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G U E S T E D I T O R S

Bryce B. Reeve, PhD

*National Cancer Institute,
Bethesda, MD*

Bryce B. Reeve, PhD, is a Psychometrician and Program Director at the US National Institutes of Health's National Cancer Institute (NCI), where he has worked since 2000. At NCI, he directs an active program to enhance the use of patient-reported outcomes (PROs; including health-related quality of life [HRQOL] and patient experiences with health care) in clinical research and practice to improve the quality of care for both pediatric and adult patients with cancer. With a degree in quantitative psychology from the University of North Carolina at Chapel Hill, his work at NCI is focused on enhancing PRO measures with innovative psychometric methodologies, and integrating PRO data in cancer research and health care delivery to inform decision making.

Dr Reeve serves as an NIH Science Officer on the Patient-Reported Outcomes Measurement Information System Network. In 2004, he organized an international conference on applying item response theory and computerized-adaptive testing methodology to enhance HRQOL assessment, and in September 2006, he organized an NCI-sponsored conference examining the value and challenges of integrating HRQOL in cancer clinical trials.

Dr Reeve was elected and now currently serves on the Board of Directors of the International Society for Quality of Life Research. He also serves on NCI's Symptom Management and Health-Related Quality of Life Steering Committee, and the Steering Committee of Assessing the Symptoms of Cancer using Patient-Reported Outcomes.

Steven B. Clauser, PhD

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Steven B. Clauser, PhD, is Chief of the Outcomes Research Branch in the National Cancer Institute (NCI) Division of Cancer Control and Population Sciences, Applied Research Program. Dr Clauser directs NCI's research program in outcomes research and quality of care. His personal research interests are in patient-centered communication, health-related quality of life of cancer patients and survivors, measurement of the clinical effectiveness of cancer care delivery, and evaluation of cancer care delivery programs. Dr Clauser serves on several committees and national advisory panels related to these interests. He received his training in health services research at the University of Minnesota.

Joseph Lipscomb, PhD

*Rollins School of Public Health
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Joseph Lipscomb, PhD, is Professor of Health Policy and Management, and Georgia Cancer Coalition Distinguished Cancer Scholar at the Rollins School of Public Health at Emory University. He is also co-director of the Cancer Control and Population Sciences Program at Emory's Winship Cancer Institute, and is formerly Chief of the Outcomes Research Branch at the National Cancer Institute. His research focuses on patient-reported outcomes assessment, quality-of-care evaluation and improvement, and the theory and practice of cost-effectiveness analysis. He is currently principal investigator on two research grants from the Centers for Disease Control and Prevention, examining patterns and quality of cancer care in Georgia. He received his PhD in economics from the University of North Carolina at Chapel Hill in 1975, and a BA in mathematics from Vanderbilt University in 1970.

ANNOUNCEMENTS

VOLUME 25 • NUMBER 32 • NOVEMBER 10 2007

JCO Impact Factor Increases to 13.598

JCO's impact factor increased from 11.81 to 13.598, as reported by Thomson Scientific in its 2006 *Journal Citation Report*. Of 126 oncology journals monitored worldwide, JCO ranks fifth (up from sixth) by impact factor and second by total citations, with 71,800 citations made to published articles—almost 13,000 more than in the previous year. An impact factor is a measure of how often the average article in a journal has been cited within a given year. In addition, JCO's immediacy index, which measures citations last year to articles published last year (not included in the impact factor calculation), rose to 3.485, the highest of any clinical oncology journal. Daniel G. Haller, editor-in-chief of JCO, said, "JCO owes this continuing improvement to the editors and editorial staff, as well as the guidance of the Editorial Board, the support of the society, and the enormous contributions of authors and reviewers. JCO's 2006 impact factor, total citations, and immediacy index reflect the Journal's continued success in delivering content that strengthens expertise, improves practice, advances medical research, and supplements academic teaching."

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August 1—Improving the Quality of Supportive Cancer Care

October 10—Translational Oncology

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JCO Offers New Manuscript Submission Checklist for Authors

Every issue of JCO now includes a submission checklist for authors to use when preparing to submit a manuscript. The checklist is meant to help authors collect all relevant information and materials before beginning the online submission process. The submission checklist is located just after the Information for Contributors section of the *Journal*.

Five New JCO International Editions Launched

JCO has added five new international editions to its current roster of publications serving oncologists around the world. Translated editions in Chinese, Russian, and Turkish have joined the current offerings in Spanish, Polish, and Hungarian. Joining the current English-language Middle Eastern edition are English-language editions distributed in Greece and Northern Africa. All of these editions are intended to expand the availability of high-impact research to oncologists worldwide. David M. Khayat, MD, PhD, who has served as an associate editor of JCO since 2001, has been appointed deputy editor for international editions and will oversee the quality and development of the program. For more information about JCO's international editions, or to subscribe to the edition of your choice, contact the ASCO Licensing, Rights, and Permissions Office at permissions@asco.org.

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Translational oncology manuscripts are now being accepted for publication in JCO. The manuscripts may represent any clinical discipline and may include, but are not limited to, such research disciplines as cancer biomarkers, angiogenesis, receptor-based therapy, epigenetics, signal transduction, genomics, proteomics, and gene profiling. Translational oncology articles originally appeared in their own separate issues, as part of the 2006 JCO Special Series. These articles were so well received that for 2007 they will be moved to the regular issues of JCO. Mary L. Disis, MD, JCO's deputy editor, is spearheading the effort to transition translational oncology articles to the 30 regular issues of JCO. To discuss the suitability of your translational oncology manuscript for submission to JCO, contact Dr Disis at disism@asco.org.

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CURRENT ABSTRACTS

VOLUME 25 • NUMBER 32 • NOVEMBER 10 2007

Issues and Challenges With Integrating Patient-Reported Outcomes in Clinical Trials Supported by the National Cancer Institute–Sponsored Clinical Trials Networks. . . Deborah Watkins Bruner, Charlene J. Bryan, Neil Aaronson, et al

pp 5051-5057

Purpose: The objective of this report is to provide a historical overview of and the issues and challenges inherent in the incorporation of patient-reported outcomes (PROs) into multinational cancer clinical trials in the cancer cooperative groups.

Methods: An online survey of 12 cancer cooperative groups from the United States, Canada, and Europe was conducted between June and August of 2006. Each of the cooperative groups designated one respondent, who was a member of one of the PRO committees within the cooperative group.

Results: There was a 100% response rate, and all of the cancer clinical trial cooperative groups reported conducting PRO research. PRO research has been conducted in the cancer cooperative groups for an average of 15 years (range, 6 to 30 years), and all groups had multidisciplinary committees focused on the design of PRO end points and the choice of appropriate PRO measures for cancer clinical trials. The cooperative groups reported that 5% to 50% of cancer treatment trials and an estimated 50% to 75% of cancer control trials contained PRO primary and secondary end points. There was considerable heterogeneity among the cooperative groups with respect to the formal and informal policies and procedures or cooperative group culture towards PROs, investigator training/mentorship, and resource availability for the measurement and conduct of PRO research within the individual cooperatives.

Conclusion: The challenges faced by the cooperative groups to the incorporation of PROs into cancer clinical trials are varied. Some common opportunities for improvement include the adoption of standardized training/mentorship mechanisms for investigators for the conduct of PRO assessments and data collection and the development of minimal criteria for PRO measure acceptability. A positive cultural shift has occurred in most of the cooperative groups related to the incorporation of PROs in clinical trials; however, financial and other resource barriers remain and need to be addressed.

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Patient-Reported Outcomes in Phase II Cancer Clinical Trials: Lessons Learned and Future Directions. . . Lynne I. Wagner,

Lari Wenzel, Edward Shaw, et al pp 5058-5062

With increasing limits on the resources available to conduct cancer clinical trials, the inclusion of patient-reported outcomes (PROs) in treatment and symptom management trials must be prioritized. Although it has been suggested on occasion that phase III trials should take precedence over phase II trials, we argue that there is a clear and important role for PRO assessment in phase II trials going forward. To illustrate the value realized from including PROs in phase II trials, we provide case examples from cancer treatment and supportive care. The benefits of including PROs in symptom management intervention research are exemplified using phase II trials targeting cognitive impairment. The inclusion of PROs in phase II cancer clinical trials adds important information about the impact of treatment in health-related quality of life, and advances the science of PRO measurement. These contributions significantly enhance the design of phase III trials, ultimately leading to the efficient utilization of clinical trial resources.

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Use of Patient-Reported Outcomes in Phase III Cancer Treatment Trials: Lessons Learned and Future Directions

Patricia A. Ganz and Carolyn C. Gotay pp 5063-5069

Purpose: This article examines the challenges, opportunities, and successes that have occurred in the incorporation of patient-reported outcomes (PROs) in phase III cancer clinical trials.

Methods: An informal survey of the leadership of US cooperative group PRO investigators identified diverse trials in which PROs had been measured. Exemplary trials were selected for lessons learned and for examination of successful strategies.

Results: We review four challenging trials in depth, illustrating some of the difficulties in integrating PROs within treatment trials, including issues related to missing data, lack of procedures for monitoring patients and ensuring collection of PRO data, and missed opportunities in publication of treatment and PRO outcomes together. Four examples of successful trials are highlighted.

Conclusion: As a result of this review, the authors make specific recommendations related to the use of PROs in phase III trials, focusing on issues related to design, choice of PRO instrument and frequency of administration, analysis, and publication strategies.

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Integrating Patient-Reported Outcomes Into Cancer Symptom Management Clinical Trials Supported by the National Cancer Institute-Sponsored Clinical Trials Networks. . . Jeff A. Sloan, Lawrence Berk, Joseph Roscoe, et al **pp 5070-5077**

Patient-reported outcomes (PROs) are often the primary end point in symptom management trials. The scientific field of PROs is evolving, as evidenced by the US Food and Drug Administration's February 2007 release of a draft guidance for using PROs in effectiveness claims for drug labeling. This article presents issues encountered during use of PROs in National Cancer Institute-sponsored symptom management trials. Selected trials are presented that exemplify the challenges often seen in symptom management trials, and solutions are described. The examples presented include defining the appropriate end point, selecting and validating assessments, and answering the research questions through statistical analysis and interpretation. Progress has been made in addressing some of the unique challenges of PRO-based symptom management research. Many challenges still remain, but a foundational body of work now exists for more consistent and rigorous application of PROs into symptom management trials. There remains a need for more research in several methodologic aspects of design, analysis, and interpretation of symptom management trials.

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Lessons Learned in the Assessment of Health-Related Quality of Life: Selected Examples From the National Cancer Institute of Canada Clinical Trials Group. . . Michael Brundage, David Osoba, Andrea Bezjak, et al **pp 5078-5081**

In this article, we provide a brief historical review of the development of patient-reported outcome measurement, analysis, and reporting in clinical trials of the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG). In doing so, we examine selected lessons learned in furthering the quality of these data and their application to clinical practice. We conclude that sequential institution of key policies within the NCIC CTG and the development of a collective philosophy within the group has enabled the routine incorporation of health-related quality of life into clinical trial protocols according to robust scientific principles; that collection of quality data is possible in a variety of circumstances (although not universally so); that patient-reported data on subjective experiences is likely to be more reliable and valid than conventional toxicity information; and that simple analyses that report group trends as well as individual patient response rates are preferred.

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International Perspective on Health-Related Quality-of-Life Research in Cancer Clinical Trials: The European Organisation for Research and Treatment of Cancer Experience. . . Andrew Bottomley and Neil K. Aaronson **pp 5082-5086**

Over recent decades, health-related quality of life (HRQOL) research has been increasingly integrated into cancer clinical trials. The purpose of this review is to examine the overall approach taken towards clinical trial-based HRQOL investigations within the European Organisation for Research and Treatment of Cancer (EORTC). This article reports a literature review of clinical trial-based HRQOL investigations and provides selective examples of HRQOL studies in phase III clinical trials in various disease sites. The findings of this review highlight that, historically, assessing HRQOL was a challenge. However, as EORTC has become more experienced in the assessment of HRQOL and has developed a portfolio of appropriate tools, HRQOL has become a more accepted end point in large-scale trials. The trials reviewed in this article show that, in general, HRQOL data do provide information that can both inform clinicians about the effectiveness of the treatments and also serve as an invaluable source of information for patients to make informed decisions regarding the treatment choice.

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Current Status of Patient-Reported Outcomes in Industry-Sponsored Oncology Clinical Trials and Product Labels

Kathleen Gondek, Pierre-Philippe Sagnier, Kim Gilchrist, et al pp 5087-5093

Assessing patient-reported outcomes (PROs) in clinical trials is of interest to clinicians, patients, regulators, and industry. The use and impact of PROs is a growing area of methodologic research, particularly as they relate to tumor types, biomarkers, and various patient populations and cultures. Both the US Food and Drug Administration (FDA) and European Agency for the Evaluation of Medicinal Products in recent guidance have acknowledged the need to account for treatment-related impact on patient symptoms and/or health-related quality of life (HRQOL). Clinical research likely reflects the informative value of PROs. A search of www.clinicaltrials.gov, the FDA Web site, and product package inserts was conducted to assess the inclusion of symptom assessment and HRQOL within industry-sponsored clinical trials in cancer and approved cancer therapies and their respective product labels. Overall, there were 2,704 industry-sponsored oncology trials, of which 322 (12%) included a PRO measure. Of the 70 FDA new or revised labels, only six package inserts include PRO data. Symptoms were assessed uniformly across the phases of clinical trials, whereas HRQOL assessment increased in the later phases of clinical trials. Collecting PRO data can enhance our understanding of cancer burden and the impact of interventions on patients' lives.

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Patient-Reported Outcomes Supporting Anticancer Product Approvals. . . *Edwin P. Rock, Dianne L. Kennedy, Melissa H. Furness, et al* pp 5094-5099

In 2006, the US Food and Drug Administration (FDA) published draft guidance to provide recommendations for development, validation, implementation, and interpretation of patient-reported outcome (PRO) measures that can support treatment benefit claims in product labeling. Here, we summarize and discuss FDA approvals of anticancer products in the context of the draft guidance. We identified anticancer product approvals having efficacy claim(s) based at least in part on a PRO. In addition, we collated limitations of PRO instruments commonly submitted for regulatory review over the period from October 1, 2004 to September 30, 2006. From 1995 onward, nine indications were approved for seven anticancer products based at least in part on a PRO. In eight of nine approvals, PRO data supplemented other evidence of clinical benefit. In seven approvals, the PRO measured a single symptom or functional domain that was directly attributable to the treatment benefit observed in the disease. The FDA's draft PRO guidance describes principles that have been used in anticancer product approvals for more than a decade. PRO end points typically support treatment benefit claims that refer to a patient's symptoms or ability to function. Single-item PROs may be acceptable. PRO data should be both internally consistent and aligned with other evidence of clinical benefit. The FDA encourages sponsors to consult with the FDA early in the process of PRO development.

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Funding Patient-Reported Outcomes in Cancer Clinical Trials. . . *Carol M. Moinpour, Andrea M. Denicoff, Deborah Watkins Bruner, et al* pp 5100-5105

We surveyed four cooperative groups to identify current funding sources for the collection and analysis effort associated with the inclusion of patient-reported outcome (PRO) data in cancer clinical trials. Survey questions included what proportion of staff effort was funded through the Cancer Therapy Evaluation Program (CTEP) and the Community Clinical Oncology Program (CCOP) grants. In addition, the groups were asked to what extent outside funding was solicited to cover an underfunded PRO effort (eg, the pharmaceutical industry, foundations, or National Institutes of Health grants). All four groups noted the challenge of making limited resources cover a number of trial responsibilities. PRO effort is usually bundled with effort required for all clinical trial data. There is variation in the use of the CTEP and CCOP grants to fund PRO research. The groups differed with respect to both the types and amount of outside funding used. This survey focused on funding sources for the conduct of PRO research in cooperative group trials; it did not assess the specific cost components associated with collecting and analyzing these data. In general, the costs for conducting PRO research have been bundled with other study costs because in most cases, the PRO has been considered an integral component of the trial. However, these data also suggest that PRO research has required the use of outside funding sources in the four surveyed cooperative groups and that PRO economic issues require attention if we are to continue the inclusion of these outcomes in cancer clinical trials.

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Standardizing Patient-Reported Outcomes Assessment in Cancer Clinical Trials: A Patient-Reported Outcomes Measurement Information System Initiative. . . *Sofia F. Garcia, David Cella, Steven B. Clauser, et al* pp 5106-5112

Patient-reported outcomes (PROs), such as symptom scales or more broad-based health-related quality-of-life measures, play an important role in oncology clinical trials. They frequently are used to help evaluate cancer treatments, as well as for supportive and palliative oncology care. To be most beneficial, these PROs must be relevant to patients and clinicians, valid, and easily understood and interpreted. The Patient-Reported Outcomes Measurement Information System (PROMIS) Network, part of the National Institutes of Health Roadmap Initiative, aims to improve appreciably how PROs are selected and assessed in clinical research, including clinical trials. PROMIS is establishing a publicly available resource of standardized, accurate, and efficient PRO measures of major self-reported health domains (eg, pain, fatigue, emotional distress, physical function, social function) that are relevant across chronic illnesses including cancer. PROMIS is also developing measures of self-reported health domains specifically targeted to cancer, such as sleep/wake function, sexual function, cognitive function, and the psychosocial impacts of the illness experience (ie, stress response and coping; shifts in self-concept, social interactions, and spirituality). We outline the qualitative and quantitative methods by which PROMIS measures are being developed and adapted for use in clinical oncology research. At the core of this activity is the formation and application of item banks using item response theory modeling. We also present our work in the fatigue domain, including a short-form measure, as a sample of PROMIS methodology and work to date. Plans for future validation and application of PROMIS measures are discussed.

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Compliance With Patient-Reported Outcomes in Multicenter Clinical Trials: Methodologic and Practical Approaches

Stephanie R. Land, Marcie W. Ritter, Joseph P. Costantino, et al pp 5113-5120

Purpose: This report describes interventions undertaken by the National Surgical Adjuvant Breast and Bowel Project (NSABP) to improve compliance with patient-reported outcome (PRO) assessments in the setting of multicenter cancer clinical trials. We describe the effectiveness of several interventions and of observational factors.

Methods: PRO submission rates were analyzed for the following three NSABP protocols: the Study of Raloxifene and Tamoxifen (STAR), B-32, and B-35. Institutions participating in protocol B-35 were randomly assigned to receive automated reminders of upcoming assessments or not. Compliance was analyzed with a logistic repeated measures mixed modeling.

Results: Compliance was high in the three protocols, with rates greater than 80% for nearly all time points. Institutions were a significant source of variability ($P < .01$). The largest institutions had the highest compliance in STAR (odds ratio [OR] = 0.68 for < 50 participants enrolled and OR = 0.82 for 50 to 99 participants enrolled v larger institutions; $P < .001$). Midsized institutions had highest compliance in B-32 (OR = 4.63 for 31 to 50 patients enrolled and OR = 3.12 for > 50 patients enrolled v small institutions; $P = .007$). Compliance increased with participant age in STAR (OR = 0.57, 0.89, and 1.01 for ages < 50 , 50 to 60, and 60 to 70 years, respectively, $v > 70$ years; $P < .001$). Race was significant in B-32 (OR = 2.63 for white v nonwhite; $P < .001$) and in STAR (OR = 1.41 for white v nonwhite; $P < .001$). Treatment group was significant in B-32 (OR = 0.74; $P = .006$). The B-35 prospective reminder did not improve compliance significantly ($P = .30$), but in B-32, delinquency sanctions were significant (OR = 1.56; $P = .007$).

Conclusion: Compliance in NSABP PRO studies is higher now than a decade ago. Results for compliance initiatives were mixed. Age and race are important factors, but institutional variation remains significant and largely unexplained.

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Patient-Reported Outcomes and the Evolution of Adverse Event Reporting in Oncology. . . Andy Trotti, A. Dimitrios Colevas,

Ann Setser, et al pp 5121-5127

Adverse event (AE) reporting in oncology has evolved from informal descriptions to a highly systematized process. The Common Terminology Criteria for Adverse Events (CTCAE) is the predominant system for describing the severity of AEs commonly encountered in oncology clinical trials. CTCAE clinical descriptors have been developed empirically during more than 30 years of use. The method of data collection is clinician based. Limitations of the CTC system include potential for incomplete reporting and limited guidance on data analysis and presentation methods. The Medical Dictionary for Regulatory Activities (MedDRA) is a comprehensive medical terminology system used for regulatory reporting and drug labeling. MedDRA does not provide for severity ranking of AEs. CTC-based data presentations are the primary method of AE data reporting used in scientific journals and oncology meetings. Patient-reported outcome instruments (PROs) cover the subjective domain of AEs. Exploratory work suggests PROs can be used with a high degree of patient engagement and compliance. Additional studies are needed to determine how PROs can be used to complement current AE reporting systems. Potential models for integrating PROs into AE reporting are described in this review. AE reporting methods will continue to evolve in response to changing therapies and growing interest in measuring the impact of cancer treatment on health status. Although integration of PROs into AE reporting may ultimately improve the comprehensiveness and quality of collected data, it may also increase the administrative burden and cost of conducting trials. Therefore, care must be used when developing health outcomes and safety data collection plans.

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Health-Related Quality of Life and Symptom Management Research Sponsored by the National Cancer Institute

Lori M. Minasian, Ann M. O'Mara, Bryce B. Reeve, et al pp 5128-5132

For almost 30 years, the National Cancer Institute (NCI) has sponsored health-related quality-of-life (HRQOL) measures in cancer research as a means of including the patient's experience. The scope of NCI's research in symptom management and HRQOL is described with attention to its evolution over time and the next steps, through the Clinical Trials Working Group Recommendations.

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Patient-Reported Outcomes Assessment in Cancer Trials: Taking Stock, Moving Forward. . . Joseph Lipscomb, Bryce B. Reeve,

Steven B. Clauser, et al pp 5133-5140

To evaluate and improve the use of cancer trial end points that reflect the patient's own perspective, the National Cancer Institute organized an international conference, Patient-Reported Outcomes Assessment in Cancer Trials (PROACT), in 2006. The 13 preceding articles in this special issue of the *Journal* were commissioned in preparation for or in response to the PROACT conference, which was cosponsored by the American Cancer Society. Drawing from these articles and also commentary from the conference itself, this concluding report takes stock of what has been learned to date about the successes and challenges in patient-reported outcome (PRO) assessment in phase III, phase II, and symptom management trials in cancer and identifies ways to improve the scientific soundness, feasibility, and policy relevance of PROs in trials. Building on this synthesis of lessons learned, this article discusses specific administrative policies and management procedures to improve PRO data collection, analysis, and dissemination of findings; opportunities afforded by recent methodologic and technological advances in PRO data collection and analysis to enhance the scientific soundness and cost efficiency of PRO use in trials; and the importance of better understanding the usefulness of PRO data to the full spectrum of cancer decision makers, including patients and families, health providers, public and private payers, regulatory agencies, and standards-setting organizations.

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F O R T H C O M I N G R E P O R T S

Prospective Study of Long-Term Impact of Adjuvant High-Dose and Conventional-Dose Chemotherapy on Health-Related Quality of Life

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Phase I Dose-Escalation Study of Trastuzumab and Tanespimycin in Trastuzumab-Refractory HER-2-Overexpressing Breast Cancer

Shanu Modi, Alison Stopeck, Michael Gordon, David Mendelson, David Solit, Rochelle Bagatell, Weining Ma, Jennifer Wheler, Neal Rosen, Larry Norton, Gillian Cropp, Robert Johnson, Alison Hannah, and Clifford Hudis

Quantitative Justification of the Change From 10% to 30% for HER-2 Scoring in the ASCO-CAP Guidelines: Tumor Heterogeneity in Breast Cancer and Its Implications for Tissue Microarray-Based Assessment of Outcome

Christopher B. Moeder, Jennifer M. Giltane, Malini Harigopal, Annette Molinaro, Andrew Robinson, Karen Gelmon, D. Huntsman, Robert Camp, and David L. Rimm

Phase II Study of Uracil-Tegafur With Leucovorin in Elderly (> 75 years old) Patients With Colorectal Cancer: ECOG 1299

Howard S. Hochster, Weixiu Luo, Elizabeta C. Popa, Bruce T. Lyman, Mary Mulcahy, Peter A. Beatty, and Al Bowen Benson

Randomized Double-Blind Trial of Prophylactic Oral Minocycline and Topical Tazarotene for Cetuximab-Associated Acnelike Eruption

Alon Scope, Anna Liza C. Agero, Stephen W. Dusza, Patricia L. Myskowski, Jocelyn A. Lieb, Leonard Saltz, Nancy E. Kemeny, and Allan C. Halpern

Characteristics of Urologists Predict the Use of Androgen Deprivation Therapy for Prostate Cancer

Vahakn B. Shahinian, Yong-Fang Kuo, Jean L. Freeman, Eduardo Orihuela, and James S. Goodwin

p53 Gene and Protein Status: The Role of p53 Alterations in Predicting Outcome in Patients With Bladder Cancer

Ben George, Ram H. Datar, Lin Wu, Jie Cai, Nancy Patten, Stephen J. Beil, Susan Groshen, John P. Stein, Donald Skinner, Peter A. Jones, and Richard J. Cote

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Mutation Status of the Residual ATM Allele Is an Important Determinant of the Cellular Response to Chemotherapy and Survival in Patients With Chronic Lymphocytic Leukemia Containing an 11q Deletion

Belinda Austen, Anna M. Skowronska, Claire Baker, Judith E. Powell, Anne Gardiner, David G. Oscier, Aneela Majid, Martin J. Dyer, Reiner Siebert, A. Malcolm R. Taylor, Paul A.H. Moss, and Tatjana Stankovic

VCAP-AMP-VECP Compared to Biweekly CHOP for Adult T-Cell Leukemia-Lymphoma: Japan Clinical Oncology Group Study JCOG9801

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Chemotherapy Compared With Biochemotherapy for the Treatment of Metastatic Melanoma: A Meta-Analysis of 18 Trials Involving 2,621 Patients

Natalie J. Ives, Rebecca L. Stowe, Paul Lorigan, and Keith Wheatley

Positron Emission Tomography for Staging of Pediatric Sarcoma Patients: Results From a Prospective Multicenter Trial

Thomas Völker, Timm Denecke, Ingo Steffen, Daniel Misch, Stefan Schönberger, Michail Plotkin, Juri Ruf, Christian Furth, Brigitte Stöver, Hubertus Hautzel, Günter Henze, and Holger Amthauer

Prospective Study of Pirarubicin and Intermediate-Dose Cytarabine and Etoposide Regimen in Children With Down Syndrome and Acute Myeloid Leukemia

Kazuko Kudo, Seiji Kojima, Ken Tabuchi, Hiromasa Yabe, Akio Tawa, Masue Imaizumi, Ryoji Hanada, Kazuko Hamamoto, Ryoji Kobayashi, Akira Morimoto, Hideki Nakayama, Masahiro Tsuchida, Keizo Horibe, Hisato Kigasawa, and Ichiro Tsukimoto

Symptom Prevalence, Intensity, and Distress in Patients With Inoperable Lung Cancer in Relation to Time of Death

Carol Tishelman, Lena-Marie Petersson, Lesley F. Degner, and Mirjam A. Sprangers

Long-Term Toxicity Monitoring via Electronic Patient-Reported Outcomes in Patients Receiving Chemotherapy

Ethan Basch, Alexia Iasonos, Allison Barz, Ann Culkin, Mark G. Kris, David Artz, Paul Fearn, John Speakman, Rena Farquhar, Howard I. Scher, Mary McCabe, and Deborah Schrag

CALENDAR OF ONCOLOGY EVENTS

MEETING/LOCATION	DATES	CONTACT
The Joint Meeting of the 4th ISC International Conference on Cancer Therapeutics and The 7th Princess Margaret Hospital Conference: New Developments in Cancer Management <i>Toronto, Canada</i>	November 15-17, 2007	www.imedex.com/calendars/oncology.asp
19th Asia Pacific Cancer Conference and 1st APCC Nursing Meeting <i>Tehran, Iran</i>	November 15-17, 2007	www.apcc-2007.org
Making Connections: A Canadian Cancer Research Conference Celebrating NCIC's 60th Anniversary <i>Toronto, Canada</i>	November 15-17, 2007	www.ncic.cancer.ca/ncic/internet/standard/0,3621,84658243_1483513437__langId-en,00.html
Society for Integrative Oncology's Fourth International Conference <i>San Francisco, California</i>	November 15-17, 2007	www.integrativeonc.org/
EORTC-NCI-ASCO Annual Meeting on "Molecular Markers in Cancer" <i>Brussels, Belgium</i>	November 15-17, 2007	www.eortc.be/seminar/ENASCO2007/default.htm
12th Annual Perspectives in Thoracic Oncology <i>New York, New York</i>	November 16-17, 2007	www.nationallungcancerpartnership.org/page.cfm?l=proEvents
Translational Therapies in Breast Cancer <i>Dallas, Texas</i>	November 17, 2007	www.cancerconferences.com/breast_cancer/ttbc_dallas_1107/index.php
2nd International Cancer Control Congress <i>Rio de Janeiro, Brazil</i>	November 25-28, 2007	www.cancercontrol2007.com/
CALGB 2007 Fall Expanded Committee Meetings <i>Chicago, Illinois</i>	November 29-December 2, 2007	www.calgb.org/Public/meetings/meetings.php
Third Annual Multidisciplinary Symposium on Head and Neck Cancer <i>Philadelphia, Pennsylvania</i>	December 1, 2007	www.cancerconferences.com/other_solid_tumors/3rd_headneck/index.php

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MEETING/LOCATION	DATES	CONTACT
5th Surgical Pathology Update <i>Asheville, North Carolina</i>	December 6-9, 2007	www.mdanderson.org/conferences
2007 CCFA National Research and Clinical Conference—6th Annual Advances in the Inflammatory Bowel Diseases <i>Miami, Florida</i>	December 7-9, 2007	www.imedex.com/calendars/gastroenterology.asp
Palliative Care Leadership Center Training—Medical College of Wisconsin <i>Milwaukee, Wisconsin</i>	December 19-21, 2007	www.capc.org/palliative-care-leadership-initiative/overview/mcw
5th European Congress: Perspectives in Gynecologic Oncology <i>Cannes, France</i>	January 18-19, 2008	www.imedex.com/announcements/317.asp
2008 Gastrointestinal Cancers Symposium <i>Orlando, Florida</i>	January 25-27, 2008	www.asco.org/portal/site/asco/menuitem.509189bfd2c2bf5ca7ffa807320041a0/?vgnextoid=9a7780efecd51110VgnVCM100000ed730ad1RCRD
Statements on Head and Neck Cancer <i>Frankfurt, Germany</i>	February 1-2, 2008	statements2008.org/
1st Asian Breast Cancer Congress <i>New Delhi, India</i>	February 9-10, 2008	www.abcc2008.com
12th International Congress on Hematologic Malignancies Focus on Leukemia, Lymphomas, and Myelomas <i>Whistler, British Columbia</i>	February 13-17, 2008	www.cancerconferences.com/hematologic/whistler_08/index.php
2008 Genitourinary Cancers Symposium <i>San Francisco, California</i>	February 14-16, 2008	www.asco.org/portal/site/ASCO/menuitem.509189bfd2c2bf5ca7ffa807320041a0/?vgnextoid=670fd56e98f81110VgnVCM100000ed730ad1RCRD
Scripps Cancer Center's Clinical Hematology & Oncology Conference <i>San Diego, California</i>	February 16-19, 2008	www.scripps.org/conferenceservices
25th Annual Miami Breast Cancer Conference <i>Orlando, Florida</i>	February 20-23, 2007	www.cancerconf.com/index.html

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MEETING/LOCATION	DATES	CONTACT
Sixth International Symposium on Supportive Care in Oncology: Cancer Management in the Era of Targeted Agents <i>New York, New York</i>	February 22-23, 2008	www.cancerconferences.com/supportive_care/6th_sc/index.php
The International Conference on Burkitt Lymphoma and Related Lymphoproliferative Disorders <i>Kampala, Uganda</i>	February 25-27, 2008	www.unisi.it/eventi/burkitt/
CALGB 2008 Spring Committee Meetings <i>Raleigh, North Carolina</i>	March 6-8, 2008	www.calgb.org/Public/meetings/meetings.php
Fifth International Symposium on Melanoma and Other Cutaneous Malignancies <i>New York, New York</i>	March 7-8, 2008	www.cancerconferences.com/other_solid_tumors/5th_melanoma/index.php
Fifth International Symposium on Ovarian Cancer and Gynecologic Malignancies <i>New York, New York</i>	March 28-29, 2008	www.cancerconferences.com/other_solid_tumors/5th_ovarian/registration.php
2008 ASCO Annual Meeting <i>Chicago, Illinois</i>	May 30-June 3, 2008	www.asco.org/portal/site/ASCO/menuitem.56bbfed7341ace64e7cba5b4320041a0/?vgnextoid=ab08201eb61a7010VgnVCM100000ed730ad1RCRD
10th International Conference on Malignant Lymphoma <i>Lugano, Switzerland</i>	June 4-7, 2008	www.lymphcon.ch/
2008 Toronto Breast Cancer Symposium <i>Toronto, Ontario</i>	June 12-13, 2008	www.cme.utoronto.ca/
Ninth International Lung Cancer Congress <i>Koloa, Hawaii</i>	June 18-21, 2008	www.cancerconferences.com/thoracic/9th_lcc/index.php
The 10th World Congress on Gastrointestinal Cancer	June 18-21, 2008	c.chase@imedex.com
CALGB 2008 Summer Group Meeting <i>Chicago, Illinois</i>	June 26-29, 2008	www.calgb.org/Public/meetings/meetings.php

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N E X T I S S U E

ORIGINAL REPORTS

Gynecologic Cancer

Prospective Determination of Prevalence of Lynch Syndrome in Young Women With Endometrial Cancer

Karen H. Lu, John O. Schorge, Kerry J. Rodabaugh, Molly S. Daniels, Charlotte C. Sun, Pamela T. Soliman, Kristin G. White, Rajyalakshmi Luthra, David Gershenson, and Russell Broaddus

Phase II Trial of Bevacizumab in Persistent or Recurrent Epithelial Ovarian Cancer or Primary Peritoneal Cancer: A Gynecologic Oncology Group Study

Robert Burger, Michael W. Sill, Bradley J. Monk, Benjamin Greer, and Joel I. Sorosky

ERCC1 Genotype and Phenotype in Epithelial Ovarian Cancer Identify Patients Likely to Benefit From Paclitaxel Treatment in Addition to Platinum-Based Therapy

Stephanie Smith, Dan Su, Irene A. Rigault de la Longrais, Peter Schwartz, Manuela Puopolo, Thomas J. Rutherford, Gil Mor, Herbert Yu, and Dionyssios Katsaros

Phase II Study of Bevacizumab in Patients With Platinum Resistant Ovarian Cancer or Peritoneal Serous Cancer

Stephen Cannistra, Ursula Matulonis, Richard Penson, Julie Hambleton, Jakob Dupont, Howard Mackey, Jeffrey Douglas, Robert Burger, Deborah Armstrong, Robert Wenham, and William McGuire

Breast Cancer

Breast Cancer Treatment Outcome With Adjuvant Tamoxifen Relative to Patient CYP2D6 and CYP2C19 Genotypes

Werner Schroth, Lydia Antoniadou, Peter Fritz, Matthias Schwab, Thomas Muerdter, Ulrich M. Zanger, Wolfgang Simon, Michel Eichelbaum, and Hiltrud Brauch

Cytokeratin-19 mRNA-Positive Circulating Tumor Cells Have Different Prognostic Value in Early Breast Cancer

Michail Ignatiadis, Nikos Xenidis, Maria Perraki, Stella Apostolaki, Eleni Politaki, Maria Kafousi, Efstathios Stathopoulos, Aliko Stathopoulou, Evi Lianidou, Grigorios Chlouverakis, Christos Sotiriou, Vassilis Georgoulas, and Dimitris Mavroudis

Increasing Use of Contralateral Prophylactic Mastectomy for Breast Cancer Patients: A Trend Toward More Aggressive Surgical Treatment

Todd M. Tuttle, Elizabeth B. Habermann, Erin H. Grund, Todd J. Morris, and Beth A. Virnig

Ixabepilone Plus Capecitabine for Metastatic Breast Cancer Progressing After Anthracycline and Taxane Treatment

Eva S. Thomas, Henry L. Gomez, Rubi K. Li, Hyun-Cheol Chung, Luis E. Fein, Valorie F. Chan, Jacek Jassem, Xavier B. Pivot, Judith V. Klimovsky, Fernando Hurtado de Mendoza, Binghe Xu, Mario Campone, Guillermo L. Lerzo, Ronald A. Peck, Pralay Mukhopadhyay, Linda T. Vahdat, and Henri H. Roché

Gastrointestinal Cancer

Progression-Free Survival Is a Surrogate for Survival in Advanced Colorectal Cancer

Marc Buyse, Tomasz Burzykowski, Kevin Carroll, Stefan Michiels, Daniel Sargent, Langdon L. Miller, Gary L. Elfring, Jean-Pierre Pignon, and Pascal Piedbois

Phase II Trial of Cetuximab in Combination With Fluorouracil, Leucovorin, and Oxaliplatin in the First-Line Treatment of Metastatic Colorectal Cancer

Josep Tabernero, Eric Van Cutsem, Eduardo Diaz-Rubio, Andres Cervantes, Yves Humblet, Thierry André, Jean Luc Van Laethem, Patrick Soulié, Esther Casado, Chris Verslype, Javier Sastre Valera, Giampaolo Tortora, Fortunato Ciardiello, Oliver Kisker, and Aimery de Gramont

Thoracic Oncology

Phase III Trial of Two Versus Four Additional Cycles Nonprogressive After Two Cycles of Platinum-Based Chemotherapy for Non–Small-Cell Lung Cancer

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Prognostic and Predictive Importance of p53 and RAS for Adjuvant Chemotherapy in Non–Small-Cell Lung Cancer

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Cost Effectiveness

Costs and Cost Effectiveness of a Low-Intensity Patient-Directed Intervention to Promote Colorectal Cancer Screening

Veena Shankaran, June M. McKoy, Neal Dandade, Narissa Nonzee, Cara A. Tigue, Charles L. Bennett, and Tom D. Denberg

Pediatric Oncology

Prognostic Role of Minimal Residual Disease in Mature B-Cell Acute Lymphoblastic Leukemia of Childhood

Lara Mussolin, Marta Pillon, Valentino Conter, Matilde Piglione, Luca Lo Nigro, Paolo Pierani, Concetta Micalizzi, Salvatore Buffardi, Giuseppe Basso, Luigi ZanESCO, and Angelo Rosolen

Disability in Adult Survivors of Childhood Cancer: A Swedish National Cohort Study

Anders Hjern, Frank Lindblad, and Krister K. Boman

Complementary Therapy

Initiation and Discontinuation of Complementary Therapy Among Cancer Patients

Sung-Gyeong Kim, Eun-Cheol Park, Jae-Hyun Park, Myung-Il Hahm, Jin-Hwa Lim, and Kui-Son Choi

Supportive Care and Quality of Life

Desire for Information and Involvement in Treatment Decisions: Elderly Cancer Patients' Preferences and Their Physicians' Perceptions

Elena B. Elkin, Susie H.M. Kim, Ephraim S. Casper, David W. Kissane, and Deborah Schrag

REVIEW ARTICLE

Neoadjuvant Cisplatin Chemotherapy Prior to Chemoradiation: A Flawed Paradigm?

Rob Glynn-Jones and Peter J. Hoskin

ASCO SPECIAL ARTICLES

American Society of Clinical Oncology 2007 Update of Recommendations for the Use of Tumor Markers in Breast Cancer

Lyndsay Harris, Herbert Fritsche, Robert Mennel, Larry Norton, Peter Ravdin, Sheila Taube, Mark Somerfield, Daniel F. Hayes, and Robert C. Bast

American Society of Clinical Oncology Endorsement of the Cancer Care Ontario Practice Guideline on Nonhormonal Therapy for Men With Metastatic Hormone-Refractory (castration-resistant) Prostate Cancer

Ethan M. Basch, Mark Somerfield, Tomasz M. Beer, Michael A. Carducci, Celestia S. Higano, Maha H.A. Hussain, and Howard I. Scher