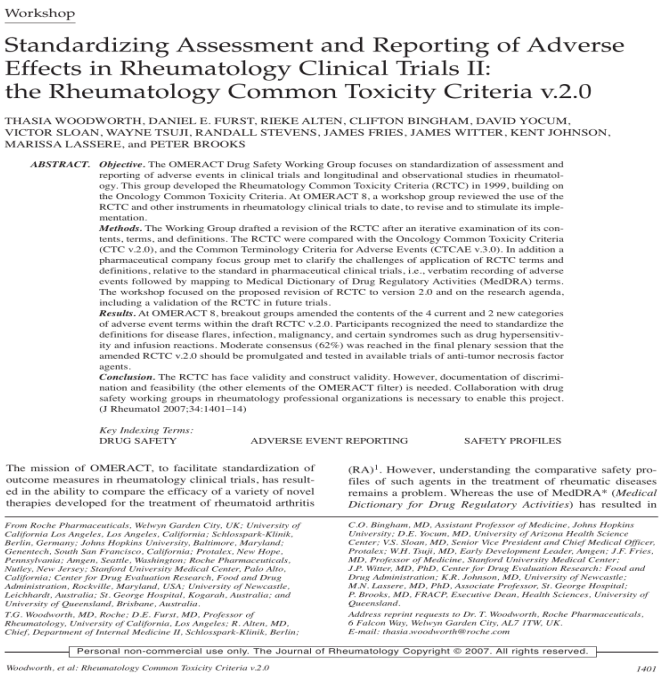
Dictionary Of The Rheumatic Diseases



Workshop

Standardizing Assessment and Reporting of Adverse Effects in Rheumatology Clinical Trials II: the Rheumatology Common Toxicity Criteria v.2.0

THASIA WOODWORTH, DANIEL E. FURST, RIEKE ALTEN, CLIFTON BINGHAM, DAVID YOCUM, VICTOR SLOAN, WAYNE TSUJI, RANDALL STEVENS, JAMES FRIES, JAMES WITTER, KENT JOHNSON, MARISSA LASSERE, and PETER BROOKS

ABSTRACT. ***Objective.*** The OMERACT Drug Safety Working Group focuses on standardization of assessment and reporting of adverse events in clinical trials and longitudinal and observational studies in rheumatology. This group developed the Rheumatology Common Toxicity Criteria (RCTC) in 1999, building on the Oncology Common Toxicity Criteria. At OMERACT 8, a workshop group reviewed the use of the RCTC and other instruments in rheumatology clinical trials to date, to revise and to stimulate its implementation.

Methods. The Working Group drafted a revision of the RCTC after an iterative examination of its contents, terms, and definitions. The RCTC were compared with the Oncology Common Toxicity Criteria (CTC v.2.0), and the Common Terminology Criteria for Adverse Events (CTCAE v.3.0). In addition a pharmaceutical company focus group met to clarify the challenges of application of RCTC terms and definitions, relative to the standard in pharmaceutical clinical trials, i.e., verbatim recording of adverse events followed by mapping to Medical Dictionary of Drug Regulatory Activities (MedDRA) terms. The workshop focused on the proposed revision of RCTC to version 2.0 and on the research agenda, including a validation of the RCTC in future trials.

Results. At OMERACT 8, breakout groups amended the contents of the 4 current and 2 new categories of adverse event terms within the draft RCTC v.2.0. Participants recognized the need to standardize the definitions for disease flares, infection, malignancy, and certain syndromes such as drug hypersensitivity and infusion reactions. Moderate consensus (62%) was reached in the final plenary session that the amended RCTC v.2.0 should be promulgated and tested in available trials of anti-tumor necrosis factor agents.

Conclusion. The RCTC has face validity and construct validity. However, documentation of discrimination and feasibility (the other elements of the OMERACT filter) is needed. Collaboration with drug safety working groups in rheumatology professional organizations is necessary to enable this project. (J Rheumatol 2007;34:1401–14)

Key Indexing Terms:
DRUG SAFETY ADVERSE EVENT REPORTING SAFETY PROFILES

The mission of OMERACT, to facilitate standardization of outcome measures in rheumatology clinical trials, has resulted in the ability to compare the efficacy of a variety of novel therapies developed for the treatment of rheumatoid arthritis (RA)[1]. However, understanding the comparative safety profiles of such agents in the treatment of rheumatic diseases remains a problem. Whereas the use of MedDRA® (*Medical Dictionary for Drug Regulatory Activities*) has resulted in

From Roche Pharmaceuticals, Welwyn Garden City, UK; University of California Los Angeles, Los Angeles, California; Schlosspark-Klinik, Berlin, Germany; Johns Hopkins University, Baltimore, Maryland; Genentech, South San Francisco, California; Protalex, New Hope, Pennsylvania; Amgen, Seattle, Washington; Roche Pharmaceuticals, Nutley, New Jersey; Stanford University Medical Center, Palo Alto, California; Center for Drug Evaluation Research, Food and Drug Administration, Rockville, Maryland, USA; University of Newcastle, Leichhardt, Australia; St. George Hospital, Kogarah, Australia; and University of Queensland, Brisbane, Australia.

T.G. Woodworth, MD, Roche; D.E. Furst, MD, Professor of Rheumatology, University of California, Los Angeles; R. Alten, MD, Chief, Department of Internal Medicine II, Schlosspark-Klinik, Berlin; C.O. Bingham, MD, Assistant Professor of Medicine, Johns Hopkins University; D.E. Yocum, MD, University of Arizona Health Science Center; V.S. Sloan, MD, Senior Vice President and Chief Medical Officer, Protalex; W.H. Tsuji, MD, Early Development Leader, Amgen; J.F. Fries, MD, Professor of Medicine, Stanford University Medical Center; J.P. Witter, MD, PhD, Center for Drug Evaluation Research: Food and Drug Administration; K.R. Johnson, MD, University of Newcastle; M.N. Lassere, MD, PhD, Associate Professor, St. George Hospital; P. Brooks, MD, FRACP, Executive Dean, Health Sciences, University of Queensland.

Address reprint requests to Dr. T. Woodworth, Roche Pharmaceuticals, 6 Falcon Way, Welwyn Garden City, AL7 1TW, UK.
E-mail: thasia.woodworth@roche.com

Rheumatic Diseases and Osteoporosis are very common diseases. This dictionary provides a comprehensive list of common terms and definitions in clinical.Arthritis & Rheumatology. Explore this journal > Arthritis & Rheumatology Dictionary of the rheumatic diseases. prepared by the american.Dictionary of the rheumatic diseases. prepared by the american rheumatism association glossary committee. volume i: signs and symptoms.any of a group of diseases of the connective tissue, of uncertain causes, including rheumatoid arthritis, gout, and rheumatic fever. Webster's New World College.Rheumatic disease definition: any of a group of diseases of the connective tissue, of uncertain causes, including Meaning, pronunciation, translations and.Medical definition of rheumatic disease: any of several diseases (as rheumatic fever or fibrositis) characterized by inflammation and pain in Medical Dictionary .Looking for online definition of rheumatic disease in the Medical Dictionary? rheumatic disease explanation free. What is rheumatic disease? Meaning of.Define rheumatic disease. rheumatic disease synonyms, rheumatic disease pronunciation, rheumatic disease translation, English dictionary definition of.Dictionary of the Rheumatic Diseases (Diagnostic Testing, Volume II) on Amazon .com. *FREE* shipping on qualifying offers.Dictionary of the Rheumatic Diseases: Signs and symptoms. Front Cover. American Rheumatism Association. Glossary Committee, American Rheumatism .kachemile.com German-English Dictionary: Translation for rheumatic diseases.Rheumatology definition, the study and treatment of rheumatic diseases. See more.Of or relating to any of various diseases and disorders that chiefly affect the joints, tendons, ligaments, muscles, and bones and are characterized by pain.PDF This dictionary provides a comprehensive list of the terms and definitions Josef Rovensky at National Institute of Rheumatic Diseases.Measurement. Dictionary of the Rheumatic Diseases: Health Status Measurement by American College of Rheumatology, Glossary Committ. Recommend.Definition of rheumatic - relating to or caused by rheumatism.