

## SOFTWARE SURVEY SECTION

Editor's Note: The following Software Descriptions have been submitted by our readers in response to our call for an open exchange of information on software programs. They are offered without review or comment to provide a rapidly published, easily accessible avenue of communication. Other readers with relevant software packages are invited to complete and submit a Software Description Form (found at the end of this section).

Software package EJCCO-047-S88

CLIN-TEAMS/DER™ V1.0  
(Drug Experience Reporting)

Contributor: Jeanne L. Oliver, R.R.A., Technical Evaluation and Management Systems, Inc., 5151 Beltline Road, Suite 1110, Dallas, TX 75240

Brief description: CLIN-TEAMS/PCS™ is a program designed to facilitate the timely collection, organization, analysis and reporting of information about adverse drug experiences as required by the FDA's regulations. It has been designed to be consistent with the FDA's "Draft Guidelines for Postmarketing Reporting of Adverse Drug Reactions." The CLIN-TEAMS/DER consists of three modules: 1) Data Collector, 2) FDA-1639 Report Generation, and 3) Periodic Report Index Generator. The primary identifier of each DER record and subsequent reports generated from that record is the "Manufacturer's Control Number" called for on the FDA-1639 under Manufacturer Information. Each record may be classified as either initial or follow-up. If the report is a follow-up, a sequence number is required. Security of the system is managed through use of a user authorization module by the system manager. Through the use of this system each user is assigned a unique password and is authorized for three levels of security. Within each security level, access to certain data screens may be restricted on a user by user basis.

Potential users: Pharmaceutical Q&A and R&D.

Fields of interest: Clinical trials/ADR reporting.

§ This application program in the area of ADR reporting has been developed for Digital-VAX to run under VMS. It is available on 600', 1600bpi, VAX BU FMT character set magnetic tape. Required memory is 4MB.

§ Distributed by Technical Evaluation and Management Services, Inc.

§ The minimum hardware configuration required is Microvax II with RA81. User training is required. There is extensive external documentation. Source code not available.

§ The package is fully operational. It has been in use at 2 sites for approximately 2 years. The contributor is available for user inquiries.

Software package EJCCO-048-S88CLIN-TEAMS<sup>TM</sup> V4.1  
CLIN-TEAMS<sup>TM</sup> V5.0

Contributor: Jeanne L. Oliver, R.R.A., Technical Evaluation and Management Systems, Inc., 5151 Beltline Road, Suite 1110, Dallas, TX 75240

Brief description: CLIN-TEAMS<sup>TM</sup> is a system of programs that allows clinical trial data to be entered into a host computer and/or remote computers or terminals in an orderly and well-controlled manner. Provides the Project Manager with a user-friendly setting for development of a computer protocol to govern the collection of data from case report forms. Screens for data collection can be made to reflect CRF's realistically. For each question, the system prompts for various parameters, including a label for reference, rules and branching. CLIN-TEAMS has report generation capabilities along with an audit trail consisting of current and prior values for an entry, date/time stamps, override reasons, CLIN-TEAMS comments, changes made at verification, correction or dropping of data. Procedure exists for creating card image files (sequential files) which can be used as input into other data management or analysis systems (i.e. SAS).

Potential users: Pharmaceutical Q&A and R&D.

Fields of interest: Clinical trials.

- § This application program in the area of clinical trials has been developed for Digital-VAX/MS-DOS PC's-remote to run under VMS, MS-DOS. It is available on 600', 1600bpi, VAX BU FMT character set magnetic tape and 5-1/4", single-sided floppy diskette. Required memory is 4MB.
- § Distributed by Technical Evaluation and Management Services, Inc.
- § The minimum hardware configuration required is Microvax II with RA81. User training is required. There is extensive external documentation. Source code not available.
- § The package is fully operational. It has been in use at 6 sites for approximately 8 years. The contributor is available for user inquiries.

Software package EJCCO-049-S88

SURVIVAL-MLT (Survival-Medical Life Tables)

Contributor: Dr. Brian Angus, Pathology Department, University of Newcastle upon Tyne, Royal Victoria Infirmary, Newcastle upon Tyne, England

Brief description: The program prepares medical life table graphs (survival curves), using the methods of Peto and Pike (1975). Chi square values and p values are produced for the LOGRANK test and the CHISQUARE TEST FOR TREND. A table of "patients at risk" is presented. The graphs can be printed (dumped) in various styles. Stratification and subgroup analysis are supported. Once prepared, life tables can be saved under a filename for instant recall at a future date. The program has a simple menu-driven structure.

Potential users: Physicians involved in clinical trials/prognostic studies.

Fields of interest: Oncology/pathology.

- § This application program in the area of statistics has been developed for Acorn/BBC range in BBC BASIC to run under Acorn operating system. It is available on 5-1/4", dual-sided floppy disk. Required memory is 32K.
- § Distributed by contributor.
- § No user training is required. There is extensive external documentation. Source code is available.
- § Design is complete. It has been in use at 3 sites for approximately 2 years. The contributor is available for user inquiries.

Software package EJCCO-050-S88

## COMPACT-Computer Program for Cancer Trials

Contributor: Mrs. Clair Chilvers, Institute of Cancer Research, Epidemiology Section, Block D, 15 Cotswold Road, Belmont, Sutton, Surrey SM2 5PX England.

Brief description: COMPACT was originally designed to fulfill the need felt by many cancer trial coordinators for a reliable and robust data management package. It has a straightforward data structure which can be easily modified to suit the demands of each individual study. It has an extremely stringent data vetting procedure which will not only check within a record but also across a respondent's set of records. [No longer can healthy children get shorter or respondents grow younger with time.]

COMPACT was initially developed by the Medical Research Council. It is now developed and funded by the Cancer Research Campaign. It is a data management package designed to support the data collection and maintenance validation and exception reporting required during longitudinal studies and clinical trials. It is menu-driven but also offers a command language which extends the functionality provided by the menus.

COMPACT has been designed to maintain a highly consistent level of data accuracy and integrity. In an easy-to-use framework, the package has been designed to be used by non-computer personnel. COMPACT's data structure has been custom-built to cater to the demands of clinical trials and longitudinal studies. It has three record types which correspond to the typical forms--the initial "Entry" form, the recurrent "Visit" form and the occasional "Single" form. The program can be interfaced with other software packages for statistical analysis. Special facilities exist for interfacing with, among others, SAS, SPSS-X and SPSS-PC.

Demonstration disk is available--£50 + VAT. Cost of program: £500 (PCs); £5,000 (mainframes) + VAT.

Potential users: Medical research workers, epidemiologists, social scientists, market researchers.

- § This application program in the area of clinical trials has been developed for IBM PC and compatibles, VAX, PRIME in FORTRAN 77 to run under MS-DOS, VMS, PRIMOS. It is available on floppy diskettes and 9-track, 1600bpi, ASCII character set magnetic tape. Required memory is 640K.
- § Distributed by Timberlake Clark Ltd.
- § No user training is required. There is extensive external documentation. Source code not available.
- § The package is fully operational. It has been in use at 6 sites for approximately 5 years. The contributor is available for user inquiries.

JOURNAL NAME EUROPEAN JOURNAL OF CANCER & CLINICAL ONCOLOGYP E R G A M O N P R E S S  
SOFTWARE DESCRIPTION FORM

Title of software program: \_\_\_\_\_

Type of program: ☐ Application ☐ Utility ☐ Other \_\_\_\_\_Category: \_\_\_\_\_ (ie. Psychological assessment,  
statistics, thermodynamics, etc.)

Developed for (name of computer/s): \_\_\_\_\_

in (language/s): \_\_\_\_\_

to run under (operating system): \_\_\_\_\_

available on: ☐ Floppy disk/diskette. Specify:Size \_\_\_\_\_ Density \_\_\_\_\_ ☐ Single-sided ☐ Dual-sided☐ Magnetic tape. Specify:

Size \_\_\_\_\_ Density \_\_\_\_\_ Character set \_\_\_\_\_

Hardware required: \_\_\_\_\_

Memory required: \_\_\_\_\_ User training required: ☐ Yes ☐ NoDocumentation: ☐ None ☐ Minimal ☐ Self-documenting  
☐ Extensive external documentationSource code available: ☐ Yes ☐ NoStage of development: ☐ Design complete ☐ Coding complete  
☐ Fully operational ☐ Collaboration welcomedIs program in use? ☐ Yes ☐ No How long? \_\_\_\_\_ How many sites? \_\_\_\_\_Is the contributor available for user inquiries: ☐ Yes ☐ No

Distributed by: \_\_\_\_\_

Cost of program: \_\_\_\_\_

Demonstration disk available? ☐ Yes ☐ No Cost: \_\_\_\_\_

(continued)

RETURN COMPLETED FORM TO:

Professor H. Tagnon  
Institut Jules Bordet  
Centre des Tumeurs  
1 rue Heger-Bordet  
B-1000 Bruxelles, Belgium

Description of what software does [maximum: 200 words]:

Potential users: \_\_\_\_\_

Field/s of interest: \_\_\_\_\_

# # # # # # #

Name of contributor: \_\_\_\_\_

Institution: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

Telephone number: \_\_\_\_\_

# # # # # # #

Reference No. [Assigned by Journal Editor] \_\_\_\_\_

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[The information below is not for publication.]

Would you like to have your program:

Reviewed? [ ] Yes [ ] No [ ] Not at this time

Marketed and distributed? [ ] Yes [ ] No [ ] Not at this time

[This Software Description Form may be photocopied without permission]