to increased survival as well as improved quality of life. The book gives an overview of the latest achievements in breast cancer and their use in clinical practice.

Management of the Breast and Axilla in the Neoadjuvant Setting

Treatment strategies for breast cancer are wide-ranging and often based on a multi-modality approach, depending on the stage and biology of the tumour and the acceptance and tolerance of the patient. They may include surgery, radiotherapy, and systemic therapy (endocrine therapy, chemotherapy, and targeted therapy). Advances in technologies such as oncoplastic surgery, radiation planning and delivery, and genomics, and the development of novel systemic therapy agents alongside their evaluation in ongoing clinical trials continue to strive for improvements in outcomes. In this Special Issue, we publish a collection of studies looking at all forms of therapeutic strategies for early and advanced breast cancer, focusing on their outcomes, notably survival.

Adjuvant Trastuzumab in the Treatment of Her-2-positive Early Breast Cancer

This concise handbook provides oncologists and other healthcare providers with crucial updates in the field, including an updated review of the current understanding of the biology of the HER2 pathway, an overview of HER2-testing, and evidence-based discussions of available and emerging HER2-targeted treatment options. An essential clinical text for physicians that screen and treat patients with breast cancer and require an accessible, up-to-date survey of the dynamic treatment landscape.

Management of Breast Cancer in Older Women

Cancer is a major healthcare burden across the world and impacts not only the people diagnosed with various cancers but also their families, carers, and healthcare systems. With advances in the

diagnosis and treatment, more people are diagnosed early and receive treatments for a disease where few treatments options were previously available. As a result, the survival of patients with cancer has steadily improved and, in most cases, patients who are not cured may receive multiple lines of treatment, often with financial consequences for the patients, insurers and healthcare systems. Although many books exist that address economic evaluation, Economic Evaluation of Cancer Drugs using Clinical Trial and Real World Data is the first unified text that specifically addresses the economic evaluation of cancer drugs. The authors discuss how to perform cost-effectiveness analyses while emphasising the strategic importance of designing cost-effectiveness into cancer trials and building robust economic evaluation models that have a higher chance of reimbursement if truly cost-effective. They cover the use of real-world data using cancer registries and discuss how such data can support or complement clinical trials with limited follow up. Lessons learned from failed reimbursement attempts, factors predictive of successful reimbursement and the different payer requirements across major countries including US, Australia, Canada, UK, Germany, France and Italy are also discussed. The book includes many detailed practical examples, case studies and thought-provoking exercises for use in classroom and seminar discussions. Iftekhar Khan is a medical statistician and health economist and a lead statistician at Oxford Unviersity's Center for Statistics in Medicine. Professor Khan is also a Senior Research Fellow in Health Economics at University of Warwick and is a Senior Statistical Assessor within the Licensing Division of the UK Medicine and Health Regulation Agency. Ralph Crott is a former professor in Pharmacoeconomics at the University of Montreal in Quebec, Canada and former head of the EORTC Health Economics Unit and former senior health economist at the Belgian HTA organization. Zahid Bashir has over twelve years experience working in the pharmaceutical industry in medical affairs and oncology drug development where he is involved in the design and execution of oncology clinical trials and development of reimbursement dossiers for HTA submission.

Adjuvant Therapy of Breast Cancer V

Physical illness cannot be effectively treated other than in the context of the psychological factors with which it is associated. The body may have the disease, but it is the patient who is ill. Research psychologists from a number of different backgrounds have, in the past few decades, turned increasingly to the study of physical illness, and there is now an extensive literature on preventive behaviors, the role of stress in the etiology of illness, the patient's reactions to illness and its treatment, and the physician-patient relationship. At the same time practicing clinical psychologists have extended their concern beyond the treatment of speci fically psychiatric disorders, to include also the psychological care of people experiencing distress through illness or injury. Traditionally, these patients have tended to fall through the net, unless their distress is so great that it assumes the proportion of a psychiatric disorder that can then be treated in its own right. Because the physical disorder is the primary one, its existence has detracted from the salience of the very real emotional disturbance to which it can give rise. Moreover, emotional reactions in this setting, being the norm, seems to have been regarded as not meriting special attention and care. This situation is chang ing, and it is not just psychologists or psychiatrists who are responsible for the shift in attitudes. Within general medicine itself, there is now a renewed empha sis on the care of the whole patient and not just the disease.

Handbook of Statistics in Clinical Oncology, Third Edition

In November 1999, the Institute of Medicine, in consultation with the Commission on Life Sciences, the Commission on Physical Sciences, Mathematics, and Applications, and the Board on Science, Technology and Economic Policy launched a one year study on technologies for early detection of breast cancer. The committee was asked to examine technologies under development for early breast cancer detection, and to scrutinize the process of medical technology development, adoption, and dissemination. The committee is gathering information on these topics for its report in a number of ways, including two public workshops that bring in outside expertise. The first workshop on "Developing Technologies for Early Breast Cancer Detection" was held in Washington DC in February 2000. The content of the presentations at the workshop is summarized here. A second workshop, which will focus on the process of technology development and adoption, will be held in Washington, DC on June 19-20. A formal report on these topics, including conclusions and recommendations, will be prepared by the committee upon completion of the one-year study.

Breast Cancer Management and Molecular Medicine

This book will examine current issues and controversies in the design of clinical trials, including topics in adaptive and sequential designs, the design of correlative genomic studies, the design of studies in which missing data is anticipated. Each chapter will be written by an expert conducting research in the topic of that chapter. As a collection, the chapters would be intended to serve as a guidance for statisticians designing trials.

Treatment Strategies and Survival Outcomes in Breast Cancer

A discussion of the diagnosis of breast cancer and the risks, benefits and limitations of treatment alternatives, particularly tamoxifen. This edition contains information on developments in the use of tamoxifen, especially in the results of the Breast Cancer Prevention Trial.

Handbook of HER2-Targeted Agents in Breast Cancer

This RRCR-conference-volume marks "number six" in a 20-year evolution of international conferences on the adjuvant therapy of primary breast cancer. Starting in 1978, a handful of some 80 en thusiastic breast cancer surgeons and oncologists, met in a se cluded mountain resort near st. Gallen in Eastern Switzerland, to exchange their early data of some pioneer trials on adjuvant sys temic therapy of early breast cancer, and to correlate their future research efforts to overcome the frustrating prognostic stagna tion of this dominant neoplastic disease in Western females dur ing the past decades. Repeated every 3-4 years, these St. Gallen International Conferences on Adjuvant Therapy of Primary Breast Cancer have continuously grown in numbers of partici pants and in normative, therapeutic influence by being published in major oncology journals [1-3], the last (6th) conference hav ing taken place from February 25-28, 1998 with more than 1800 attendees from over 50 countries worldwide. What is the fascination of adjuvant therapy in primary (early) breast cancer, and what has changed,during the last 3 years since March 1995, to justify another international gathering of this size, and of the world's leading experts in the field? There is no question, that providing even more effective care and designing appropriate recommendations for the multitudes of patients with so-called early breast cancer or at high risk of developing the disease, remain highly important public health goals.

Economic Evaluation of Cancer Drugs

Now published in its Second Edition, the Textbook of Clinical Trials offers detailed coverage of trial methodology in diverse areas of medicine in a single comprehensive volume. Praise for the First Edition: "... very useful as an introduction to clinical research, or for those planning specific studies within therapeutic or disease areas." BRITISH JOURNAL OF SURGERY, Vol. 92, No. 2, February 2005 The book’s main concept is to describe the impact of clinical trials on the practice of medicine. It separates the information by therapeutic area because the impact of clinical trials, the problems encountered, and the numbers of trials in existence vary tremendously from specialty to specialty. The sections provide a background to the disease area and general clinical trial methodology before concentrating on particular problems experienced in that area. Specific examples are used throughout to address these issues. The Textbook of Clinical Trials, Second Edition: Highlights the various ways clinical trials have influenced the practice of medicine in many therapeutic areas Describes the challenges posed by those conducting clinical trials over a range of medical specialities and allied fields Additional therapeutic areas are included in this Second Edition to fill gaps in the First Edition as the number and complexity of trials increases in this rapidly developing area Newly covered or updated in the Second Edition: general surgery, plastic surgery, aesthetic surgery, palliative care, primary care, anaesthesia and pain, transfusion, wound healing, maternal and perinatal health, early termination, organ transplants, ophthalmology, epilepsy, infectious disease, neuro-oncology, adrenal, thyroid and urological cancers, as well as a chapter on the Cochrane network An invaluable resource for pharmaceutical companies, the Textbook of Clinical Trials, Second Edition appeals to those working in contract research organizations, medical departments and in the area of public health and health science alike.

Psychological Aspects of Early Breast Cancer

Of all cancers, probably breast cancer is one of the most emotive. Increasingly patients with breast cancer are participating in the surgical and/or medical decisions about their treatment. This involvement raises ethical issues about the rights of patients and their ability to give an informed consent, concerns about the process of communication between the medical staff and the patient, and also issues about the psychology of not only the woman with breast cancer, but also the doctor. This book addresses

these issues relating to shared decision making and in particular those areas where a choice of treatment option involves some degree of risk/benefit analysis. It covers the ethical principles and then looks at the evidence that women who are fully informed and who have taken part in the decision making process regarding their treatment, and who have a positive attitude towards their illness, tend to do better in the long run. Appropriate experts have contributed sections on the different treatment options to provide a brief overview of the treatments available and highlight the issues that should be considered by the woman and the doctor in the decision making process. There is also a section on the patients perspective and vignettes throughout to illustrate the importance of communication.

Developing Technologies for Early Detection of Breast Cancer

In the late 1980s, a promising new treatment for breast cancer emerged: high-dose chemotherapy with autologous bone marrow transplantation or HDC/ABMT. By the 1990s, it had burst upon the oncology scene and disseminated rapidly before having been carefully evaluated. By the time published studies showed that the procedure was ineffective, more than 30,000 women had received the treatment, shortening their lives and adding to their suffering. This book tells of the rise and demise of HDC/ABMT for metastatic and early stage breast cancer, and fully explores the story's implications, which go well beyond the immediate procedure, and beyond breast cancer, to how we in the United States evaluate other medical procedures, especially life-saving ones. It details how the factors that drove clinical use--patient demand, physician enthusiasm, media reporting, litigation, economic exploitation, and legislative and administrative mandates--converged to propel the procedure forward despite a lack of proven clinical effectiveness. It also analyzes the limited effect of technology assessments before randomized clinical trials evaluated decisively the procedure and the ramifications of this system on healthcare today. Sections of the book consider the initial conditions surrounding the emergence of the new breast cancer treatment, the drivers of clinical use, and the struggle for evidence-based medicine. A concluding section considers the significance of the story for our healthcare system.

Designs for Clinical Trials

This issue of Surgical Oncology Clinics of North America, guest edited by Dr. Elin R. Sigurdson, is devoted to Clinical Trials in Surgical Oncology. Dr. Sigurdson has assembled expert authors to review the following topics: Commentary on Randomized Controlled Trials; Randomized Clinical Trials in Soft Tissue Sarcoma; Randomized Clinical Trials in Gastrointestinal Stromal Tumors; Randomized Clinical Trials in Melanoma; Randomized Clinical Trials in Breast Cancer; Randomized Clinical Trials in Gastroesophageal Carcinoma; Randomized Clinical Trials in Hepatocellular Carcinoma; An Update on Randomized Clinical Trials in Advanced and Metastatic Colorectal Carcinoma; Randomized Clinical Trials in Colon and Rectal Cancer; Randomized Clinical Trials in Anal Cancers; The Elderly in Randomized Clinical Trials; Hereditary Syndromes in Clinical Trials; Future Clinical Trials: Genetically Driven Trials; Randomized Clinical Trials in Neuroendocrine Tumors, and more!

Tamoxifen and Breast Cancer

In Meeting Psychosocial Needs of Women with Breast Cancer, the National Cancer Policy Board of the Institute of Medicine examines the psychosocial consequences of the cancer experience. The book focuses specifically on breast cancer in women because this group has the largest survivor population (over 2 million) and this disease is the most extensively studied cancer from the standpoint of psychosocial effects. The book characterizes the psychosocial consequences of a diagnosis of breast cancer, describes psychosocial services and how they are delivered, and evaluates their effectiveness. It assesses the status of professional education and training and applied clinical and health services research and proposes policies to improve the quality of care and quality of life for women with breast cancer and their families. Because cancer of the breast is likely a good model for cancer at other sites, recommendations for this cancer should be applicable to the psychosocial care provided generally to individuals with cancer. For breast cancer, and indeed probably for any cancer, the report finds that psychosocial services can provide significant benefits in quality of life and success in coping with serious and life-threatening disease for patients and their families.

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Textbook of Clinical Trials