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Project Summary

User's Guide: Chromosomal Aberration Data Analysis and Interpretation System

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This user's manual provides guidance to researchers and the regulatory community for interacting with a data analysis and statistical interpretation system, designated as CA. CA is dedicated to the in vivo chromosome aberration assay, 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 intercomparability of assay test results across laboratories, thus providing researchers and government decision makers with a means to assure comparable analyses of test data. The CA data analysis system has been developed in consultation with a panel of biostatisticians and experts in the field of cytogenetics. Software for executing CA and two 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

CA is a data analysis and interpretation system designed for chromosomal aberration and mitotic index 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 analysis of chromosomal aberrations and mitotic index data; and 3) presenting the results of these statistics through graphs and tables.

The user's guide consists of two parts. The first describes the CA installation program provided on the program disk. The second part describes how to use CA. This 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

CA is intended to run on an IBM PC compatible with hard disk under DOS. The program files take up approximately 360K of storage on the hard disk, while the sample test data require about 85K.

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

Operation

Each CA 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 spreadsheet 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 CA

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 (Endpoints and Optional Fields) determine which of the nondefault fields will appear on the spreadsheet. 'Endpoint' allows the selection of either or both the chromosomal aberration and the mitotic index endpoints. 'Optional Fields' provides a way to define up to 15 additional data fields.

Data Entry

The Data Entry routines (Experiment Description and Spreadsheet) are the means by which data are entered into CA 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 a CA file from disk and makes it the current file. 'Save' writes the current CA file to disk. 'Import' and 'Export' being multistep operations, are too complicated to execute as a single menu selection. When selected as main menu items, 'Import' and 'Export' display text screens describing the procedures.

Analysis

'Statistics' conducts specialized statistical analyses on selected endpoints and presents the results via the screen with an option to print as well. The CA software is designed to analyze an in vivo experiment involving either one or both sexes, from one to five scorers, and a maximum of eight dose groups and six sample times. 'Graph' plots the means of selected response variables.

Utility

'List' produces a hard copy listing through a printer connected to the serial port. There are a number of parameters with which the user can determine the form of the report. '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 Set Up fields, in effect starting over.

Miscellaneous

'Key Field Search' produces a report listing either 1) the values of selected fields for all CA files in the indicated search path, or 2) the names of all CA files in the indicated search path whose values for selected fields match key values entered here. 'GLP Log' presents by screen or printer a record of all accesses to the file and, after locking, all new entries or changes to existing entries, who made them and when.

Sample Data Sets

To assist the user in becoming familiar with CA, data from two sample experiments (CATEST01.ILS and CATEST02.ILS) have been included. Both experiments present data in which male and female mice were treated once with a test chemical, bone marrow samples collected at 24, 48 and 72 hours after treatment and the frequency and distribution of chromosomal aberrations and the mitotic index were determined by two scorers. In CATEST01, the chromosomal aberration data include cells containing 0, 1 or 2 aberrations. In CATEST02, cells containing multiple aberrations were detected among the treated mice. The same outlier data are included in both data sets. The statistical analyses of the chromosomal aberration data are based on the assumption that excluding the data at the highest dose would always be considered and that scorer differences would be evaluated. Hard copies of the experimental information, the chromosomal aberration and mitotic index data and the results of the various statistical analyses are provided in an Appendix. It is suggested that the user recall the sample test data files, page through the various screens and invoke each of the subroutines in order to become familiar with the capabilities of the software.

Software Availability

The Chromosomal Aberration 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 on the Chromosomal Aberration 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

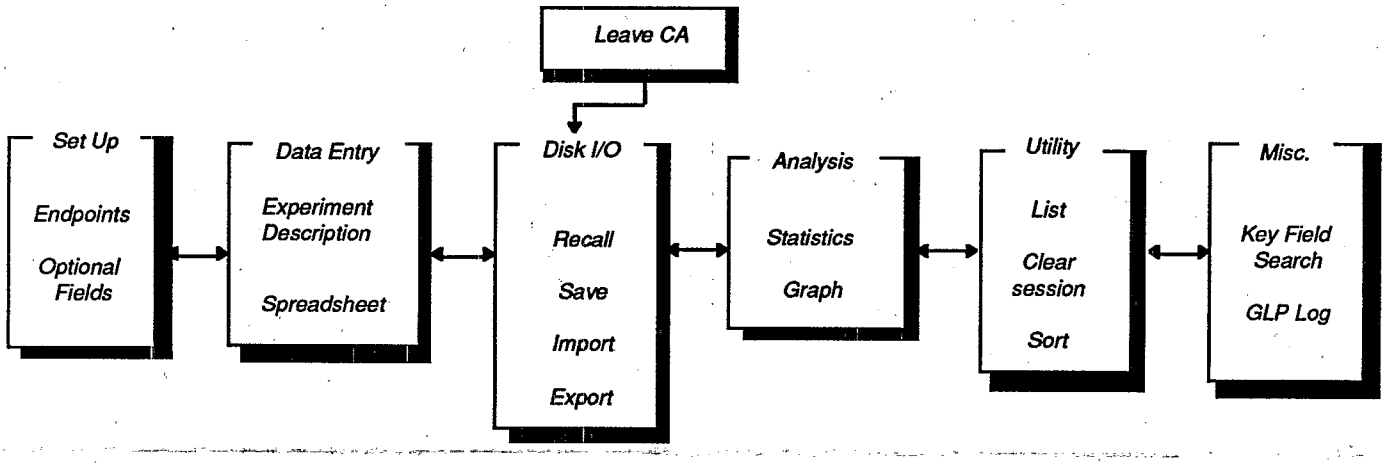

Figure 1. *Main menu.*

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The complete report, entitled "User's Guide: Chromosomal Aberration Data Analysis and Interpretation System," Order No. PB91- 140 376/AS; Cost: $23.00, 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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