



Project Summary

User's Guide--Micronucleus Assay Data Management and Analysis System

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This user's manual provides guidance to researchers and the regulatory community for interacting with a data management and statistical analysis system, designated as MN. MN is dedicated to the *in vivo* micronucleus test, a routinely used genetic toxicology assay for chemical compounds which may be of health concern. The objective in developing this system has been to promote consistency and inter-comparability of assay test results across laboratories, thus providing researchers and government decision makers with a means to assure comparable analyses of test data. The MN data management and analysis system has been developed in consultation with a panel of biostatisticians and experts in the field of cytogenetics. Software for executing MN and three sets of test data, contained on two 5.25 inch floppy disks, accompany the user's guide.

This Project Summary was developed by EPA's Environmental Monitoring Systems Laboratory, Las Vegas, NV, to announce key findings of the research project that is fully documented in a separate report of the same title (see Project Report ordering information at back).

Introduction

MN is a data management and analysis system designed for micronucleus data collected using *in vivo* test systems. The software consists of a set of routines for 1) entering, editing and storing

experimental data and descriptive information; 2) generating statistics appropriate to the micronucleus test; and 3) presenting the results of these statistics through graphs and tables.

The user's guide consists of two parts. The first describes the MN installation program provided on the program disk. The guide should be read carefully to ensure that installation is performed correctly. The second part describes how to use MN. The description follows the organization of the program, describing the main menu first, followed by the individual routines corresponding to each of the menu entries.

Procedure

MN is intended to run on an IBM PC compatible with hard disk under DOS. The program files take up approximately 300K of storage on the hard disk, while the sample test data require about 175K.

The installation procedure creates two directories, C:\MN and C:\MN\HELP, and copies executable and help files into these directories. Copying the three test data files into the C:\MN directory simplifies recalling these data when needed; otherwise, these files may be recalled from the second floppy disk.

Operation

Each MN session maintains two distinct data sets. The first is a multi-page fixed form containing descriptive information relating to the several aspects of the experiment. The second is a spreadsheet for the experimental data (entered from current experiments or from one of the test data sets), where the rows represent observations and the

columns represent fields. This form has a number of fixed fields and a number of optional fields that may be selected to tailor a session to the nature of the experiment. Help screens are available within each menu selection.

The main menu (Figure 1) is a single selection menu. When a selection is made, the menu closes and the selected operation begins. All but one of the sixteen items of the main menu are grouped into six classes: Setup, Data entry, Disk I/O, Analysis, Utility, and Miscellaneous.

Leave MN

This is a special item outside the six functional categories. Selecting this item will prompt for disposition of any unsaved changes and return to DOS.

Setup

The Setup routines (Cell Types and Optional Fields) determine which of the nondefault fields will appear on the spreadsheet. Cell Types allows the selection of any combination of four cell types for micronucleus analysis and one of two configurations for toxicity analysis. Optional Fields provides a way to define up to fifteen additional data fields.

Data Entry

The Data Entry routines (Experiment Description and Spreadsheet) are the means by which data are entered into MN sessions by keyboard. Experiment Description consists of a six-page form with which to enter descriptive information pertaining to the experiment, test article, solvent, positive control, test system, and treatment. The spreadsheet allows access to the actual data.

Disk I/O

Recall reads an MN file from hard or floppy disk and makes it current. Save writes the current MN file to disk. Import and Export (not yet implemented) will allow equivalent operations on ASCII files, providing a means to move data between MN and other applications.

Analysis

Statistics conducts specialized tests on selected cell types and presents the results via screen or printer. Graph plots the means of selected response variables.

Utility

List prints the data with the form of the report subject to considerable user control. Sort reorders the lines of the spreadsheet (and optionally subsequent listings) according to the values of any combination of key fields, either ascending or descending. Clear Session deletes all data and removes all Setup fields, in effect starting over.

Miscellaneous

Key Field Search produces a report listing either 1) the values of selected fields for all MN files in the indicated search path, or 2) the names of all MN files in the indicated search path whose values for selected fields match key values which have been entered. GLP Log presents by screen or printer a record of all changes ever made to non-empty fields for the current file, who made them and when.

Sample Data Sets

To assist the user in becoming familiar with MN, three sample experiments (MNTEST-1, -2, -3) have been included. MNTEST-1 presents data on an experiment in which male and female

mice were injected with a test chemical on three consecutive days, bone marrow samples were collected 24 hours after the last injection and numbers of MN-PCE (micronucleated polychromatic erythrocytes) and the percentage of PCE were determined by a single scorer. MNTEST-2 presents data on an experiment in which male and female mice were treated once with a test chemical, bone marrow samples were collected at 24, 48, and 72 hours after treatment and numbers of MN-PCE, MN-NCE (micronucleated normo-chromatic erythrocytes) and the percentage of PCE were determined by two scorers. MNTEST-3 is identical to MNTEST-2 except that the control data have been restructured to only the 48-hour sample time.

Software Availability

The Micronucleus Assay Data Management and Analysis System software can be obtained by sending two formatted 5.25 inch 360KB disks to the following address:

Dr. Charles H. Nauman
U.S. EPA, EMSL, MC-EAD
P.O. Box 93478
Las Vegas, NV 89193-3478

For further information the Micronucleus Assay Data Management and Analysis System source code and programmer documentation, contact:

EPA Software Development Project
Integrated Laboratory Systems
P. O. Box 13501
Research Triangle Park, NC 27709

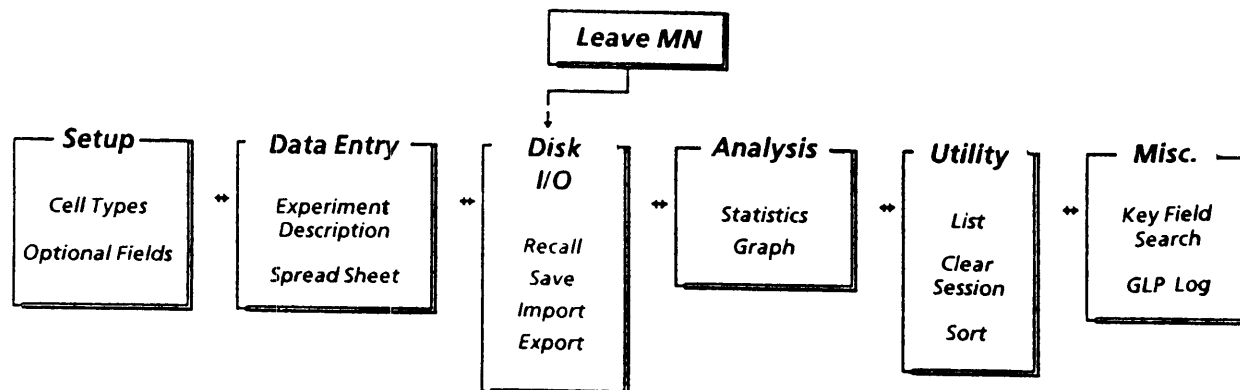


Figure 1. Main Menu.

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Charles H. Nauman is the EPA Project Officer (see below).

The complete report, entitled "User's Guide--Micronucleus Assay Data Management and Analysis System," (Order No. PB-90-212-598AS; Cost: \$17.00 subject to change) will be available only from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Telephone: 703-487-4650

The EPA Project Officer can be contacted at:

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