OMERACT 5 Drug Safety Working Group Report: Introduction

The objective for the drug safety module was to review the work of the OMERACT Safety Working Party, specifically to discuss better and more complete reporting of adverse events and the development of longterm databases to monitor adverse events.

The initial task was well described in the 1994 OMERACT 2 Toxicity Workshop Report[1]; the Research Recommendations made in that report included 4 recommendations:

1. Harmonization of approaches including the development of a standard dictionary of adverse events.

2. Better and more complete reporting of ADR.

3. Develop methodology and collect data to understand efficacy/toxicity trade-offs.

The first 3 recommendations have been further addressed by the enclosed articles:

• The World Health Organization Programme for International Drug Monitoring, Its Database and the Technical Support of the Uppsala Monitoring Center, by Marie Lindquist and I. Ralph Edwards

• Standardizing Assessment of Adverse Effects in Rheumatology Clinical Trials — Status of OMERACT Toxicity Working Group 2000, by Thasia G. Woodworth

• Patient Based Method of Assessing Adverse Events in Clinical Trials in Rheumatology: The Revised Stanford Toxicity Index, by Vivian A. Welch, et al.

The last recommendation was:

4. Establish appropriate means of longterm data collection from patients who have completed randomized controlled trials or PMS projects.

The following articles address this issue:

• A Proposal for Developing a Large Patient Population Cohort for Longterm Safety Monitoring in Rheumatoid Arthritis, by John Lipani, et al

• Arthritis, Rheumatism and Aging Medical Information System Post-Marketing Surveillance, by Gurkirpal Singh

The Drug Safety Module started with an introduction of the 4 key areas: (a) methodology for collecting adverse events, (b) logistics of adverse event reporting, (c) links to existing databases, and (d) funding. The participants were divided into breakout sessions, each with a group leader and rapporteur. The group leaders facilitated discussions around a set of draft questions. After the sessions, the group leaders, rapporteurs, and module leaders were asked to summarize the recommendations from the breakout sessions and the specific recommendations from the sessions were presented in an open forum. Opinions were elicited from all OMERACT participants by voting, using electronic keypads.

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REFERENCE

1. Brooks PM, Day RO. Toxicity of antirheumatic drugs [workshop report]. J Rheumatol 1995;22:998-9.