

Introduction

The objective of ART is to track and report patient allergy and adverse reaction data. This is accomplished via the four major components of the package.

1. Data Entry Options - Adverse Reaction Tracking has two options where a user can enter data.
 - a. Enter/Edit Patient Reaction Data - This option allows the clinical users (i.e., doctors, nurses, other clinicians and clerks) to enter data into ART.
 - b. Verify Patient Reaction Data - This option allows the verifiers designated by ART to verify the correctness of data entered by the clinical users into ART. This option does NOT perform evaluation of suspected Advanced Drug Reactions (ADR) as described in Section 5.a.(2).(d) of Directive 10-92-070.
2. Reporting options - These options report the patient causative agent data to the user via a print option. Also, this data is made available to other software applications via a data extract utility.
3. Enter/Edit Site Configurable Files - This menu allows the various site configurable files to be modified to allow ART to better meet the needs of an individual site.
4. Adverse Drug Reaction (ADR) options - These options support implementation of Directive 10-92-070. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070. This component also generates the reports needed by the FDA.

There are four major users of the software.

1. Clinical users - These are the doctors, nurses, other clinicians and clerks entering the data into ART. They are required to enter data pertinent for a particular allergy/adverse reaction. If the allergy/adverse reaction was observed at the site, data pertaining to any possible legal action could be tracked. This data would then be made available to users of any service utilizing the Reporting options, thus avoiding any errors in care. Two other data elements that are tracked are the date/time that the patient chart was marked and the date/time that the patient ID band was marked indicating

the patient's reaction to the particular causative agent. Automated mail bulletins are sent to the appropriate users when the date/time patient chart marked data field has not been recorded.

2. Verifiers - These are designated users by the site who verify the correctness of the data in ART. The verifiers are designated when the Information Resources Management Service (IRM) allocates the GMRA-ALLERGY VERIFY security key to a user and have the ART Verifier Menu. The verifiers may be clinical pharmacists, dietitians, and other clinical personnel. Automated mail bulletins will be sent to the ART verifiers when an allergy/adverse reaction has been entered and signed (completed) by a user. Verification may be important in observed instances of adverse drug reactions where a Quality Assurance (QA) investigation may be conducted. In general, it is a good principle to have someone verify all of the data entered into ART.
3. Pharmacy and Therapeutics (P&T) Committee users - These users are the members of the hospital's P&T Committee and are assigned the P&T Committee Menu option. They will use the information in ART to review ADRs in the hospital, classify them as significant reactions and determine whether they are related to particular drugs, and depending on the severity of the ADR may report it further to the FDA. A printed copy of the form used to report to the Food and Drug Administration (FDA) can be generated by ART. Automated mail bulletins will be sent to the P&T Committee users when an observed drug reaction is entered into the system.
4. Software developers - These users will utilize the data extract utility (GMRADPT routine) to gather ART data for display within their specific DHCP application.

Orientation

The Preface, Introduction, and Orientation sections of the manual provide generic package information about ART. The rest of the manual contains information specific to the users of ART. Please refer to other DHCP instructional manuals which provide basic information about general computing and your computer system (e.g., the DHCP User's Guide to Computing).

Special Commands, Keys, and Conventions

For purposes of this manual, when a character is enclosed in quotes (e.g., "^"), the user should only enter the character(s), not the quotes.

NOTE: There is a difference between the letter "O" and the number "0", as well as between the number "1" and the letter "l". The space bar functions as a character key as well as an apparent function key which moves the cursor on the screen.

Special Function Keys modify the operation of the terminal. Whenever a reference is made to the use of a function key, its name will be bracketed with "<" and ">" (e.g., <RET>;).

1. The Shift Key (SHIFT) is the most commonly used key. There frequently is one Shift Key on either side of the keyboard labeled "SHIFT". If a QUME terminal is being used, however, the <SHIFT> key is labeled with an open arrow pointing upwards. Some keys are used in conjunction with the <SHIFT> key. To use them, first depress the <SHIFT> key and continue holding it while depressing one of the following:
 - a. The At Sign "@" means line deletion and deletes data before a double slash (//) and removes that data from the database. The "@" is generally located on the "2" key. There are exceptions, however.
 - b. The Up-arrow "^" is frequently located on the "6" key and is used as follows:
 - 1) Quit -- by inserting "^", the user quits/exits a prompt.
 - 2) Rapid Out -- by inserting "^^", the user is sent to the next level (screen or returns to primary menu). Not all DHCP software has this capability.

- c. The question mark "?" is located next to the lower right <SHIFT> key and is used to request help in understanding the format or obtaining a list from which to make a selection.
 - 1) "?" -- will produce a listing of possible responses, if available from the computer.
 - 2) "??" -- will result in a more complete help message, if available from the computer.
2. <CAPS LOCK> maintains the <SHIFT> key in the lock position so that all letter keys display as upper case letters. Unlike the Shift Lock Key on a typewriter, it does not shift any key other than the alphabet keys.
3. In general, the carriage Return or Return key <RET>, is the most frequently used key. It signals the computer that the user has finished entering data. Information is held without action until the <RET> is pressed.
4. will backspace and delete one character at a time if <RET> has not yet been depressed. As each character is removed, the cursor automatically backspaces one position.
5. <NO SCROLL> is used to suspend printing of a listing that is longer than the screen. Simply depress <NO SCROLL> or (on the WYSE terminal) <HOLD SCREEN> to read the screen display. Depress the key again to resume printing the remainder of the display.

General Computer Usage Instruction

The user of ART sends information to and receives information from the computer. The computer acts as an intermediary between the user and another user (or the initial user later) to store, reorganize, calculate, and then recall the information. Because many individuals are unfamiliar with computers, programmers have developed a dialog with the computer which helps it communicate with the user. The computer is programmed to ask questions, and data can be entered to complete the inquiry. Once a user enters a response, the computer interprets that response literally. The computer does not think on its own; it simply responds to information entered by the user.

This section will assist the user in obtaining the desired question(s) from the computer and in responding to screen prompts. It is divided into five parts:

Terminology	Describes some basic programming terminology.
Prompts	Assists the user in recognizing the various types of prompts.
Responses	Discusses user responses to prompts.
Data Types	Provides a brief description of data types and the kind of data that can be entered.
Queueing Reports	Describes how to send reports to a printer which will print in the future.

Terminology

Attribute: A specific piece of information about a thing or an entity. Another term for attribute is "element".

Record: A grouping of attributes which relate to a common entity. Every person has a name, age, address, social security number (SSN), and date of birth; each has a value. These field names together with their respective values form a record.

File: A group of records that are of the same type. For example, the record defined in the previous paragraph might be found in a group of similar records in a personnel file.

Prompts

A prompt is a question displayed on the screen by the computer. The user responds to the prompt by entering information.

Basic: The basic prompt will display what data is to be entered, followed by a colon.

Select the number(s) of the entry(ies) you wish to add/edit:

Here the prompt is asking the user to enter selections from the listing on the screen. The user supplies an answer that applies.

Default: The default prompt asks a question and supplies an answer. The answer either reflects the most common response associated with the question or, data (a value) that was previously entered.

Do you really want to Halt? YES//

If <RET> is pressed, the computer recognizes the "YES" default as the accepted answer, and will halt/stop. Notice the "/" after the "YES". This means that the user can change the default answer to something else. In this example, if the user entered "NO" after the "/", the system would permit the user to continue working on the computer.

Select: The select prompt indicates that an answer is expected from the user. If the user's answer is accepted by the computer, the data will be stored and another prompt usually appears. If the user's answer is not on the accepted list, the terminal will beep and "???" will appear after the original question. The question will then be repeated.

If the list within the computer is short, it will be displayed on the screen to help the user in making a selection.

If a list does not display, enter a "?" for a "help message" to appear on the screen. The message should assist the user to respond to the question.

Responses

ART is designed to allow the user to enter specific information pertaining to the report in question. As a convention, all user responses in the Adverse Reaction Tracking documentation will be in bold letters so that they are differentiated from screen displays.

There should be no space between the comma and first name in a Patient's Name prompt. The convention used in entering names does not use a space in that position. When doing a look-up on a name, the user will be beeped from the computer if a space has been entered between the last and first names. Enter it as:

"LAST NAME,FIRST NAME".

Remember to use HELP when questions arise. The user can type "?", "??", or "???" after any prompt to get a help message. The help message generally tells the user what to do. In some instances, a specific list of possible responses is displayed.

Field names in ART have descriptions associated with them. When the user types "??" after the prompt, the description of the attributes will be displayed. This utility acts as a glossary within the programs.

Not all prompts must be answered. When the user presses <RET> after the prompt without entering data, no value will be assigned to the attribute. The next prompt is then displayed. An attribute with no value in the data element is called a "NULL".

Data Types

Data is entered and used by a variety of individuals. Therefore, not all data is the same nor is it used for the same purposes. Similarly, not all specific data types perform the same functions. It is important that the user understands and recognizes the different types of data associated with Adverse Reaction Tracking.

- Free Text:** Allows a limited number of any combination of alphabetic characters as well as numbers and punctuation marks. Any meaningful sequence of symbols can be entered.
- Date/Time:** The name of this data type explains the content. All time related date entries must have a date including a time.
- Enter "T-1@3PM" for yesterday at 3 in the afternoon. "T" is a special character which stands for today's date.
- Enter "NOW" for today's date and current time.
- You may enter date information in any of the following ways:
- JAN 22 1957 or 22 JAN 57 or 1/22/57 or 012257
 T (for TODAY), T+1 (for TOMORROW), T+2, T+7, etc.
 T-1 (for YESTERDAY), T-3W (for 3 WEEKS AGO), etc.
 N = Now (to enter the current date and time)
 If the year is omitted, the computer uses the CURRENT YEAR. Sometimes the system allows you to omit the precise day, as: JAN, 1957

Orientation

- Numeric:** Is a field comprised exclusively of numbers, such as a dollar amount. A list of numbers is a group of numbers separated by commas with ranges of the numbers separated by hyphens (-).
- For example, 1-2,5 is a valid entry and would mean that the user wanted to select choices 1, 2, and 5. Also, the entry 1,2,5 would mean the same thing.
- Computed:** Is a field whose value is computed from values of other attributes. Computed field data does not appear in ART. A computed field cannot be edited. Only fields which determine the value of the computed field can be edited (e.g., age is computed from Date of Birth (DOB)).
- Set of Codes:** Refers to a short list of values (set when the field was developed) each of which can be identified by a brief code.
- Pointer to a File:** Is a field which refers to an entry in another file. This relationship is called a pointer.
- Variable Pointer:** Is similar to a "pointer", except that the relationship is to several files. As an example, there could be a field that chooses either from the GMR Allergies file or the National Drug file for its entry choices.

Word Processing: Is similar to free text in that any characters can be entered; however, there is no limit to the amount of text that can be entered. The built-in word processor in the DHCP System is an elemental line-oriented type of system that is easy to use. Help messages are available to the user. There are two characteristics of the line editor that may not be obvious. Text will not wrap-around, therefore, it is best to track the cursor on the screen and press the Return key to begin a new line. Secondly, while a line of text is being entered, the only editing permitted is through the use of the key (to delete characters to the left of the cursor). However, once an entire text is entered, it can be edited with the Replace technique.

Replace Technique:

For example, the user enters the following:

```
1>This is an example of how to use thye REPLACE<RET>
2>technique to edit text entered by the user.<RET>
3><RET>
```

After the user has entered the text, the system gives the user the option to edit the text line by line. The user's input is in bold.

```
Edit Option: EDIT line 1 <RET>
1>This is an example of how to use thye REPLACE
REPLACE thye <RET> WITH the <RET>
```

The system returns the corrected piece of text.

```
1>This is an example of how to use the REPLACE
Edit Line: <RET>
```

Other features of the Replace are:

Type "... " at the Replace prompt to replace the entire line of text.

Type "END" at the Replace prompt to append text at the end of the current line of text.

Queueing Reports

When a report must be printed and a user wishes the CRT available for data entry, the desired report can be queued in the following manner:

1. Select a print option from an appropriate display.
2. Enter at Device prompt: Q (QUEUE TO PRINT ON).
3. The Device prompt will again display; the user must enter the name of the device.
4. The user will also need to set the right margin (e.g., 132 or 80 columns); usually the default is selected.
5. Another prompt "Requested Time to Print" must also be completed before the queueing parameters are completed.

Example:

DEVICE: HOME// Q<RET> QUEUE TO PRINT ON

DEVICE: HOME// (Enter Printer Name; e.g., 132<RET>)

REQUESTED TIME TO PRINT: NOW// (Select from options listed below)

- a. Pressing the Return key will print the report immediately if the printer is available.
- b. Specific time such as: 10:25AM (NOV 28, 1996 10:25AM).
- c. "^" will allow you to exit and the report will not be queued by indicating TRY LATER.

If either (a) or (b) is entered by the user, the report will be printed by the appropriate printer device; the CRT can be used concurrently while the report is printing. The computer will display the following message:

REQUEST QUEUED!

Sign On/Sign Off

1. To sign on, you must use the access and verify codes you were assigned. Keep both codes confidential!

Respond to the prompts:

ACCESS CODE: First, enter your access code. Then, press the Return key.

VERIFY CODE: Enter your verify code. Then, press the Return key.

To insure security, your ACCESS and VERIFY CODES will not be visible on the screen.

Example:

Prompt:	User Entry:
ACCESS CODE:	TRAIN12 <RET>
VERIFY CODE:	NURSE34 <RET>

2. To SIGN OFF, either:
 - a. Press the Return key or,
 - b. Enter an up-arrow (^) and then press the Return key until the following prompt appears:

"Do you really want to halt"? Yes// <RET>

Orientation

Package Management

This package does not impose any additional legal requirements on the user, nor does it relieve the user of any legal requirements. All users are reminded that many of the reports and mail bulletins generated by this package contain confidential patient information which is protected by the Privacy Act.

A basic knowledge of the Decentralized Hospital Computer Program (DHCP) is presumed for most users of the software. The Application Coordinator (ADPAC) should have more than a basic knowledge of DHCP and the needs of a clinical environment.

The software does contain two security keys. The GMRA ALLERGY VERIFY key is needed to verify allergy/adverse reactions. The GMRA SUPERVISOR key should be given only to those users who have the authority to override the software's security in order to edit data.

The software itself does not prompt for a user's electronic signature. However, it does contain a programming interface with the Progress Notes package in order to create, edit and sign progress notes. The Progress Notes software does prompt the user for an electronic signature.

The software generates mail bulletins when certain events happen and sends a bulletin to a specified mail group. The mail groups are:

- 1) GMRA MARK CHART - A list of users who will need to mark a patient's chart to record an allergy/adverse reaction.
- 2) GMRA VERIFY DRUG ALLERGY - A list of all verifiers who will need to be sent drug reaction information.
- 3) GMRA VERIFY FOOD ALLERGY - A list of all verifiers who will need to be sent food reaction information.
- 4) GMRA VERIFY OTHER ALLERGY - A list of all verifiers who will need to be sent other types of reaction information (i.e., not drug or food).
- 5) GMRA P&T COMMITTEE FDA - A list of the members of the Pharmacy and Therapeutic (P&T) Committee.

Contact the ADPAC or IRM support staff if you need to be a member of one of these mail groups.

Package Management

Package Operation

The ART software includes six menus to assist users in tracking and reporting allergy/adverse reaction data. They are:

- 1) Adverse Reaction Tracking [GMRAMGR] - This is the top level menu. It should be given to the package's ADPAC and/or IRM support person.
- 2) Adverse Reaction Tracking User Menu [GMRA USER MENU] - This menu can be assigned to clerks who will enter adverse reaction data.
- 3) Adverse Reaction Tracking Clinician Menu [GMRA CLINICIAN MENU] - This menu can be assigned to clinicians who will use the package.
- 4) Adverse Reaction Tracking Verifier Menu [GMRA VERIFIER MENU] - This menu should be assigned to users who will verify adverse reaction data.
- 5) P&T Committee Menu [GMRA P&T MENU] - This menu can be given to Pharmacy and Therapeutic Committee members.

The rest of this chapter describes the menus and options. Also, examples of each option are given.

Adverse Reaction Tracking

This is the main menu that has all options of the Adverse Reaction Tracking System. This menu should only be given to the ART Applications Coordinator (ADPAC) and/or IRM support personnel.

1. Enter/Edit Site Configurable Files ...
2. Adverse Reaction Tracking User Menu ...
3. Adverse Reaction Tracking Clinician Menu ...
4. Adverse Reaction Tracking Verifier Menu ...
5. P&T Committee Menu ...

Enter/Edit Site Configurable Files

This is a menu of the various options that the site can use to tailor ART to better meet its needs. This menu should be used by the ADPAC or IRM Support Staff only.

1. Edit Allergy File
2. Enter/Edit Signs/Symptoms Data
3. Enter/Edit Site Parameters
4. Sign/Symptoms List
5. Allergies File List

Edit Allergy File

This option allows the site to enter its own allergies into the system for selection by the user. These entries are considered local entries and can be edited by the site. The software is distributed with a list of entries that is categorized as NATIONAL allergies. The site can edit the SYNONYM field for national entries only. The data is stored in the GMR ALLERGIES file (#120.82).

Example of an allergy added.

```
Select Enter/Edit Site Configurable Files Option:  1  Edit Allergy File

Select a LOCAL ALLERGY/ADVERSE REACTION:  STINKWEED
Are you adding 'STINKWEED' as a new GMR ALLERGIES (the 117TH)?  Y (Yes)
GMR ALLERGIES ALLERGY TYPE:  ??
This field contains the type(s) for this allergy/adverse reaction.  The
user can enter the type(s) separated by commas, or the following codes:
D=Drug, F=Food, O=Other.  If codes are used, do not use commas to
separate multiple codes.  Examples of valid entries are:  DRUG or DRUG,
FOOD or D or DF or OTHER.
GMR ALLERGIES ALLERGY TYPE:  O
NAME: STINKWEED// <RET>
Select SYNONYM:  WEED
Are you adding 'WEED' as a new SYNONYM (the 1ST for this GMR ALLERGIES)?  Y
(Yes)
Select SYNONYM:  <RET>
1  Drug
2  Food
3  Other
Select the type(s) for this reaction:  3//  <RET>
Select DRUG INGREDIENT:  ?
Answer with DRUG INGREDIENTS
You may enter a new DRUG INGREDIENTS, if you wish

Enter one of the drug ingredients that make up this allergy.
Answer with DRUG INGREDIENTS NAME
Do you want the entire 3585-Entry DRUG INGREDIENTS List?  N (No)
Select DRUG INGREDIENT:  <RET>
Select VA DRUG CLASSES:  ?
Answer with VA DRUG CLASSES
You may enter a new VA DRUG CLASSES, if you wish
Answer with VA DRUG CLASS CODE, or CLASSIFICATION
Do you want the entire 494-Entry VA DRUG CLASS List?  N (No)
Select VA DRUG CLASSES:  <RET>

Select a LOCAL ALLERGY/ADVERSE REACTION:  <RET>
```

Example of adding a synonym to a nationally distributed allergy.

Select Enter/Edit Site Configurable Files Option: 1 Edit Allergy File
Select a LOCAL ALLERGY/ADVERSE REACTION: **CAFFEINE** NATIONAL ALLERGY

CANNOT EDIT NAME FIELD OF A NATIONAL ALLERGY.

Select SYNONYM: **STIMULANT**

Are you adding 'STIMULANT' as a new SYNONYM (the 1ST for this GMR ALLERGIES)? **Y**

(Yes)

Select SYNONYM: **<RET>**

Select a Local Allergy/Adverse Reaction: **<RET>**

Enter/Edit Signs/Symptoms Data

This option allows the addition/editing of the site-specific allergy reactions. The site may find the signs/symptoms list provided by ART inadequate for its needs. This option will allow the site to add any data as appropriate. This data is stored in the Sign/Symptoms file (#120.83).

Select Enter/Edit Site Configurable Files Option: **2** Enter/Edit Signs/Symptoms Data

Select a LOCAL SIGN/SYMPTOM: **HAIR LOSS**

NAME: HAIR LOSS// **<RET>**

Select SYNONYM: BALD// **<RET>**

Select a LOCAL SIGN/SYMPTOM: **<RET>**

Enter/Edit Site Parameters

The Enter/Edit Site Parameters [GMRA SITE FILE] option allows site configuration for multiple divisions at the site. The software provides a generic site configuration entry called HOSPITAL. The site can customize this entry to fit its needs. These parameters are stored in the GMR Allergy Site Parameters file (#120.84).

The site can configure the following:

1. The list of the ten most common signs/symptoms that the user will see.
2. The autoverification of data. Autoverification is the process by which the software automatically changes the status of the data to verified when the user who entered the data signs off (completes) on it. The site can determine which of the types of reactions are to be autoverified and which are to follow the normal verification procedure. There are three parameters used to autoverify data: Autoverify Food/Drug/Other, Autoverify Observed/Historical and Autoverify Logical Operator. The verification of data is important. Minimally, all drug reactions will need verification. Depending on the site, food and other allergies may also need to be verified. The users who will verify the data must have the GMRA-ALLERGY VERIFY security key.
3. Whether the originator of the data should provide comments.
4. Whether the site documents the marking of a patient's ID band or chart to indicate the presence of an allergy/adverse reaction. There are three parameters with regards to this documentation: Mark ID Band Flag Method of Notification, Alert ID Band/Chart Mark and Send Chart Mark Bulletin for New Admissions.
5. FDA reporting data. The site can choose to require the user to enter FDA data at the time a reaction is entered. Also, the site may edit the reporter information that will appear on the FDA Adverse Reaction reports.
6. Whether to allow comments to be added to the reaction data that is entered in error. This allows the user to indicate why the data is incorrect.

Enter/Edit Site Configurable Files

Select Enter/Edit Site Configurable Files Option: 3 Enter/Edit Site Parameters

Select GMR ALLERGY SITE PARAMETERS NAME: ??
HOSPITAL

This field is the name of this set of parameters. The name of the base set that is sent out is "HOSPITAL". The code will work more efficiently if the name of the base set of parameters is not changed from "HOSPITAL".

Select GMR ALLERGY SITE PARAMETERS NAME: HOSPITAL
NAME: HOSPITAL// (No editing)
Select DIVISION: HINES// <RET>

The following are the ten most common signs/symptoms:

- | | |
|--------------------------|--------------|
| 1. ANXIETY | 6. DIARRHEA |
| 2. ITCHING,WATERING EYES | 7. HIVES |
| 3. HYPOTENSION | 8. DRY MOUTH |
| 4. DROWSINESS | 9. CHILLS |
| 5. NAUSEA,VOMITING | 10. RASH |

Enter the number of the sign/symptom that you would like to edit: 5
REACTION: NAUSEA,VOMITING// ??

One of the ten most commonly selected reactions.

Choose from:

AGITATION NATIONAL SIGN/SYMP TOM
AGRANULOCYTOSIS NATIONAL SIGN/SYMP TOM
ALOPECIA NATIONAL SIGN/SYMP TOM
ANAPHYLAXIS NATIONAL SIGN/SYMP TOM
ANEMIA NATIONAL SIGN/SYMP TOM
ANOREXIA NATIONAL SIGN/SYMP TOM
ANXIETY NATIONAL SIGN/SYMP TOM
APNEA NATIONAL SIGN/SYMP TOM
APPETITE,INCREASED NATIONAL SIGN/SYMP TOM
ARRHYTHMIA NATIONAL SIGN/SYMP TOM
ASTHENIA NATIONAL SIGN/SYMP TOM
ASTHMA NATIONAL SIGN/SYMP TOM
ATAXIA NATIONAL SIGN/SYMP TOM
ATHETOSIS NATIONAL SIGN/SYMP TOM
BRADYCARDIA NATIONAL SIGN/SYMP TOM
BREAST ENGORGEMENT NATIONAL SIGN/SYMP TOM
BRONCHOSPASM NATIONAL SIGN/SYMP TOM
CARDIAC ARREST NATIONAL SIGN/SYMP TOM
CHEST PAIN NATIONAL SIGN/SYMP TOM
CHILLS NATIONAL SIGN/SYMP TOM
CHOKING

^

REACTION: NAUSEA,VOMITING// CHEST PAIN NATIONAL SIGN/SYMP TOM

The following are the ten most common signs/symptoms:

- | | |
|--------------------------|--------------|
| 1. ANXIETY | 6. DIARRHEA |
| 2. ITCHING,WATERING EYES | 7. HIVES |
| 3. HYPOTENSION | 8. DRY MOUTH |
| 4. DROWSINESS | 9. CHILLS |
| 5. CHEST PAIN | 10. RASH |

Enter the number of the sign/symptom that you would like to edit: <RET>
AUTOVERIFY FOOD/DRUG/OTHER: AUTOVERIFY FOOD/OTHER// ??

This field determines which types of allergies a site wants autoverified at the user sign off.

Choose from:

```

0      NO AUTOVERIFY
1      AUTOVERIFY DRUG ONLY
2      AUTOVERIFY FOOD ONLY
3      AUTOVERIFY DRUG/FOOD
4      AUTOVERIFY OTHER ONLY
5      AUTOVERIFY DRUG/OTHER
6      AUTOVERIFY FOOD/OTHER
7      AUTOVERIFY ALL
AUTOVERIFY FOOD/DRUG/OTHER: AUTOVERIFY FOOD/OTHER//  <RET>
AUTOVERIFY OBSERVED/HISTORICAL:  ??

```

This field is configurable by the site to allow autoverification of observed or historical allergies.

Choose from:

```

0      NO AUTOVERIFY
1      AUTOVERIFY HISTORICAL ONLY
2      AUTOVERIFY OBSERVED ONLY
3      AUTOVERIFY BOTH

```

```

AUTOVERIFY OBSERVED/HISTORICAL:  3  AUTOVERIFY BOTH
AUTOVERIFY LOGICAL OPERATOR:  ??

```

This field will determine how the Autoverify Food/Drug/Other and Autoverify Observed/Historical parameters relate to each other. OR means that the reaction will be autoverified if it meets the criteria of one of the two parameters, while AND means the reaction will be autoverified only if it meets the criteria of both parameters. If this field is left null, the OR condition will be used.

For example, if you want to verify only observed drug reactions, you would set the Autoverify Food/Drug/Other parameter to AUTOVERIFY FOOD/OTHER and the Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY, and the Autoverify Logical Operator to OR. This means that a reaction that has a type of Food/Other OR is Historical will be autoverified, thus leaving observed drug reactions to be verified.

Another example would be if you wanted to verify all observed reactions and all drug reactions whether observed or historical. The parameters should be set accordingly: Autoverify Food/Drug/Other to AUTOVERIFY FOOD/OTHER, Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY and Autoverify Logical Operator to AND. In this case to be autoverified, a reaction has to have a type of Food/Other AND it must be Historical, all other reactions will need to be verified.

Choose from:

```

!      OR
&      AND

```

```

AUTOVERIFY LOGICAL OPERATOR:  AND  AND
REQUIRE ORIGINATOR COMMENTS: NO//  <RET>
MARK ID BAND FLAG: YES//  <RET>
METHOD OF NOTIFICATION: BULLETIN//  <RET>
ALERT ID BAND/CHART MARK: YES//  <RET>

```

```

SEND CHART MARK BULLETIN FOR NEW ADMISSIONS:  ??

```

This is to indicate if the site wants to send chart mark bulletin for a new admission.

Choose from:

```

1      YES
0      NO

```

```

SEND CHART MARK BULLETIN FOR NEW ADMISSIONS:  1  YES

```

Enter/Edit Site Configurable Files

FDA DATA REQUIRED: NO// <RET>
ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: YES// <RET>

REPORTER NAME:
ADDRESS:
CITY:
STATE:
ZIP:
PHONE:
OCCUPATION:

Do you want to edit Reporter Information shown above? No// <RET> (No)

NOTE: These “Reporter” data fields contain the site’s default values that will appear on the FDA adverse reaction reports. This information may be left blank. The user will be prompted for the reporter information when creating an FDA report.

Sign/Symptoms List

This option will print a list of entries in the Sign/Symptoms file (#120.83). The user may print all entries by accepting the default value (FIRST) at the "Name" prompt or may select a subset of entries. The listing includes the name of the sign/symptom, whether it is a nationally distributed entry or a locally created entry, and any of its synonyms. This option is meant to be a useful tool for the ADPAC to maintain the Sign/Symptoms file.

```
Select Enter/Edit Site Configurable Files Option:  4  Sign/Symptoms List
START WITH NAME: FIRST//  <RET>
DEVICE: <RET> HOME      RIGHT MARGIN: 80//  <RET>
```

```
SIGN/SYMP TOMS LIST                                FEB  2,1996  08:21    PAGE 1
NAME                                                Nat'l/Local      SYNONYM
```

```
-----
AGITATION                                           National
AGRANULOCYTOSIS                                    National
ALOPECIA                                           National
ANAPHYLAXIS                                        National
ANEMIA                                             National
ANOREXIA                                           National
ANXIETY                                            National
APNEA                                             National
APPETITE , INCREASED                              National
ARRHYTHMIA                                        National
ASTHENIA                                           National
ASTHMA                                             National
ATAXIA                                             National
ATHETOSIS                                         National
BRACHYCARDIA                                       National
BREAST ENGORGEMENT                                National
```

^

Allergies File List

This option prints a captioned list of all entries in the GMR Allergies file (#120.82). The list is sorted alphabetically by NAME. The user may list all entries by accepting the default answer (FIRST) to the "start with" prompt or may select a subset to print. The list contains the allergy name; type; whether it is a nationally distributed entry; synonyms, if any; VA Drug Class, if applicable; and drug ingredients, if applicable. This option is meant to be a helpful tool for the ADPAC to maintain the GMR Allergies file.

```
Select Enter/Edit Site Configurable Files Option: 5 Allergies File List
START WITH NAME: FIRST// <RET>
DEVICE: <RET> HOME RIGHT MARGIN: 80// <RET>
```

```
GMR ALLERGIES LIST FEB 2,1996 08:21 PAGE 1
-----
```

```
NAME: ADHESIVE TAPE ALLERGY TYPE: OTHER
NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ALCOHOL ALLERGY TYPE: DRUG, FOOD
NATIONAL ALLERGY: NATIONAL ALLERGY
DRUG INGREDIENT: ALCOHOL

NAME: ANIMAL HAIR ALLERGY TYPE: OTHER
NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ANISE OIL ALLERGY TYPE: DRUG, FOOD
NATIONAL ALLERGY: NATIONAL ALLERGY
DRUG INGREDIENT: ANISE OIL

NAME: ANTIRABIES SERUM ALLERGY TYPE: DRUG, FOOD
NATIONAL ALLERGY: NATIONAL ALLERGY
^
```

Adverse Reaction Tracking User Menu

This menu is assigned to all clerks of Adverse Reaction Tracking who are not clinicians, verifiers, or ADP coordinators. The options on this menu allow the user to enter, edit and display allergy/adverse reaction data.

1. Enter/Edit Patient Reaction Data
2. Active Listing of Patient Reactions
3. Edit Chart and ID Band
4. List by Location of Unmarked ID Bands/Charts
5. Patient Allergies Not Signed Off
6. List by Location of Undocumented Allergies
7. Print Patient Reaction Data
8. Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. The user is prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

Selecting a Patient:

The user may select a patient by name (last name, first name), full Social Security Number (SSN), the last four digits of the SSN (e.g., 1234), the first letter of the last name and last four digits of the SSN (e.g., A1234), or ward location (e.g., 1 North).

Does the patient have any known allergies/adverse reactions?

If the selected patient does not have any allergies/adverse reactions stored in the ART database the user is asked the above question. A Yes response will allow the user to make an entry. A No response will take the user back to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient the software will not ask this question, but will instead display information about the existing reactions. The software will display the name of the causative agent, the type of causative agent (e.g., food), any signs/symptoms, its mechanism (e.g., Allergy or Pharmacologic), whether it was an observed reaction or historical, and whether or not it was verified.

Selecting a Causative Agent:

The lookup procedure that is performed when the user enters a causative agent deserves a detailed explanation.

- 1) If the causative agent exists as an entry for the patient, then the user has the opportunity to edit the data concerning that entry.
- 2) If the user's response is not part of that patient's entry or the user does not want to edit an existing choice given in Step 1, then a lookup for the particular agent is done using five files of choices which are searched in the following order:
 - a) GMR Allergies (#120.82) - this file is distributed with the ART software and contains nationally distributed food and other type agents plus any entries added locally by the facility,

- b) Drug Ingredients (#50.416) - this file contains the names of individual generic drugs which are components of various drug products,
 - c) VA Drug Class (#50.605) - this file contains the names of the various drug classes used within the Department,
 - d) National Drug (#50.6) - this file contains the names of available drug products including trade names and manufacturer, and
 - e) Drug (#50) - this file contains the names of drugs that can be used to fill a prescription.
- 3) If the user's response is not found after Steps 1 and 2, then he/she is asked if the response should be added to the patient's record. The response entered by the user will be saved in the patient's database entry and will be displayed on subsequent lookups while the causative agent will be linked to the OTHER ALLERGY/ADVERSE REACTION entry in the GMR Allergies file. When adding a causative agent for a patient's record that is not in any of the five files, the user is asked to identify the type of agent. The choices are Food, Drug or Other. The type is required and its value determines the appropriate logic that is followed by the rest of the data entry for this entry.

NOTE: If a particular causative agent is commonly selected, but it comes from a lookup on one of the later files (i.e., 2b, 2c, 2d or 2e) and the facility wishes to minimize the response lookup time, then that causative agent can be added to the GMR Allergies file as a local entry. Since this is the first file that is looked up in Step 2, the response time will be reduced.

NOTE: When selecting entries from the Drug file (#50) the user may see the various dosages associated with the drugs. The user only needs to pick one of these dose forms. The software will figure out which ingredients from that drug the patient had a reaction to and set that information into the database automatically.

Observed vs. Historical Reaction:

An observed reaction is an event that actually happened to the patient during the patient's stay/visit at the facility. A historical reaction is one that is reported, but not observed by the facility personnel. If the reaction is observed the user will be asked to enter the observation date. The time of day may be entered, but it is optional.

Observed Report:

For an observed reaction, the user is asked for additional information. The user may enter the name of the person who observed the reaction (the default response is the name of the user entering the data), the severity of the reaction (i.e., mild, moderate or severe), and the date a medical doctor was notified. Also, the user may edit the date and time of the observation. The user will only see these prompts if he/she has the GMRA-ALLERGY VERIFY KEY.

Signs/Symptoms:

A sign/symptom is an effect of the reaction on the patient (e.g., itching). The software comes with a list of nationally recognized signs/symptoms. The site can add additional signs/symptoms to the list. The software displays to the user a list of commonly reported signs/symptoms to choose from. The user may choose from this abbreviated list or from the full list of choices. The user may select as many signs/symptoms as applicable. The site may customize the abbreviated list the user sees to meet its needs. Observed reactions require the user to enter signs/symptoms. A historical reaction allows, but does not require the user to enter signs/symptoms.

Also, the user is asked to enter the date the sign/symptom appeared. The time of day may be entered, but it is optional.

Mechanism:

The mechanism is the type of reaction. The choices are Allergy, Pharmacologic or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions such as exposure to a large amount. Unknown is provided if the user is not sure what mechanism to enter. The user will only see these prompts if he/she has the GMRA-ALLERGY VERIFY KEY.

Note: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

Comments:

The site can determine whether comments from the originator of the entry are required by setting a software parameter. If that site parameter is set to YES the user is required to enter comments concerning the entry. If the entry is being edited and any existing comments exist for this causative agent the software will

display those comments and whether they were entered by the originator of the entry, a verifier or a person who marked the entry as entered in error.

FDA Data:

When the type of the causative agent is a drug, the user may enter further information about the reaction which will be used by the software to generate an FDA report. The questions for the FDA report are categorized in four sections. Users are encouraged to provide as much information about the reaction as possible. The site can determine if the user will be required to enter FDA data by setting a software parameter. The user will only see these prompts if he/she has the GMRA-ALLERGY VERIFY KEY.

Verification of Data:

Entries can be verified by a user or by the software. The latter is known as autoverification. The site can determine how the entries are verified by setting three software parameters. The combination of these three parameters allows the software to automatically verify none, some or all entries. Conversely, sites may wish to have their users verify none, some or all entries.

If the entry must be verified by a user and the user has the verification key, GMRA-ALLERGY VERIFY, the software will allow the verification of the data during the enter/edit option. The user has an opportunity to review and edit the data before verifying the entry.

Generating Progress Notes:

The ART software has an interface to the Progress Notes package. A progress note will be generated when the user verifies, signs off, or marks as entered in error an observed reaction. The progress note is displayed and the user may electronically sign, edit or delete it. Also, the user may print the note. The user will only see these prompts if he/she has the GMRA-ALLERGY VERIFY KEY.

Mark Patient Chart and ID Band:

The user is asked if the patient chart was marked to show that the patient is allergic to the causative agent.

For an inpatient, the user is asked if the patient identification band was marked to show an allergic reaction to the causative agent. The site can determine with a software parameter whether the user should be asked this question.

Adverse Reaction Tracking User Menu

There are three other software parameters the site can set concerning the patient chart and ID band. The site can set a software parameter to determine who will be notified that a chart or ID band is not marked. A notification bulletin can be sent to the GMRA MARK CHART mail group, an Order Entry Team or not sent at all.

The site can set a software parameter to determine if an alert should be sent to the GMRA MARK CHART mail group or an Order Entry Team when the mark chart or mark ID band questions are not answered.

Also, the site can set a software parameter to determine if users from outside the package can send a bulletin to mark a patient chart for an reaction. Specifically, when a patient is admitted a bulletin may be sent to mark the patient chart for the particular reaction identified in the bulletin.

Signing Off on an Entry:

Signing off (i.e., is the data correct?) on an entry means the user who entered/edited the entry is satisfied with the data entered. It does not mean an electronic signature. Users who have the verification key will not be asked to sign off on an entry if they verify it. Users who have the verification key will be asked to sign off on an entry if they do not verify it. Users who do not have the verification key will be asked to sign off on the entry.

```
Select Adverse Reaction Tracking User Menu Option:  1  Enter/Edit Patient
Reaction Data

Select PATIENT NAME:  VASQUEZ,BOB          04-01-23      300000000      SC
VETERAN

OBS/
REACTANT                                VER.   MECH.   HIST   TYPE
-----                                ----   ----   ----   ----
ASPIRIN                                AUTO  ALLERGY HIST   DRUG
    Reactions: CHILLS, DRY MOUTH, CHEST PAIN
DILANTIN                                YES   ALLERGY OBS   DRUG
    (PHENYTOIN)
    Reactions: DROWSINESS
IBUPROFEN                                NO    UNKNOWN OBS   DRUG
PENICILLIN                               YES   UNKNOWN OBS   DRUG
    Reactions: HIVES, DROWSINESS
PHENOBARBITAL                           YES   ALLERGY OBS   DRUG
    Reactions: DEPRESSION
TETRACYCLINE                             YES   PHARM   OBS   DRUG
    Reactions: DROWSINESS

Enter Causative Agent:  ANTIRABIES SERUM
    ANTIRABIES SERUM  OK? Yes//  <RET> (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction:  O  OBSERVED
```


Active Listing of Patient Reactions

This option will give a brief listing of the active (i.e., data that is signed off and not entered in error) allergy/adverse reaction data for a selected patient. The user may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select Adverse Reaction Tracking User Menu Option: **2** Active Listing of Patient Reactions

Select PATIENT: **ALMOND, BILLY** 06-15-63 33354 2222 ACTIVE DUTY

DEVICE: HOME// **<RET>** HYPER SPACE

Adverse Reaction Tracking User Menu

ACTIVE ALLERGY/ADVERSE REACTION LISTING

Run Date/Time: 1/16/96 12:12:57 pm

ALMOND, BILLY

333-54-2222

JUN 15, 1963 (32)

ADVERSE REACTION	VERIFIED	OBS/ HIST

TYPE: DRUG =====		
DEMECARIUM Reactions:	NO	OBS
ITCHING, WATERING EYES (Dec 13, 1995), NAUSEA, VOMITING (Dec 13, 1995), ANXIETY (Dec 13, 1995), DROWSINESS (Dec 13, 1995), HYPOTENSION (Dec 13, 1995)		
THE SP Reactions:	YES	OBS
ITCHING, WATERING EYES (Nov 06, 1995@14:01), TINGLING (Dec 01, 1995), NAUSEA, VOMITING (Dec 01, 1995), ANXIETY (Dec 01, 1995), ZINGLING (Dec 01, 1995)		
Enter RETURN to continue or '^' to exit:		

ACTIVE ALLERGY/ADVERSE REACTION LISTING

Run Date/Time: 1/16/96 12:12:57 pm

ALMOND, BILLY

333-54-2222

JUN 15, 1963 (32)

ADVERSE REACTION	VERIFIED	OBS/ HIST

TWO-DYNE Reactions:	YES	OBS
ITCHING, WATERING EYES (Oct 18, 1995@13:47), ANXIETY (Oct 18, 1995@13:47), HYPOTENSION (Oct 18, 1995@13:47)		
TYLOXAPOL Reactions:	YES	OBS
HIVES (Oct 26, 1995@13:05), ITCHING, WATERING EYES (Oct 26, 1995@13:05), NAUSEA, VOMITING (Oct 26, 1995@13:05), DIARRHEA (Oct 26, 1995@13:05), ANXIETY (Oct 26, 1995@13:05), DROWSINESS (Oct 26, 1995@13:05), DRY MOUTH (Oct 26, 1995@13:05), DRY NOSE (Oct 26, 1995@13:05), HYPOTENSION (Oct 26, 1995@13:05)		
Enter RETURN to continue or '^' to exit: ^		

List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that the user will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by the user. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent and whether the patient ID band, patient chart, or both were unmarked.

```
Select Adverse Reaction Tracking User Menu Option:    4 List by Location of
Unmarked ID Bands/Charts
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
```

```
Enter the number(s) for those groups to be used in this report: (1-4):    4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.
```

```
Enter START Date (time optional):    T-90 (OCT 19, 1995)
Enter END Date (time optional): T//    <RET> (JAN 17, 1996)
```

The location prompt allows the user to select the ward or clinic that he/she wants to print, or select all the wards/clinics by entering the word ALL and the system will select all the appropriate hospital locations.

```
Select Location:  ?
```

You may deselect from the list by typing a '-' followed by location name.

E.g. -3E would delete 3E from the list of locations already selected.

You may enter the word ALL to select all appropriate locations.

Answer with HOSPITAL LOCATION NAME, or ABBREVIATION

```
Choose from:
```

```
1N
```

```
1S
```

```
GMC DR. PETIT
```

```
PHYSICAL EXAM
```

```
Select Location:  1N
```

```
Another Location: <RET>
```

```
QUEUE TO PRINT ON
```

```
DEVICE:  SELECT APPROPRIATE PRINTER
```

```
Requested Start Time: NOW//    <RET> (JAN 17, 1996@13:42:26)
```

```
Request queued...
```

Adverse Reaction Tracking User Menu

Jan 17,1996

PATIENTS WITH UNMARKED ID BAND/CHART
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Oct 19,1995 TO Jan 17,1996

PAGE 1

PATIENT	SSN	ALLERGY	UNMARKED

	WARD: 1N		
JONES,SUE	111-12-4443	PENICILLIN	ID BAND/CHART
		CYCLOSPORINE	ID BAND/CHART
		AMPICILLIN	ID BAND/CHART
		GENTAMICIN	ID BAND/CHART
MILLS,BOBBY	111-00-0001	MILK	ID BAND/CHART
		SMOKE	ID BAND/CHART
		DUST	ID BAND/CHART
		SALT SUBSTITUTE	ID BAND/CHART

Jan 17,1996

PATIENTS WITH UNMARKED ID BAND/CHART
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Oct 19,1995 TO Jan 17,1996

PAGE 2

PATIENT	SSN	ALLERGY	UNMARKED

CLINIC: GMC DR. PETERS			
No Patients for this Clinic			

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. The user may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

Select Adverse Reaction Tracking User Menu Option: 5 Patient Allergies Not Signed Off

DEVICE: HOME// <RET> HYPER SPACE

ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 1/18/96 1:23:52 pm

ORIGINATOR	PATIENT	ALLERGY	ORIGINATION DATE/TIME
ACKERTON, WILLIA	LARD, BILL(9012)	PENICILLIN	FEB 18, 1993@10:59
ACKERTON, WILLIA	LARD, BILL(9012)	FROG	FEB 18, 1993@15:14
ACKERTON, WILLIA	LARD, BILL(9012)	THORAZINE 10MG	FEB 22, 1993@13:20
ACKERTON, WILLIA	DALY, RICHARD (2222)	PENICILLIN	JUN 22, 1993@11:44
ACKERTON, WILLIA	DALY, RICHARD (2222)	PHENYTOIN	JUN 22, 1993@11:48
ACKERTON, WILLIA	DALY, RICHARD (2222)	DEMECARIUM	JUN 22, 1993@12:00
ACKERTON, WILLIA	DALY, RICHARD (2222)	ASPIRIN	JUN 22, 1993@12:08
ACKERTON, WILLIA	DUCK, DONALD(6789)	PHENOBARBITAL	JUN 25, 1993@10:33
ACKERTON, WILLIA	DALY, RICHARD (2222)	PHENOBARBITAL	JUN 25, 1993@10:39
ACKERTON, WILLIA	LARD, BILL(9012)	CODEINE	JUN 30, 1993@08:55
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	THOR - PROM	AUG 11, 1993@10:35
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	IMMUNE GLOBULIN	AUG 18, 1993@10:02
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	CYCLOBENZAPRINE	JUL 11, 1994@14:11
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	SULFABENZAMIDE/S	JUL 11, 1994@14:14
ACKERTON, WILLIA	DUCK, DONALD(6789)	DUCK	JAN 06, 1995@11:13

Enter RETURN to continue or '^' to exit: ^

List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that the user will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered by the user. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of
Undocumented Allergies
  1 Current Inpatients
  2 Outpatients over Date/Time range
  3 New Admissions over Date/Time range
  4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180 (JUL 23, 1995)
Enter END Date (time optional): T// <RET> (JAN 19, 1996)
```

The location prompt allows the user to select the ward or clinic that he/ she wants to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ??
```

You may deselect from the list by typing a '-' followed by location name.

E.g. -3E would delete 3E from the list of locations already selected.

You may enter the word ALL to select all appropriate locations.

Answer with HOSPITAL LOCATION NAME, or ABBREVIATION

Choose from:

1N

1S

GMC DR. PETIT

PHYSICAL EXAM

```
Select Location: 1N
```

```
Another Location: PHYSICAL EXAM <RET>
```

```
Another Location: <RET>
```

```
QUEUE TO PRINT ON
```

```
DEVICE: SELECT APPROPRIATE PRINTER
```

Adverse Reaction Tracking User Menu

Requested Start Time: NOW// <RET> (JAN 19, 1996@10:29:44)

Request queued...

Print Patient Reaction Data

This option will allow the user to get a captioned data display of all of the patient's allergy/adverse reaction data. The user can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

The user can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). The user then selects the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run and the patient's name, SSN, date of birth and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Adverse Reaction Tracking User Menu Option:    7  Print Patient Reaction
Data

Select PATIENT:  STARK,ANTHONY           10-12-69      123456777      SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy:  (1-3):  1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?:  (1-2):  1

DEVICE: HOME//  <RET>  HYPER SPACE
```

Adverse Reaction Tracking User Menu

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 1/19/96 2:04:23 pm
STARK, ANTHONY 123-45-6777 OCT 12, 1969 (26)

STATUS: ACTIVE

TYPE: DRUG
=====

AGENT: AMIODARONE
INGREDIENTS: AMIODARONE

VA DRUG CLASSES:

ORIGINATOR: MILLER, ROBERT
SIGN OFF: YES

ORIGINATED: AUG 13, 1993@12:45
OBS/HIST: OBSERVED

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: HYPOTENSION

.....
AGENT: PENICILLIN
Enter RETURN to continue or '^' to exit: <RET>

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 1/19/96 2:04:23 pm
STARK, ANTHONY 123-45-6777 OCT 12, 1969 (26)

INGREDIENTS: PENICILLIN

VA DRUG CLASSES:

ORIGINATOR: ALBERT, BILL
SIGN OFF: YES

ORIGINATED: MAR 12, 1993@08:32
OBS/HIST: HISTORICAL

ORIGINATOR
COMMENTS:

Date: Mar 12, 1993@08:32:55

User: ACKERTON, WILL

Title: NURSE

XX

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: DROWSINESS

.....
Enter RETURN to continue or '^' to exit: <RET>

Adverse Reaction Tracking User Menu

ALLERGY/ADVERSE REACTION REPORTS

Run Date/Time: 1/19/96 2:04:23 pm
STARK, ANTHONY 123-45-6777 OCT 12, 1969 (26)

AGENT: PREDNISON
INGREDIENTS: PREDNISON

VA DRUG CLASSES:

ORIGINATOR: PETERS, JON
SIGN OFF: YES

ORIGINATED: JUL 29, 1991@10:54
OBS/HIST: OBSERVED

ORIGINATOR
COMMENTS:

Date: Jul 29, 1991@10:54

User: PETERS, JON
Title: NURSE

Patient gets drowsy after usage.

ID BAND MARKED: MAR 29, 1993@13:52:11 CHART MARKED: MAR 29,
1993@13:52:09

SIGNS/SYMPTOMS: DROWSINESS

Enter RETURN to continue or '^' to exit:

ALLERGY/ADVERSE REACTION REPORTS

Run Date/Time: 1/19/96 2:04:23 pm
STARK, ANTHONY 123-45-6777 OCT 12, 1969 (26)

.....
STATUS: ACTIVE

TYPE: DRUG, FOOD
=====

AGENT: ASPIRIN
INGREDIENTS: ATROPINE

VA DRUG CLASSES:

ORIGINATOR: PETERS, JON
SIGN OFF: YES

ORIGINATED: AUG 28, 1991@09:57
OBS/HIST: OBSERVED

ORIGINATOR
COMMENTS:

Date: Aug 28, 1991@09:57

User: PETERS, JON
Title: NURSE

THE PATIENT GOT VERY IRRITATED AND CRIED AFTER TAKING

Enter RETURN to continue or '^' to exit:

Adverse Reaction Tracking User Menu

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 1/19/96 2:04:23 pm
STARK, ANTHONY 123-45-6777 OCT 12, 1969 (26)

ASPIRIN.

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: ITCHING, WATERING EYES
ANXIETY

.....
Enter RETURN to continue or '^' to exit: <RET>

Online Reference Card

This option provides the user with an online reference guide to the ART software. Users can browse through the text using the arrow keys on the keyboard. To exit the option, follow the screen text. For example, press the PF1 key and the letter E. The PF1 key is also labeled as "Num Lock" on some keyboards.

VA FileMan Browser DOCUMENT 1

INTRODUCTION

The purpose of the Adverse Reaction Tracking (ART) software, Version 4.0, is to permit clinical users to track and report adverse drug reactions. The Hines IRM Field Office developed this software and reference material to provide a "quick" reference for use with the ART software.

The intended users of this software are physicians, nurses, other clinicians, and clerks. Each VA site will designate persons to serve as verifiers. The primary function of verifiers is to confirm the correctness of the data entered in ART by users. The verifiers may be clinical pharmacists, dietitians, and other clinical personnel.

ORIENTATION AND HELPFUL HINTS

Throughout this manual, the carriage return or return key on the keyboard is represented as <RET>.

At any prompt in Adverse Reaction Tracking (ART), the user can enter ?? to get additional help.

Prompts that have the words "DATE/TIME" in them (e.g., Select DATE/TIME
Col> 1 | <PF1>H=Help <PF1>E=Exit | Line> 22 of 506 Screen> 1 of 23

Adverse Reaction Tracking User Menu

Adverse Reaction Tracking Clinician Menu

This menu is assigned to all clinicians of Adverse Reaction Tracking who are not verifiers or ADP coordinators. The options on this menu will allow the user to enter, edit and display allergy data, enter Food and Drug Administration report data, run various reports of importance to the clinician and edit the patient's chart and identification band.

This menu should only be given to the clinicians of ART. This option looks as follows:

1. Enter/Edit Patient Reaction Data
2. FDA Enter/Edit Menu ...
3. Reports Menu ...
4. Edit Chart and ID Band
5. Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. The user is prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

Selecting a Patient:

The user may select a patient by name (last name, first name), full Social Security Number (SSN), the last four digits of the SSN (e.g., 1234), the first letter of the last name and last four digits of the SSN (e.g., A1234), or ward location (e.g., 1 North).

Does the patient have any known allergies/adverse reactions?

If the selected patient does not have any allergies/adverse reactions stored in the ART database the user is asked the above question. A Yes response will allow the user to make an entry. A No response will take the user back to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient the software will not ask this question, but will instead display information about the existing reactions. The software will display the name of the causative agent, the type of causative agent (e.g., food), any signs/symptoms, its mechanism (e.g., Allergy or Pharmacologic), whether it was an observed reaction or historical, and whether or not it was verified.

Selecting a Causative Agent:

The lookup procedure that is performed when the user enters a causative agent deserves a detailed explanation.

- 1) If the causative agent exists as an entry for the patient, then the user has the opportunity to edit the data concerning that entry.
- 2) If the user's response is not part of that patient's entry or the user does not want to edit an existing choice given in Step 1, then a lookup for the particular agent is done using five files of choices which are searched in the following order:
 - a) GMR Allergies (#120.82) - this file is distributed with the ART software and contains nationally distributed food and other type agents plus any entries added locally by the facility,

- b) Drug Ingredients (#50.416) - this file contains the names of individual generic drugs which are components of various drug products,
 - c) VA Drug Class (#50.605) - this file contains the names of the various drug classes used within the Department,
 - d) National Drug (#50.6) - this file contains the names of available drug products including trade names and manufacturer, and
 - e) Drug (#50) - this file contains the names of drugs that can be used to fill a prescription.
- 3) If the user's response is not found after Steps 1 and 2, then he/she is asked if the response should be added to the patient's record. The response entered by the user will be saved in the patient's database entry and will be displayed on subsequent lookups while the causative agent will be linked to the OTHER ALLERGY/ADVERSE REACTION entry in the GMR Allergies file. When adding a causative agent for a patient's record that is not in any of the five files, the user is asked to identify the type of agent. The choices are Food, Drug or Other. The type is required and its value determines the appropriate logic that is followed by the rest of the data entry for this entry.

NOTE: If a particular causative agent is commonly selected, but it comes from a lookup on one of the later files (i.e., 2b, 2c, 2d or 2e) and the facility wishes to minimize the response lookup time, then that causative agent can be added to the GMR Allergies file as a local entry. Since this is the first file that is looked up in Step 2, the response time will be reduced.

NOTE: When selecting entries from the Drug file (#50) the user may see the various dosages associated with the drugs. The user only needs to pick one of these dose forms. The software will figure out which ingredients from that drug the patient had a reaction to and set that information into the database automatically.

Observed vs. Historical Reaction:

An observed reaction is an event that actually happened to the patient during the patient's stay/visit at the facility. A historical reaction is one that is reported, but not observed by the facility personnel. If the reaction is observed the user will be asked to enter the observation date. The time of day may be entered, but it is optional.

Observed Report:

For an observed reaction, the user is asked for additional information. The user may enter the name of the person who observed the reaction (the default response is the name of the user entering the data), the severity of the reaction (i.e., mild, moderate or severe), and the date a medical doctor was notified. Also, the user may edit the date and time of the observation.

Signs/Symptoms:

A sign/symptom is an effect of the reaction on the patient (e.g., itching). The software comes with a list of nationally recognized signs/symptoms. The site can add additional signs/symptoms to the list. The software displays to the user a list of commonly reported signs/symptoms to choose from. The user may choose from this abbreviated list or from the full list of choices. The user may select as many signs/symptoms as applicable. The site may customize the abbreviated list the user sees to meet its needs. Observed reactions require the user to enter signs/symptoms. A historical reaction allows, but does not require the user to enter signs/symptoms.

Also, the user is asked to enter the date the sign/symptom appeared. The time of day may be entered, but it is optional.

Mechanism:

The mechanism is the type of reaction. The choices are Allergy, Pharmacologic or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions such as exposure to a large amount. Unknown is provided if the user is not sure what mechanism to enter. The clinician will only see this prompt if he/she has the GMRA-ALLERGY VERIFY key.

Note: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

Comments:

The site can determine whether comments from the originator of the entry are required by setting a software parameter. If that site parameter is set to YES the user is required to enter comments concerning the entry. If the entry is being edited and any existing comments exist for this causative agent the software will display those comments and whether they were entered by the originator of the entry, a verifier or a person who marked the entry as entered in error.

FDA Data:

When the type of the causative agent is a drug, the user may enter further information about the reaction which will be used by the software to generate an FDA report. The questions for the FDA report are categorized in four sections. Users are encouraged to provide as much information about the reaction as possible. The site can determine if the user will be required to enter FDA data by setting a software parameter.

Verification of Data:

Entries can be verified by a user or by the software. The latter is known as autoverification. The site can determine how the entries are verified by setting three software parameters. The combination of these three parameters allows the software to automatically verify none, some or all entries. Conversely, sites may wish to have their users verify none, some or all entries.

If the entry must be verified by a user and the user has the verification key, GMRA-ALLERGY VERIFY, the software will allow the verification of the data during the enter/edit option. The user has an opportunity to review and edit the data before verifying the entry.

Generating Progress Notes:

The ART software has an interface to the Progress Notes package. A progress note will be generated when the user verifies, signs off, or marks as entered in error an observed reaction. The progress note is displayed and the user may electronically sign, edit or delete it. Also, the user may print the note.

Mark Patient Chart and ID Band:

The user is asked if the patient chart was marked to show that the patient is allergic to the causative agent.

For an inpatient, the user is asked if the patient identification band was marked to show an allergic reaction to the causative agent. The site can determine with a software parameter whether the user should be asked this question.

There are three other software parameters the site can set concerning the patient chart and ID band. The site can set a software parameter to determine who will be notified that a chart or ID band is not marked. A notification bulletin can be sent to the GMRA MARK CHART mail group, an Order Entry Team or not sent at all.

Adverse Reaction Tracking Clinician Menu

The site can set a software parameter to determine if an alert should be sent to the GMRA MARK CHART mail group or an Order Entry Team when the mark chart or mark ID band questions are not answered.

Also, the site can set a software parameter to determine if users from outside the package can send a bulletin to mark a patient chart for an reaction. Specifically, when a patient is admitted a bulletin may be sent to mark the patient chart for the particular reaction identified in the bulletin.

Signing Off on an Entry:

Signing off (i.e., is the data correct?) on an entry means the user who entered/edited the entry is satisfied with the data entered. It does not mean an electronic signature. Users who have the verification key will not be asked to sign off on an entry if they verify it. Users who have the verification key will be asked to sign off on an entry if they do not verify it. Users who do not have the verification key will be asked to sign off on the entry.

Select Adverse Reaction Tracking Clinical Menu Option: **1** Enter/Edit Patient Reaction Data

Select PATIENT NAME: **DOODY, HOWDY** 02-03-56 333000111 NSC
VETERAN

REACTANT	VER.	MECH.	OBS/ HIST	TYPE
-----	----	-----	----	----
DEMEROL APAP (ACETAMINOPHEN, MEPERIDINE) Reactions: CONFUSION	AUTO	UNKNOWN	HIST	DRUG
DOG HAIR Reactions: LOSS OF APPETITE	YES	UNKNOWN	OBS	DRUG
PHOSPHORIC ACID Reactions: ANXIETY	YES	ALLERGY	HIST	DRUG
TYLENOL WITH CODEINE (ACETAMINOPHEN, CODEINE) Reactions: ITCHING, WATERING EYES	YES	ALLERGY	OBS	DRUG
CAT HAIR OTHER Reactions: ITCHING, WATERING EYES, SNEEZING	YES	ALLERGY	HIST	

Enter Causative Agent: ANTIRABIES SERUM
ANTIRABIES SERUM OK? Yes// **<RET>** (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: **O** OBSERVED
Select date reaction was OBSERVED (Time Optional): **NOW** (FEB 29, 1996@14:18)
FEB 29, 1996@14:18 (FEB 29, 1996@14:18)

Are you adding 'FEB 29, 1996@14:18' as
a new ADVERSE REACTION REPORTING? **Y** (Yes)

Adverse Reaction Tracking Clinician Menu

No signs/symptoms have been specified. Please add some now.

The following are the top ten most common signs/symptoms:

- | | |
|--------------------------|------------------------|
| 1. CONFUSION | 7. HIVES |
| 2. ITCHING,WATERING EYES | 8. DRY MOUTH |
| 3. HYPOTENSION | 9. CHILLS |
| 4. DROWSINESS | 10. RASH |
| 5. CHEST PAIN | 11. OTHER SIGN/SYMPTOM |
| 6. DIARRHEA | |

Enter from the list above : **9**

Date(Time Optional) of appearance of Sign/Symptom(s): Feb 29, 1996@14:18//
(FEB 29, 1996@14:18)

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms	Date Observed
-----	-----
1 CHILLS	Feb 29, 1996@14:18

Select Action (A)DD, (D)ELETE OR <RET>: **<RET>**

COMMENTS:

1>**chills and sweating**

2>

EDIT Option:

Complete the observed reaction report? Yes// **<RET>** (Yes)

DATE/TIME OF EVENT: FEB 29,1996@14:18// **<RET>**

OBSERVER: WIDOW,MARY// **<RET>**

SEVERITY: **moderate** MODERATE

DATE MD NOTIFIED: Feb 29,1996@14:18// **<RET>** (FEB 29, 1996@14:18)

Indicate which FDA Report Sections to be completed:

1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Initial Reporter

Choose number(s) of sections to be edited: (1-4): 1-4// **1**

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

1 CHILLS

Select Action (A)DD, (D)ELETE OR <RET>: **<RET>**

Patient died?: **n** NO

Reaction treated with RX drug?: **n** NO

Life Threatening illness?: **n** NO

Required hospitalization?: **n** NO

Prolonged Hospitalization?: **n** NO

Resulted in permanent disability?: **n** NO

Is this event a Congenital Anomaly?: **n** NO

Did this event require intervention to prevent impairment/damage?: **y** YES

Adverse Reaction Tracking Clinician Menu

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT

Select Action (A/D/E): **<RET>**

Enter another Causative Agent? YES// **n** NO

Causative Agent Data edited this Session:

ADVERSE REACTION

ANTIRABIES SERUM

Reactions: CHILLS

OBSERVED

ORIGINATOR

COMMENTS:

Date: Feb 29, 1996@14:18:49

User: TRAINER,FRANK

Title: NURSE

chills and sweating

Is this correct? NO// **y** YES

Select a Hospital Location for this patient: **PHYSICAL EXAM**

Patient: DOODY,HOWDY 333-00-0111

Written: 02/29/96 14:19

Title: ALLERGY/ADVERSE REACTION

Author: WIDOW,MARY

Pat Loc: PHYSICAL EXAM

This patient has had the following reaction

signed-off on Feb 29, 1996@14:19:43.

ANTIRABIES SERUM

(S)ign, (E)dit, or (D)elete this note? S// **<RET>** IGN

Enter your Current Signature Code: SIGNATURE VERIFIED

Print this note? Yes// **N** (No)

This session you have CHOSEN:

ANTIRABIES SERUM

Have the Chart(s) been marked for this CAUSATIVE AGENT? **Y** (Yes)

Select PATIENT NAME: **<RET>**

FDA Enter/Edit Menu (Clinician)

This menu should be given to users responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu will allow the user to enter and edit the FDA data.

1. Enter/Edit FDA Report Data
2. Enter/Edit P&T Committee Data

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, the user may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), the user may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date and how the drug was given (SIG Code). The user can also enter a word processing type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), the user may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15 day report was completed and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows the user to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option:  1  Enter/Edit FDA Report Data

Select PATIENT NAME:  DALY,RICHARD          10-04-69      123122222      SC
                        VETERAN

Select CAUSATIVE AGENT:  ASPIRIN           10-04-69      123122222      SC
                        VETERAN
                        ASPIRIN

Select date reaction was OBSERVED (Time Optional):  T-10  (JAN 13, 1996)  JAN
13, 1996  (JAN 13, 1996)
Are you adding 'JAN 13, 1996' as
```

Adverse Reaction Tracking Clinician Menu

a new ADVERSE REACTION REPORTING? **Y** (Yes)

Indicate which FDA Report Sections to be completed:

- 1. Reaction Information
- 2. Suspect Drug(s) Information
- 3. Concomitant Drugs and History
- 4. Manufacturer Information
- 5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): **1**

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

-
- 1 ANXIETY

Select Action (A)DD OR (D)ELETE: **A**

The following are the top ten most common signs/symptoms:

- 1. ANXIETY
- 2. ITCHING, WATERING EYES
- 3. HYPOTENSION
- 4. DROWSINESS
- 5. CHEST PAIN
- 6. DIARRHEA
- 7. HIVES
- 8. DRY MOUTH
- 9. CHILLS
- 10. RASH
- 11. OTHER SIGN/SYMP TOM

Enter from the list above : **7**

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

-
- 1 ANXIETY
 - 2 HIVES

Select Action (A)DD OR (D)ELETE: **<RET>**

Patient died?: **N** NO
 Reaction treated with RX drug?: **N** NO
 Life Threatening illness?: **N** NO
 Required hospitalization?: **N** NO
 Prolonged Hospitalization?: **N** NO
 Resulted in permanent disability?: **N** NO
 Is this event a Congenital Anomaly?: **N** NO
 Did this event require intervention to prevent impairment/damage?: **N** NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT

Select Action (A/D/E): **ADD**

View Tx/Test from: JAN 13, 1996// **<RET>** (JAN 13, 1996)

To: JAN 13, 1996// **<RET>** (JAN 13, 1996)

LAB TEST:

Collection DT	Test Name	Specimen	Results	Hi/Low
---------------	-----------	----------	---------	--------

THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.

Select TEST: **??**

Choose from:

Adverse Reaction Tracking Clinician Menu

1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS,TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
2Hr.GTT (URINE)
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
^

Select TEST: **1/2Hr.GTT (URINE)**

Are you adding '1/2Hr.GTT (URINE)' as
a new RELEVANT TEST/LAB DATA (the 1ST for this ADVERSE REACTION
REPORTING)? **Y** (Yes)

RESULTS: ??

This field will contain the results for the particular test.

RESULTS: Enter results here.

COLLECTION D/T: **T-10** (JAN 13, 1996)

Select TEST:

This patient has the following Test selected:

TEST/TX	RESULTS	DRAW DATE/TIME
1) 1/2Hr.GTT (URINE)	Enter results here.	01/13/96

Select Action (A/D/E):

Indicate which FDA Report Sections to be completed: **<RET>**

1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): **<RET>**

Enter/Edit P&T Committee Data

This option will allow the user to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician. The user can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu Option:  2  Enter/Edit P&T Committee Data

Select PATIENT NAME:  DALY,RICHARD          10-04-69      123122222      SC
VETERAN

Select CAUSATIVE AGENT:  PENICILLIN          10-04-69      123122222      SC
VETERAN          PENICILLIN

Select date reaction was OBSERVED (Time Optional):  T  (JAN 24, 1996)  JAN
24, 1996  (JAN 24, 1996)

Are you adding 'JAN 24, 1996' as
a new ADVERSE REACTION REPORTING?  Y  (Yes)
```

P&T Report Completion

Serious ADR?: ??

This field determines if the reaction is considered serious.

Choose from:

```
  y      YES
  n      NO
```

Serious ADR?: y YES

ADR related to new drug?: n NO

Unexpected ADR?: y YES

ADR related to therapeutic failure?: n NO

Dose related?: n NO

P&T ACTION FDA REPORT: ??

This field indicates if the P&T committee determined whether to send the report to FDA.

Choose from:

```
  y      YES
  n      NO
```

P&T ACTION FDA REPORT: n NO

P&T ACTION MFR REPORT: n NO

ADDENDUM:

1>ADD COMMENTS HERE

2>

EDIT Option: <RET>

Select PATIENT NAME: <RET>

Reports Menu (Clinician)

This menu is part of the Adverse Reaction Tracking Clinician Menu. It is the only print option that the clinician needs for ART.

1. Active Listing of Patient Reactions
2. Print Patient Reaction Data
3. Print an FDA report for a Patient
4. List by Location of Unmarked ID Bands/Charts
5. Patient Allergies Not Signed Off
6. List by Location of Undocumented Allergies
7. List by Location Not Verified Reactions
8. List by Location and Date all Sign Reaction
9. List FDA data by Report Date

Active Listing of Patient Reactions

This option will give a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. This report may be sent to a printer for a hard copy printout or displayed to the terminal screen. The user may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select Reports Menu Option: 1 Active Listing of Patient Reactions

Select PATIENT: ALMOND, BILLY 06-15-63 333542222 ACTIVE DUTY

DEVICE: HOME// <RET> HYPER SPACE

ACTIVE ALLERGY/ADVERSE REACTION LISTING

Run Date/Time: 1/16/96 12:12:57 pm

ALMOND, BILLY 333-54-2222 JUN 15, 1963 (32)

ADVERSE REACTION	VERIFIED	OBS/ HIST

TYPE: DRUG =====		
DEMECARIUM Reactions:	NO	OBS
ITCHING, WATERING EYES (Dec 13, 1995), NAUSEA, VOMITING (Dec 13, 1995), ANXIETY (Dec 13, 1995), DROWSINESS (Dec 13, 1995), HYPOTENSION (Dec 13, 1995)		
THE SP Reactions:	YES	OBS
ITCHING, WATERING EYES (Nov 06, 1995@14:01), TINGLING (Dec 01, 1995), NAUSEA, VOMITING (Dec 01, 1995), ANXIETY (Dec 01, 1995), ZINGLING (Dec 01, 1995)		

Enter RETURN to continue or '^' to exit: <RET>

Adverse Reaction Tracking Clinician Menu

ACTIVE ALLERGY/ADVERSE REACTION LISTING

Run Date/Time: 1/16/96 12:12:57 pm

ALMOND, BILLY

333-54-2222

JUN 15, 1963 (32)

ADVERSE REACTION	VERIFIED	OBS/ HIST

TWO-DYNE Reactions:	YES	OBS
ITCHING, WATERING EYES (Oct 18, 1995@13:47), ANXIETY (Oct 18, 1995@13:47), HYPOTENSION (Oct 18, 1995@13:47)		
TYLOXAPOL Reactions:	YES	OBS
HIVES (Oct 26, 1995@13:05), ITCHING, WATERING EYES (Oct 26, 1995@13:05), NAUSEA, VOMITING (Oct 26, 1995@13:05), DIARRHEA (Oct 26, 1995@13:05), ANXIETY (Oct 26, 1995@13:05), DROWSINESS (Oct 26, 1995@13:05), DRY MOUTH (Oct 26, 1995@13:05), DRY NOSE (Oct 26, 1995@13:05), HYPOTENSION (Oct 26, 1995@13:05)		
Enter RETURN to continue or '^' to exit: ^		

Print Patient Reaction Data

This option will allow the user to get a captioned data display of all of the patient's allergy/adverse reaction data. The user can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

The user can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). The user then selects the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run and the patient's name, SSN, date of birth and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

Select Reports Menu Option: 2 Print Patient Reaction Data

Select PATIENT: STARK, ANTHONY 10-12-69 123456777 SC VETERAN
 Select 1:DRUG, 2:FOOD, 3:OTHER
 Type of allergy: (1-3): 1
 Select 1:ACTIVE, 2:ENTERED IN ERROR
 Which would you like to see?: (1-2): 1

DEVICE: HOME// <RET> HYPER SPACE

ALLERGY/ADVERSE REACTION REPORTS
 Run Date/Time: 1/19/96 2:04:23 pm
 STARK, ANTHONY 123-45-6777 OCT 12, 1969 (26)

 STATUS: ACTIVE

TYPE: DRUG
 =====

AGENT: AMIODARONE
 INGREDIENTS: AMIODARONE

VA DRUG CLASSES:

ORIGINATOR: MILFAJT, ROBERT
 SIGN OFF: YES

ORIGINATED: AUG 13, 1993@12:45
 OBS/HIST: OBSERVED

ID BAND MARKED:

CHART MARKED:

Adverse Reaction Tracking Clinician Menu

SIGNS/SYMPTOMS: HYPOTENSION

.....
AGENT: PENICILLIN
Enter RETURN to continue or '^' to exit: <RET>

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 1/19/96 2:04:23 pm
STARK,ANTHONY 123-45-6777 OCT 12,1969 (26)

INGREDIENTS: PENICILLIN VA DRUG CLASSES:
ORIGINATOR: ACKERTON,WIL ORIGINATED: MAR 12, 1993@08:32
SIGN OFF: YES OBS/HIST: HISTORICAL
ORIGINATOR
COMMENTS:
Date: Mar 12, 1993@08:32:55 User: ACKERTON,WILL
Title: NURSE
ASDF ASDF ASDF ASDF ASDF ASDF ASDF AS DFAS DAS FAS DF

ID BAND MARKED: CHART MARKED:

SIGNS/SYMPTOMS: DROWSINESS

.....
Enter RETURN to continue or '^' to exit: <RET>

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 1/19/96 2:04:23 pm
STARK,ANTHONY 123-45-6777 OCT 12,1969 (26)

AGENT: PREDNISON
INGREDIENTS: PREDNISON VA DRUG CLASSES:
ORIGINATOR: PETERS,ERIC ORIGINATED: JUL 29, 1991@10:54
SIGN OFF: YES OBS/HIST: OBSERVED
ORIGINATOR
COMMENTS:
Date: Jul 29, 1991@10:54 User: PETERS,ERIC
Title: NURSE
XX.

ID BAND MARKED: MAR 29, 1993@13:52:11 CHART MARKED: MAR 29,
1993@13:52:09

SIGNS/SYMPTOMS: DROWSINESS

Enter RETURN to continue or '^' to exit: ^

Print an FDA Report for a Patient

This option will allow the user to print an individual FDA report for a patient. This option will also produce a listing of all allergy/adverse reactions that are awaiting sign off by the person entering the data into the system. The report should be queued to run on a printer with a 132 column width.

Select Reports Menu Option: **3** Print an FDA Report for a Patient

Select PATIENT NAME: **JONES,SUE** 12-01-34 111124443 SC VETERAN
 Select CAUSATIVE AGENT: **??**

CHOOSE FROM:
 AMPICILLIN
 CYCLOSPORINE
 GENTAMICIN
 PENICILLIN

Select CAUSATIVE AGENT: **AMPI** 12-01-34 111124443 SC VETERAN
 AMPICILLIN

Select date reaction was OBSERVED (Time Optional): **1/10/96** (JAN 10,
 1996).1249

...OK? Yes// (Yes)

THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.

QUEUE TO PRINT ON
 DEVICE: **PRINTER 132** (132 COLUMN)

Requested Start Time: NOW// **<RET>** (JAN 25, 1996@10:36:17)

Request queued...

Adverse Reaction Tracking Clinician Menu

MEDWatch

Approved by FDA on 10/20/93

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence #

Page 1 of 1

A. Patient Information

1. Patient Identifier | 2. DOB: 12/1/34 | 3. Sex | 4. Weight
 J4443 | AGE: 61 yrs | FEMALE | 0.0

B. Adverse Event or Product Problem

1. Adverse Event | Product problem
 2. Outcomes attributed to adverse event
 death | disability
 life-threatening | congenital anomaly
 Hospitalization | required intervention to
 initial or prolonged | prevent impairment/damage
 other

3. Date of event | 4. Date of this report
 01/10/96 | 01/30/96

5. Describe event or problem
 RASH

6. Relevant test/laboratory data, including dates
 treatment)

7. Other relevant History, including preexisting medical
 conditions

Mail to: MedWatch | or FAX to:
 5600 Fishers Lane | 1-800-FDA-0178
 Rockville, MD 20852-9787

Manufacturer,

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

C. Suspect Medication(s)

1. Name
 #1 : AMPICILLIN

2. Dose, frequency & route used | 3. Therapy dates
 #1: | #1 :

4. Diagnosis for use (indication) | 5. Event abated after use
 #1: | #1: [N/A]
 stopped or dose reduced?

6. Lot # (if known) | 7. Exp. date | 8. Event reappeared after
 #1: | #1: | #1: []
 reintroduction

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates(exclude

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event
 involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #:

2. Health professional? | 3. Occupation | 4. Reported to Mfr.
 | | [NO]

5. If you don't want your identity disclosed to the

place an "X" in the box. []

List by Location of Unmarked ID Bands/Charts

This option will find all patients in the system who have not had their ID bands or charts marked. This option will also produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that the user will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

```
Select Reports Menu Option:  4  List by Location of Unmarked ID Bands/Charts
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):  4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional):  T-90  (OCT 19, 1995)
Enter END Date (time optional):  T//  <RET> (JAN 17, 1996)
```

The location prompt allows the user to select the ward or clinic that he/she wants to print, or select all the wards/clinics by entering the word ALL and the system will select all the appropriate hospital locations.

```
Select Location:  ?
```

```
You may deselect from the list by typing the - followed by location name.
E.g.  -3E would delete 3E from the list of locations already selected.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
    1N
    1S
    GMC DR. PETIT
    PHYSICAL EXAM
```

```
Select Location:  1N
Another Location:  <RET>
```

```
QUEUE TO PRINT ON
DEVICE:  SELECT APPROPRIATE PRINTER
```

```
Requested Start Time: NOW//  <RET> (JAN 17, 1996@13:42:26)
```

```
Request queued...
```

Adverse Reaction Tracking Clinician Menu

Jan 17,1996

PATIENTS WITH UNMARKED ID BAND/CHART
 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
 FROM Oct 19,1995 TO Jan 17,1996

PAGE 1

PATIENT	SSN	ALLERGY	UNMARKED

	WARD: 1N		
JONES,SUE	111-12-4443	PENICILLIN	ID BAND/CHART
		CYCLOSPORINE	ID BAND/CHART
		AMPICILLIN	ID BAND/CHART
		GENTAMICIN	ID BAND/CHART
MILLS,BOBBY	111-00-0001	MILK	ID BAND/CHART
		SMOKE	ID BAND/CHART
		DUST	ID BAND/CHART
		SALT SUBSTITUTE	ID BAND/CHART

Jan 17,1996

PATIENTS WITH UNMARKED ID BAND/CHART
 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
 FROM Oct 19,1995 TO Jan 17,1996

PAGE 2

PATIENT	SSN	ALLERGY	UNMARKED

CLINIC: GMC DR. PETERS			
No Patients for this Clinic			

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. The user may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

Select Reports Menu Option: 5 Patient Allergies Not Signed Off

DEVICE: HOME// <RET> HYPER SPACE

ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF

Run Date/Time: 1/18/96 1:23:52 pm

ORIGINATOR	PATIENT	ALLERGY	ORIGINATION DATE/TIME
ACKERTON, WILLIA	LARD, BILL(9012)	PENICILLIN	FEB 18, 1993@10:59
ACKERTON, WILLIA	LARD, BILL(9012)	FROG	FEB 18, 1993@15:14
ACKERTON, WILLIA	LARD, BILL(9012)	THORAZINE 10MG	FEB 22, 1993@13:20
ACKERTON, WILLIA	DALY, RICHARD (2222)	PENICILLIN	JUN 22, 1993@11:44
ACKERTON, WILLIA	DALY, RICHARD (2222)	PHENYTOIN	JUN 22, 1993@11:48
ACKERTON, WILLIA	DALY, RICHARD (2222)	DEMECARIUM	JUN 22, 1993@12:00
ACKERTON, WILLIA	DALY, RICHARD (2222)	ASPIRIN	JUN 22, 1993@12:08
ACKERTON, WILLIA	DUCK, DONALD(6789)	PHENOBARBITAL	JUN 25, 1993@10:33
ACKERTON, WILLIA	DALY, RICHARD (2222)	PHENOBARBITAL	JUN 25, 1993@10:39
ACKERTON, WILLIA	LARD, BILL(9012)	CODEINE	JUN 30, 1993@08:55
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	THOR - PROM	AUG 11, 1993@10:35
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	IMMUNE GLOBULIN	AUG 18, 1993@10:02
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	CYCLOBENZAPRINE	JUL 11, 1994@14:11
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	SULFABENZAMIDE/S	JUL 11, 1994@14:14
ACKERTON, WILLIA	DUCK, DONALD(6789)	DUCK	JAN 06, 1995@11:13

Enter RETURN to continue or '^' to exit: ^

List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that the user will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered by the user. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN and provider. The room-bed will appear for current inpatients.

Select Adverse Reaction Tracking User Menu Option: **6** List by Location of Undocumented Allergies

- 1 Current Inpatients
- 2 Outpatients over Date/Time range
- 3 New Admissions over Date/Time range
- 4 All of the above

Enter the number(s) for those groups to be used in this report: (1-4): **4**

Enter date/time range in which patients were admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): **T-180** (JUL 23, 1995)

Enter END Date (time optional): T// **<RET>** (JAN 19, 1996)

The location prompt allows the user to select the ward or clinic that he/ she wants to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

Select Location: **??**

You may deselect from the list by typing a '-' followed by location name.

E.g. -3E would delete 3E from the list of locations already selected.

You may enter the word ALL to select all appropriate locations.

Answer with HOSPITAL LOCATION NAME, or ABBREVIATION

Choose from:

- 1N
- 1S
- GMC DR. PETIT
- PHYSICAL EXAM

Select Location: **1N**

Another Location: **PHYSICAL EXAM <RET>**

Another Location: **<RET>**

QUEUE TO PRINT ON

DEVICE: **SELECT APPROPRIATE PRINTER**

Requested Start Time: NOW// **<RET>** (JAN 19, 1996@10:29:44)

Request queued...

Jan 19,1996

PATIENTS NOT ASKED ABOUT ALLERGIES
CURRENT INPATIENTS

PAGE 1

PATIENT

SSN

PROVIDER

WARD: 1N

* No Patients for this Ward *

Jan 19,1996

PATIENTS NOT ASKED ABOUT ALLERGIES
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jul 23,1995 TO Jan 19,1996

PAGE 2

PATIENT

SSN

PROVIDER

CLINIC: PHYSICAL EXAM

* No Patients for this Clinic *

If the user selected a ward/clinic location where no patients met the report's criteria (i.e., all patients were asked about allergies), then an appropriate message as such will appear (No Patients for this Ward).

List by Location Not Verified Reactions

This is a new option. It prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient and reaction. The user can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV.

The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

Select Reports Menu Option: 7 List by Location Not Verified Reactions

DEVICE: HOME// <RET> HOME

Report Date: Jan 25, 1996 Page: 1

List of Unverified Reactions by Ward Location

Ward Location: 1N

Origination Date/Time	Originator	Reaction
200-1 JONES,SUE (111-12-4443)		
Jul 29, 1993@10:05	PETRI,DON	CYCLOSPORINE

Enter RETURN to continue or '^' to exit:

Report Date: Jan 25, 1996 Page: 2

List of Unverified Reaction by Ward Location

Ward Location: 1S

Origination Date/Time	Originator	Reaction
100-1 GORBACHEV,MIKAEL (411-41-1411)		
Aug 11, 1993@08:57	ACKERTON,WILLIAM	THEODUR (KEY PHARM)
Aug 13, 1993@12:44	MILLER,ROBERT	WARFARIN
Aug 09, 1994@14:06	ACKERTON,WILLIAM	CHEESE
Aug 09, 1994@14:31	ACKERTON,WILLIAM	SPAM
100-2 NUDD,RAY (432-45-7677)		
Aug 03, 1994@10:50	ACKERTON,WILLIAM	IODINE CONTRAST DYE

Enter RETURN to continue or '^' to exit: ^

List by Location and Date all Signed Reactions

This is a new option. It prints a list of all patient reactions that have been signed off (completed) for a user supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on the user's terminal screen.

The header of the report contains the title, the date range selected by the user, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option:  8  List by Location and Date All Signed Reactions
Enter Start Date:  T-120  (NOV 21, 1995)
Enter Ending Date:  T  (MAR 20, 1996)
```

```
DEVICE: HOME//  <RET>  HOME
```

One moment please...

```
Mar 20, 1996Page: 1
```

```
List all Signed Patient Reactions for Ward Location 1N
From Nov 21, 1995 to Mar 20, 1996
```

```
Date                Originator                Type Causative Agent
```

```
-----
Patient: JONES,SUE (111-12-4443)
Jan 10, 1996@12:49  ASHTON,WILLIAM            D  AMPICILLIN
Jan 10, 1996@12:50  ASHTON,WILLIAM            D  GENTAMICIN
Feb 29, 1996@13:15  TRIMBLE,FRANK             D  TETRACYCLINE
Feb 29, 1996@13:13  TRIMBLE,FRANK             DF ANTIRABIES SERUM
```

```
Patient: MILLER,BOBBY (111-00-0001)
Dec 15, 1995@16:02  BETFORD,TINA              D  SALT SUBSTITUTE
Feb 29, 1996@13:52  TRIMBLE,FRANK             DF ANTIRABIES SERUM
```

```
Patient: TAYLOR,BOB (124-56-2345)
Feb 09, 1996@08:54  TRIMBLE,FRANK            D  FROG
Feb 09, 1996@12:57  ASHTON,WILLIAM            D  PATCHES
Feb 09, 1996@13:08  ASHTON,WILLIAM            D  HEARTBURN TABS
Mar 14, 1996@08:12  TRIMBLE,FRANK            D  PREDNISONE
Mar 14, 1996@09:10  TRIMBLE,FRANK            D  RELA
Mar 14, 1996@09:12  TRIMBLE,FRANK            D  MONOBENZONE
```

```
Enter RETURN to continue or '^' to exit:  ^
```

List FDA Data by Report Date

This is a new option. It displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. The user must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that the user selected and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option:  9  List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date:  T-30  (DEC 26, 1995)
Enter Ending Date:  T   (JAN 25, 1996)
```

```
DEVICE: HOME//  <RET> HOME
```

```
Report Date: Jan 25, 1996
```

```
Page: 1
```

```
Adverse Reaction Tracking Report
From: 12/26/95 To: 1/25/96
```

Patient	Dates	Related Reaction
ACKERTON, BILL (333-54-2345) Loc: OUT PATIENT Obs:	Obs DT: 1/8/96 Trk DT: 1/8/96 ----- 0 Days Difference	SPAM
ACKERTON, BILL (333-54-2345) Loc: OUT PATIENT Obs:	Obs DT: 1/8/96 Trk DT: 1/8/96 ----- 0 Days Difference	FUZZEL
MILLER, BOB (111-00-0001) Loc: 1N Obs:	Obs DT: 1/8/96 Trk DT: 1/8/96 ----- 0 Days Difference	SALT SUBSTITUTE
TREVOR, BOB (124-56-2345) Loc: 1N Obs:	Obs DT: 1/9/96 Trk DT: 1/9/96 ----- 0 Days Difference	POLLEN

```
Enter RETURN to continue or '^' to exit:  ^
```

Edit Chart and ID Band

This option allows the user to enter if the patient ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. The user selects a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected by the user to indicate whether the patient chart has been marked.

Select Adverse Reaction Tracking Clinician Menu Option: **4** Edit Chart and ID Band

Select Patient: **DALY,RICHARD** 10-04-69 123122222 SC VETERAN

CHOOSE FROM:

ASPIRIN
 COD LIVER OIL
 DEMECARIUM
 FROGS
 PENBUTOLOL
 PENICILLIN
 PHENOBARBITAL
 PHENYTOIN
 PREDNISONE
 THOR - PROM
 TIMOLOL
 TYLOXAPOL

Select CAUSATIVE AGENT: **ASPIRIN** 10-04-69 123122222 SC VETERAN
 ASPIRIN

Select another CAUSATIVE AGENT: **PENICILLIN** 10-04-69 123122222
 SC VETERAN PENICILLIN

Select another CAUSATIVE AGENT: **<RET>**

This session you have CHOSEN:

PENICILLIN
 ASPIRIN

Have the Chart(s) been marked for these CAUSATIVE AGENTS? **??**

ANSWER YES IF THE Chart(s) HAS BEEN MARKED, ELSE ANSWER NO.

Have the Chart(s) been marked for these CAUSATIVE AGENTS? **Y** (Yes)

Online Reference Card

This option provides the user with an online reference guide to the ART software. Users can browse through the text using the arrow keys on the keyboard. To exit the option, follow the screen text. For example, press the PF1 key and the letter E. The PF1 key is also labeled as "Num Lock" on some keyboards.

VA FileMan Browser DOCUMENT 1

INTRODUCTION

The purpose of the Adverse Reaction Tracking (ART) software, Version 4.0, is to permit clinical users to track and report adverse drug reactions. The Hines IRM Field Office developed this software and reference material to provide a "quick" reference for use with the ART software.

The intended users of this software are physicians, nurses, other clinicians, and clerks. Each VA site will designate persons to serve as verifiers. The primary function of verifiers is to confirm the correctness of the data entered in ART by users. The verifiers may be clinical pharmacists, dietitians, and other clinical personnel.

ORIENTATION AND HELPFUL HINTS

Throughout this manual, the carriage return or return key on the keyboard is represented as <RET>.

At any prompt in Adverse Reaction Tracking (ART), the user can enter ?? to get additional help.

Prompts that have the words "DATE/TIME" in them (e.g., Select DATE/TIME
Col> 1 | <PF1>H=Help <PF1>E=Exit | Line> 22 of 506 Screen> 1 of 23

Adverse Reaction Tracking Verifier Menu

This menu should be given to the verifiers of the Adverse Reaction Tracking data. The options on this menu will allow the user to edit/verify/print the data.

This menu should only be given to the verifiers of ART.

1. Enter/Edit Patient Reaction Data
2. Verify Patient Reaction Data
3. Reports Menu ...
4. Edit Chart and ID Band
5. FDA Enter/Edit Menu ...
6. Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. The user is prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs or symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

Selecting a Patient:

The user may select a patient by name (last name, first name), full Social Security Number (SSN), the last four digits of the SSN (e.g., 1234), the first letter of the last name and last four digits of the SSN (e.g., A1234), or ward location (e.g., 1 North).

Does the patient have any known allergies/adverse reactions?

If the selected patient does not have any allergies/adverse reactions stored in the ART database the user is asked the above question. A Yes response will allow the user to make an entry. A No response will take the user back to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient the software will not ask this question, but will instead display information about the existing reactions. The software will display the name of the causative agent, the type of causative agent (e.g., food), any signs/symptoms, its mechanism (e.g., Allergy or Pharmacologic), whether it was an observed reaction or historical, and whether or not it was verified.

Selecting a Causative Agent:

The lookup procedure that is performed when the user enters a causative agent deserves a detailed explanation.

- 1) If the causative agent exists as an entry for the patient, then the user has the opportunity to edit the data concerning that entry.
- 2) If the user's response is not part of that patient's entry or the user does not want to edit an existing choice given in Step 1, then a lookup for the particular agent is done using five files of choices which are searched in the following order:
 - a) GMR Allergies (#120.82) - this file is distributed with the ART software and contains nationally distributed food and other type agents plus any entries added locally by the facility,

- b) Drug Ingredients (#50.416) - this file contains the names of individual generic drugs which are components of various drug products,
 - c) VA Drug Class (#50.605) - this file contains the names of the various drug classes used within the Department,
 - d) National Drug (#50.6) - this file contains the names of available drug products including trade names and manufacturer, and
 - e) Drug (#50) - this file contains the names of drugs that can be used to fill a prescription.
- 3) If the user's response is not found after Steps 1 and 2, then he/she is asked if the response should be added to the patient's record. The response entered by the user will be saved in the patient's database entry and will be displayed on subsequent lookups while the causative agent will be linked to the OTHER ALLERGY/ADVERSE REACTION entry in the GMR Allergies file. When adding a causative agent for a patient's record that is not in any of the five files, the user is asked to identify the type of agent. The choices are Food, Drug or Other. The type is required and its value determines the appropriate logic that is followed by the rest of the data entry for this entry.

NOTE: If a particular causative agent is commonly selected, but it comes from a lookup on one of the later files (i.e., 2b, 2c, 2d or 2e) and the facility wishes to minimize the response lookup time, then that causative agent can be added to the GMR Allergies file as a local entry. Since this is the first file that is looked up in Step 2, the response time will be reduced.

NOTE: When selecting entries from the Drug file (#50) the user may see the various dosages associated with the drugs. The user only needs to pick one of these dose forms. The software will figure out which ingredients from that drug the patient had a reaction to and set that information into the database automatically.

Observed vs. Historical Reaction:

An observed reaction is an event that actually happened to the patient during the patient's stay/visit at the facility. A historical reaction is one that is reported, but not observed by the facility personnel. If the reaction is observed the user will be asked to enter the observation date. The time of day may be entered, but it is optional.

Observed Report:

For an observed reaction, the user is asked for additional information. The user may enter the name of the person who observed the reaction (the default response is the name of the user entering the data), the severity of the reaction (i.e., mild, moderate or severe), and the date a medical doctor was notified. Also, the user may edit the date and time of the observation.

Signs/Symptoms:

A sign/symptom is an effect of the reaction on the patient (e.g., itching). The software comes with a list of nationally recognized signs/symptoms. The site can add additional signs/symptoms to the list. The software displays to the user a list of commonly reported signs/symptoms to choose from. The user may choose from this abbreviated list or from the full list of choices. The user may select as many signs/symptoms as applicable. The site may customize the abbreviated list the user sees to meet its needs. Observed reactions require the user to enter signs/symptoms. A historical reaction allows, but does not require the user to enter signs/symptoms.

Also, the user is asked to enter the date the sign/symptom appeared. The time of day may be entered, but it is optional.

Mechanism:

The mechanism is the type of reaction. The choices are Allergy, Pharmacologic or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions such as exposure to a large amount. Unknown is provided if the user is not sure what mechanism to enter.

Note: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

Comments:

The site can determine whether comments from the originator of the entry are required by setting a software parameter. If that site parameter is set to YES the user is required to enter comments concerning the entry. If the entry is being edited and any existing comments exist for this causative agent the software will display those comments and whether they were entered by the originator of the entry, a verifier or a person who marked the entry as entered in error.

FDA Data:

When the type of the causative agent is a drug, the user may enter further information about the reaction which will be used by the software to generate an FDA report. The questions for the FDA report are categorized in four sections. Users are encouraged to provide as much information about the reaction as possible. The site can determine if the user will be required to enter FDA data by setting a software parameter.

Verification of Data:

Entries can be verified by a user or by the software. The latter is known as autoverification. The site can determine how the entries are verified by setting three software parameters. The combination of these three parameters allows the software to automatically verify none, some or all entries. Conversely, sites may wish to have their users verify none, some or all entries.

If the entry must be verified by a user and the user has the verification key, GMRA-ALLERGY VERIFY, the software will allow the verification of the data during the enter/edit option. The user has an opportunity to review and edit the data before verifying the entry.

Generating Progress Notes:

The ART software has an interface to the Progress Notes package. A progress note will be generated when the user verifies, signs off, or marks as entered in error an observed reaction. The progress note is displayed and the user may electronically sign, edit or delete it. Also, the user may print the note.

Mark Patient Chart and ID Band:

The user is asked if the patient chart was marked to show that the patient is allergic to the causative agent.

For an inpatient, the user is asked if the patient identification band was marked to show an allergic reaction to the causative agent. The site can determine with a software parameter whether the user should be asked this question.

There are three other software parameters the site can set concerning the patient chart and ID band. The site can set a software parameter to determine who will be notified that a chart or ID band is not marked. A notification bulletin can be sent to the GMRA MARK CHART mail group, an Order Entry Team or not sent at all.

Adverse Reaction Tracking Verifier Menu

The site can set a software parameter to determine if an alert should be sent to the GMRA MARK CHART mail group or an Order Entry Team when the mark chart or mark ID band questions are not answered.

Also, the site can set a software parameter to determine if users from outside the package can send a bulletin to mark a patient's chart for an reaction. Specifically, when a patient is admitted a bulletin may be sent to mark the patient's chart for the particular reaction identified in the bulletin.

Signing Off on an Entry:

Signing off (i.e., is the data correct?) on an entry means the user who entered/edited the entry is satisfied with the data entered. It does not mean an electronic signature. Users who have the verification key will not be asked to sign off on an entry if they verify it. Users who have the verification key will be asked to sign off on an entry if they do not verify it. Users who do not have the verification key will be asked to sign off on the entry.

Select Adverse Reaction Tracking Verifier Menu Option: **1** Enter/Edit Patient Reaction Data

Select PATIENT NAME: **VASQUEZ,BOB** 04-01-23 30000000 SC VETERAN

REACTANT	VER.	MECH.	OBS/ HIST	TYPE
-----	----	-----	----	----
ASPIRIN Reactions: CHILLS, DRY MOUTH, CHEST PAIN	AUTO	ALLERGY	HIST	DRUG
DILANTIN (PHENYTOIN) Reactions: DROWSINESS	YES	ALLERGY	OBS	DRUG
IBUPROFEN	NO	UNKNOWN	OBS	DRUG
PENICILLIN Reactions: HIVES, DROWSINESS	YES	UNKNOWN	OBS	DRUG
PHENOBARBITAL Reactions: DEPRESSION	YES	ALLERGY	OBS	DRUG

Enter Causative Agent: **TETRACY** CLINE
TETRACYCLINE OK? Yes// **<RET>** (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: **O** OBSERVED
Select date reaction was OBSERVED (Time Optional): **T** (FEB 20, 1996) FEB
20, 1996 (FEB 20, 1996)

Are you adding 'FEB 20, 1996' as
a new ADVERSE REACTION REPORTING? **Y** (Yes)

No signs/symptoms have been specified. Please add some now.

The following are the top ten most common signs/symptoms:
1. CONFUSION 7. HIVES

Adverse Reaction Tracking Verifier Menu

- 2. ITCHING,WATERING EYES
- 3. HYPOTENSION
- 4. DROWSINESS
- 5. CHEST PAIN
- 6. DIARRHEA
- 8. DRY MOUTH
- 9. CHILLS
- 10. RASH
- 11. OTHER SIGN/SYMPTOM

Enter from the list above : 4

Date(Time Optional) of appearance of Sign/Symptom(s): Feb 20, 1996// <RET>
(FEB 20, 1996)

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms	Date Observed
1 DROWSINESS	Feb 20, 1996

Select Action (A)DD, (D)ELETE OR <RET>: <RET>

Choose one of the following:

- A - ALLERGY
- P - PHARMACOLOGICAL
- U - UNKNOWN

MECHANISM: UNKNOWN// P PHARMACOLOGIC

COMMENTS:

- 1>Enter any comments you feel are necessary to explain the reaction.
- 2>

EDIT Option: <RET>

Complete the observed reaction report? Yes// <RET> (Yes)

DATE/TIME OF EVENT: FEB 20,1996// <RET>

OBSERVER: TAYLOR,FRANK// <RET>

SEVERITY: mild MILD

DATE MD NOTIFIED: Feb 20,1996// <RET> (FEB 20, 1996)

Indicate which FDA Report Sections to be completed:

- 1. Reaction Information
- 2. Suspect Drug(s) Information
- 3. Concomitant Drugs and History
- 4. Initial Reporter

Choose number(s) of sections to be edited: (1-4): 1-4// 1

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms
1 DROWSINESS

Select Action (A)DD, (D)ELETE OR <RET>: <RET>

Patient died?: n NO

Reaction treated with RX drug?: n NO

Life Threatening illness?: n NO

Required hospitalization?: y YES

Prolonged Hospitalization?: n NO

Adverse Reaction Tracking Verifier Menu

Resulted in permanent disability?: **n** NO
Is this event a Congenital Anomaly?: **n** NO
Did this event require intervention to prevent impairment/damage?: **y** YES

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT
Select Action (A/D/E): **<RET>**

Currently you have verifier access.
Would you like to verify this Causative Agent now? Yes// **<RET>** (Yes)

CAUSATIVE AGENT: TETRACYCLINE
TYPE: DRUG
INGREDIENTS: TETRACYCLINE
VA DRUG CLASSES:
OBS/HIST: OBSERVED

SIGNS/SYMPTOMS: DROWSINESS (Feb 20, 1996)

MECHANISM: PHARMACOLOGIC

Would you like to edit any of this data? **n** (No)
PATIENT: VASQUEZ,BOB CAUSATIVE AGENT: TETRACYCLINE
INGREDIENTS: TETRACYCLINE VA DRUG CLASSES:
ORIGINATOR: TRAINER,FRANK ORIGINATED: FEB 20, 1996@10:22
SIGN OFF: NO OBS/HIST: OBSERVED

ORIGINATOR
COMMENTS:
Date: Feb 20, 1996@10:22:41 User: TRAINER,FRANK
Title: NURSE

Enter any comments you feel are necessary to explain the
reaction.

ID BAND MARKED: CHART MARKED:

SIGNS/SYMPTOMS: DROWSINESS (Feb 20, 1996)

Change status of this allergy/adverse reaction to verified? **y** (Yes)
Select a Hospital Location for this patient: **physical** EXAM

NOTE: In this example a Progress Note is created because the reaction was verified.

Patient: VASQUEZ,BOB 300-00-0000 Written: 02/20/96 10:25
Title: ALLERGY/ADVERSE REACTION Author: TRAINER,FRANK
Pat Loc: PHYSICAL EXAM

This patient has had an adverse reaction reported for TETRACYCLINE
verified on Feb 20, 1996@10:25:05.

(S)ign, (E)dit, or (D)elete this note? S// **<RET>** IGN

Adverse Reaction Tracking Verifier Menu

Enter your Current Signature Code: SIGNATURE VERIFIED

Print this note? Yes// **n** (No)

Enter another Causative Agent? YES// **n** NO

This session you have CHOSEN:

TETRACYCLINE

Have the Chart(s) been marked for this CAUSATIVE AGENT? **y** (Yes)

Select PATIENT NAME: **<RET>**

Verify Patient Reaction Data

This option allows designated verifiers to verify the correctness of data entered by the clinical users. The verifier may select a single patient's data to verify or a list or range (e.g., 1,3,7 or 1-10) of patients to verify. The verifier may select to view/verify drug reactions only, non-drug reactions only, or drug and non-drug reactions. The reaction data is displayed and the verifier may edit the causative agent, type, ingredients, drug class, observed/historical response, signs/symptoms and mechanism. The verifier may enter any appropriate comments.

If the verifier answers YES to the "change status of this allergy/adverse reaction to verified" prompt, the reaction will be marked as verified. If the verifier answers NO to that prompt, the reaction is marked as entered in error.

If no hospital location is associated with the patient, the verifier will be prompted to enter a location.

A progress note is created. The verifier may electronically sign, edit or delete the progress note. The verifier may print the progress note, too.

```
Select Adverse Reaction Tracking Verifier Menu Option:      2 Verify Patient
Reaction Data
Would you like to verify a single patient's data? NO//      YES
Select PATIENT NAME:   JONES ,SUE                12-01-34      111124443      YES      SC
VETERAN
```

```
      D Drug
      N Non-drug
      B Both
```

Select type of AGENT to verify:(D/N/B): DRUG

```
      PATIENT                ALLERGY                OBS/
      -----                -----                HIST ADR TYPE
1. JONES,SUE (4443) 1N      CYCLOSPORINE                OBS  UNK  DRUG
Select a number between 1-1:  1
```

Adverse Reaction Tracking Verifier Menu

PATIENT: JONES,SUE
INGREDIENTS: CYCLOSPORINE

CAUSATIVE AGENT: CYCLOSPORINE
VA DRUG CLASSES:

ORIGINATOR: PETIT,YVENS
SIGN OFF: YES

ORIGINATED: JUL 29, 1993@10:05
OBS/HIST: OBSERVED

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: RENAL FAILURE

MECHANISM: UNKNOWN

Is the reaction information correct? Yes// **<RET>** (Yes)

CAUSATIVE AGENT: CYCLOSPORINE
TYPE: DRUG
INGREDIENTS: CYCLOSPORINE
VA DRUG CLASSES:
OBS/HIST: OBSERVED

SIGNS/SYMPTOMS: RENAL FAILURE
MECHANISM: UNKNOWN

Would you like to edit any of this data? **N** (No)

COMMENTS:

1>**Add any necessary comments here.**

2>

EDIT Option:

PATIENT: JONES,SUE
INGREDIENTS: CYCLOSPORINE

CAUSATIVE AGENT: CYCLOSPORINE
VA DRUG CLASSES:

ORIGINATOR: PETRI,BOB
SIGN OFF: YES

ORIGINATED: JUL 29, 1993@10:05
OBS/HIST: OBSERVED

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: RENAL FAILURE

MECHANISM: UNKNOWN

Change status of this allergy/adverse reaction to verified? **y** (Yes)

Adverse Reaction Tracking Verifier Menu

Patient: JONES,SUE 111-12-4443
Title: ALLERGY/ADVERSE REACTION
Pat Loc: 1N

Written: 02/29/96 10:02
Author: TRAINER,JIM

This patient has had an allergy to CYCLOSPORINE
verified on Feb 29, 1996@10:02:09.

(S)ign, (E)dit, or (D)elete this note? S// <RET> IGN

Enter your Current Signature Code: SIGNATURE VERIFIED
Print this note? Yes// n (No)

Users can enter/edit their own electronic signature code. Use the Online Reference Card option to view an example of how to create or edit your electronic signature code.

Reports Menu (Verifier)

This menu is part of the Adverse Reaction Tracking Verifier Menu. It is the only print menu that the verifier will need for ART.

1. Active Listing of Patient Reactions
2. Print Patient Reaction Data
3. Print an FDA report for a Patient
4. Print all FDA events within D/T range
5. Print Patient FDA Exception Data
6. Print all FDA Exceptions within a D/T range
7. List by Location of Unmarked ID Bands/Charts
8. Patient Allergies Not Signed Off
9. List by Location of Undocumented Allergies
10. List Autoverified Reaction Data
11. List by Location Not Verified Reactions
12. List by Location and Date all Sign Reactions
13. List FDA Data by Report Date

Active Listing of Patient Reactions

This option will give a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. The user may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select Reports Menu Option: 1 Active Listing of Patient Reactions

Select PATIENT: ALMOND, BILLY 06-15-63 333542222 ACTIVE DUTY

DEVICE: HOME// <RET> HYPER SPACE

```

                ACTIVE ALLERGY/ADVERSE REACTION LISTING
                Run Date/Time: 1/16/96 12:12:57 pm
ALMOND, BILLY      333-54-2222          JUN 15, 1963 (32)

-----
ADVERSE REACTION                                VERIFIED      OBS/
-----
TYPE: DRUG
=====
DEMECARIUM                                NO            OBS
  Reactions:
    ITCHING, WATERING EYES (Dec 13, 1995),
    NAUSEA, VOMITING (Dec 13, 1995),
    ANXIETY (Dec 13, 1995),
    DROWSINESS (Dec 13, 1995),
    HYPOTENSION (Dec 13, 1995)
THE SP                                       YES           OBS
  Reactions:
    ITCHING, WATERING EYES (Nov 06, 1995@14:01),
    TINGLING (Dec 01, 1995),
    NAUSEA, VOMITING (Dec 01, 1995),
    ANXIETY (Dec 01, 1995),
    ZINGLING (Dec 01, 1995)
Enter RETURN to continue or '^' to exit:
    
```

Adverse Reaction Tracking Verifier Menu

ACTIVE ALLERGY/ADVERSE REACTION LISTING

Run Date/Time: 1/16/96 12:12:57 pm

ALMOND,BILLY

333-54-2222

JUN 15,1963 (32)

ADVERSE REACTION	VERIFIED	OBS/ HIST

TWO-DYNE Reactions:	YES	OBS
ITCHING,WATERING EYES (Oct 18, 1995@13:47), ANXIETY (Oct 18, 1995@13:47), HYPOTENSION (Oct 18, 1995@13:47)		
TYLOXAPOL Reactions:	YES	OBS
HIVES (Oct 26, 1995@13:05), ITCHING,WATERING EYES (Oct 26, 1995@13:05), NAUSEA,VOMITING (Oct 26, 1995@13:05), DIARRHEA (Oct 26, 1995@13:05), ANXIETY (Oct 26, 1995@13:05), DROWSINESS (Oct 26, 1995@13:05), DRY MOUTH (Oct 26, 1995@13:05), DRY NOSE (Oct 26, 1995@13:05), HYPOTENSION (Oct 26, 1995@13:05)		
Enter RETURN to continue or '^' to exit: ^		

Print Patient Reaction Data

This option will allow the user to get a captioned data display of all of the patient's allergy/adverse reaction data. The user can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

The user can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). The user then selects the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run and the patient's name, SSN, date of birth and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Reports Menu Option:  2  Print Patient Reaction Data

Select PATIENT:  STARK,ANTHONY           10-12-69       123456777       SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy:  (1-3):  1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?:  (1-2):  1

DEVICE: HOME//  <RET>  HYPER SPACE
```

Adverse Reaction Tracking Verifier Menu

ALLERGY/ADVERSE REACTION REPORTS

Run Date/Time: 1/19/96 2:04:23 pm

STARK, ANTHONY

123-45-6777

OCT 12, 1969 (26)

STATUS: ACTIVE

TYPE: DRUG
=====

AGENT: AMIODARONE
INGREDIENTS: AMIODARONE

VA DRUG CLASSES:

ORIGINATOR: MILLER, ROBERT
SIGN OFF: YES

ORIGINATED: AUG 13, 1993@12:45
OBS/HIST: OBSERVED

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: HYPOTENSION

AGENT: PENICILLIN

Enter RETURN to continue or '^' to exit: <RET>

ALLERGY/ADVERSE REACTION REPORTS

Run Date/Time: 1/19/96 2:04:23 pm

STARK, ANTHONY

123-45-6777

OCT 12, 1969 (26)

INGREDIENTS: PENICILLIN

VA DRUG CLASSES:

ORIGINATOR: ALBERT, BILL
SIGN OFF: YES

ORIGINATED: MAR 12, 1993@08:32
OBS/HIST: HISTORICAL

ORIGINATOR
COMMENTS:

Date: Mar 12, 1993@08:32:55

User: ACKERTON, WILL

Title: NURSE

XX.

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: DROWSINESS

Enter RETURN to continue or '^' to exit: <RET>

Adverse Reaction Tracking Verifier Menu

```
ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 1/19/96 2:04:23 pm
STARK,ANTHONY      123-45-6777      OCT 12,1969 (26)
-----

AGENT: PREDNISON
INGREDIENTS: PREDNISON      VA DRUG CLASSES:

ORIGINATOR: PETERS,JON      ORIGINATED: JUL 29, 1991@10:54
SIGN OFF: YES      OBS/HIST: OBSERVED

ORIGINATOR
COMMENTS:
    Date: Jul 29, 1991@10:54      User: PETERS,JON
                                Title: NURSE
    Patient gets drowsy after usage.

ID BAND MARKED: MAR 29, 1993@13:52:11      CHART MARKED: MAR 29,
1993@13:52:09

SIGNS/SYMPTOMS: DROWSINESS

Enter RETURN to continue or '^' to exit:
```

```
ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 1/19/96 2:04:23 pm
STARK,ANTHONY      123-45-6777      OCT 12,1969 (26)
-----

.....
STATUS: ACTIVE
-----
TYPE: DRUG, FOOD
=====

AGENT: ASPIRIN
INGREDIENTS: ATROPINE      VA DRUG CLASSES:

ORIGINATOR: PETERS,JON      ORIGINATED: AUG 28, 1991@09:57
SIGN OFF: YES      OBS/HIST: OBSERVED

ORIGINATOR
COMMENTS:
    Date: Aug 28, 1991@09:57      User: PETERS,JON
                                Title: NURSE
    THE PATIENT GOT VERY IRRITATED AND CRIED AFTER TAKING
Enter RETURN to continue or '^' to exit:
```

Adverse Reaction Tracking Verifier Menu

ALLERGY/ADVERSE REACTION REPORTS

Run Date/Time: 1/19/96 2:04:23 pm
STARK, ANTHONY 123-45-6777 OCT 12, 1969 (26)

ASPIRIN.

ID BAND MARKED:

CHART MARKED:

SIGNS/SYMPTOMS: ITCHING, WATERING EYES
ANXIETY

.....
Enter RETURN to continue or '^' to exit: <RET>

Print an FDA Report for a Patient

This option will allow the user to print an individual FDA report for a patient. This option will produce a listing of all allergy/adverse reactions that are awaiting sign off by the person entering the data into the system. The report should be queued to run on a printer with a 132 column width.

Select Reports Menu Option: 3 Print an FDA Report for a Patient

Select PATIENT NAME: JONES ,SUE 12-01-34 111124443 SC VETERAN
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
AMPICILLIN
CYCLOSPORINE
GENTAMICIN
PENICILLIN

Select CAUSATIVE AGENT: AMPI 12-01-34 111124443 SC VETERAN
AMPICILLIN

Select date reaction was OBSERVED (Time Optional): 1/10/96 (JAN 10,
1996).1249

...OK? Yes// (Yes)
THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER (132 COLUMN)

Requested Start Time: NOW// <RET> (JAN 25, 1996@10:36:17)

Request queued...

Print all FDA Events Within D/T Range

This report prints all the FDA reports over a given date range, entered by the user. The user may choose to print Complete FDA Adverse Event Reports or an abbreviated listing of reports. Complete reports should be queued to a printer that has 132 column width. An abbreviated listing may be sent to a printer or CRT. If an abbreviated listing is chosen and if the report has been sent to the FDA, the listing will display the date that the report was sent.

Select Reports Menu Option: **4** Print All FDA Events within D/T Range
 Select Start Date/Time: **T-30** (DEC 27, 1995)
 Select End Date/Time: (12/27/95 - 1/26/96): T// **<RET>** (JAN 26, 1996)
 Do you want an Abbreviated report? Yes// **<RET>** (Yes)

DEVICE: HOME// **<RET>** HOME

Jan 26, 1996@12:36:40

Page: 1

PATIENT	FDA ABBREVIATED REPORT SUSPECTED AGENT	D/T OF EVENT
ACKERTON, BILLY (333-54-2345)	PSUEDOEPHEDRINE	Jan 1, 1996
MILLERS, BOBBY (111-00-0001)	SALT SUBSTITUTE	Jan 8, 1996
ACKERTON, BILLY (333-54-2345)	DUST	Jan 8, 1996@09:29
ACKERTON, BILLY (333-54-2345)	FUZZEL	Jan 8, 1996@09:39
TRAINER, BOB (124-56-2345)	POLLEN	Jan 9, 1996@08:35
UNGER, JIM (799-99-9999)	MILK	Jan 10, 1996
TRAINER, BOB (124-56-2345)	ASPIRIN	Jan 10, 1996
UNGER, JIM (799-99-9999)	ASPIRIN	Jan 10, 1996
ACKERTON, BILLY (333-54-2345)	ASPIRIN	Jan 10, 1996
UNGER, JIM (799-99-9999)	PENICILLIN	Jan 10, 1996
ACKERTON, BILLY (333-54-2345)	TYLENOL	Jan 10, 1996
TRAINER, BOB (124-56-2345)	MILK	Jan 10, 1996
JONES, SUE (111-12-4443)	AMPICILLIN	Jan 10, 1996@12:49
JONES, SUE (111-12-4443)	GENTAMICIN	Jan 10, 1996@12:51
UNGER, JIM (799-99-9999)	LACTOSE	Jan 11, 1996
ACKERTON, BILLY (333-54-2345)	PSUEDOEPHEDRINE	Jan 11, 1996
UNGER, JIM (799-99-9999)	AMPICILLIN	Jan 11, 1996
UNGER, JIM (799-99-9999)	PHENOBARBITAL	Jan 12, 1996

Enter RETURN to continue or '^' to exit: ^

Print Patient FDA Exception Data

This option allows the user to print a list of all observed or drug allergies from a given date to the present for a patient that has been signed off (completed), but is missing sign/symptom data. The user selects a patient and the date from which to start the search.

The header of the report contains the name of the report and the date/time that it was run. The body contains the patient's name, SSN, the causative agent, the origination date/time of the entry and name of the originator.

Select Reports Menu Option: 5 Print Patient FDA Exception Data

Select PATIENT NAME: ERICSON,DONALD 10-04-39 123456789 SC VETERAN
 Enter the Date to start search (Time optional): T-30// T-365 (JAN 31, 1995)

Select Print DEVICE: HOME// <RET>

JAN 31, 1996 11:33:43

Page: 1

FDA EXCEPTION REPORT

ORIGINATION D/T	CAUSA TIVE AGENT	ORIGINATOR
-----------------	------------------	------------

Patient: ERICSON,DONALD (123-45-6789)		
JUL 26,199 5@15:41	OIL RETENTION ENEMA	MIL LER,ROBERT
JUL 31,199 51@12:39	DIMETHYL SULFOXIDE	NAMON,BOB
NOV 6,199 5@17:45	ACETAMINOPHEN/CODEINE	PETERS,JON
DEC 7,199 5@16:16	PENICILLIN	DILG,LEON
JAN 7,199 6@14:36	MVI PEDIATRIC INJECTION	LIGHTFOOT ,WILLIAM

Select PATIENT NAME: <RET>

Print all FDA Exceptions within a D/T Range

This option allows the user to select a date range from which to print a list of all patients who had an Observed Drug Reaction that has not been reported to the FDA. The report can be sent to a printer or to the user's terminal screen.

The header of the report contains the name of the report, the date range selected by the user and the date/time that the report was run. The body of the report contains the patient's name and SSN, the causative agent, the name of the person who originated the data entry, and the origination date/time of the data.

```
Select Reports Menu Option:  6  Print All FDA Exceptions within a D/T Range
Select Start Date:  1/1/93  (JAN 01, 1993)
Select End Date:  (1/1/93 - 1/26/96): T//  <RET> (JAN 26, 1996)
```

```
DEVICE: HOME//  <RET>  HOME
```

```
Jan 26,1996 14:34:57
```

```
Page: 1
```

```
FDA EXCEPTION REPORT (1/1/93 to 1/26/96)
ORIGINATION D/T      CAUSATIVE AGENT      ORIGINATOR
```

```
-----
      Patient: GORBACHEV,MIKAEL (411-41-1411)
Aug 9,1994@14:06      ASPIRIN              ACKERTON,WILL
      Patient: DALY,RICHARD J (123-12-2222)
Aug 9,1994@14:08      TIMOLOL              ACKERTON,WILL
Aug 9,1994@14:21      PENBUTOLOL          ACKERTON,WILL
Enter RETURN to continue or '^' to exit:
```

List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that the user will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by the user. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent and whether the patient ID band, patient chart, or both were unmarked.

```
Select Reports Menu Option:  7 List by Location of Unmarked ID Bands/Charts
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):    4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional):  T-90 (OCT 19, 1995)
Enter END Date (time optional):  T// <RET> (JAN 17, 1996)
```

The location prompt allows the user to select the ward or clinic that he/she wants to print, or select all the wards/clinics by entering the word ALL and the system will select all the appropriate hospital locations.

```
Select Location:  ?
```

You may deselect from the list by typing a '-' followed by location name.

E.g. -3E would delete 3E from the list of locations already selected.

You may enter the word ALL to select all appropriate locations.

Answer with HOSPITAL LOCATION NAME, or ABBREVIATION

```
Choose from:
```

```
  1N
```

```
  1S
```

```
  GMC DR. PETIT
```

```
  PHYSICAL EXAM
```

```
Select Location:  1N
```

```
Another Location:  <RET>
```

```
QUEUE TO PRINT ON
```

```
DEVICE:  SELECT APPROPRIATE PRINTER
```

Adverse Reaction Tracking Verifier Menu

Requested Start Time: NOW// <RET> (JAN 17, 1996@13:42:26)

Request queued...

Jan 17,1996 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Oct 19,1995 TO Jan 17,1996

PATIENT	SSN	ALLERGY	UNMARKED

WARD: 1N			
JONES,SUE	111-12-4443	PENICILLIN	ID BAND/CHART
		CYCLOSPORINE	ID BAND/CHART
		AMPICILLIN	ID BAND/CHART
MILLS,BOBBY	111-00-0001	GENTAMICIN	ID BAND/CHART
		MILK	ID BAND/CHART
		SMOKE	ID BAND/CHART
		DUST	ID BAND/CHART
		SALT SUBSTITUTE	ID BAND/CHART

Jan 17,1996 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 2
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Oct 19,1995 TO Jan 17,1996

PATIENT	SSN	ALLERGY	UNMARKED

CLINIC: GMC DR. PETERS			
No Patients for this Clinic			

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. The user may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

Select Reports Menu Option: 8 Patient Allergies Not Signed Off

DEVICE: HOME// <RET> HYPER SPACE

ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 1/18/96 1:23:52 pm

ORIGINATOR	PATIENT	ALLERGY	ORIGINATION DATE/TIME
ACKERTON, WILLIA	LARD, BILL(9012)	PENICILLIN	FEB 18, 1993@10:59
ACKERTON, WILLIA	LARD, BILL(9012)	FROG	FEB 18, 1993@15:14
ACKERTON, WILLIA	LARD, BILL(9012)	THORAZINE 10MG	FEB 22, 1993@13:20
ACKERTON, WILLIA	DALY, RICHARD (2222)	PENICILLIN	JUN 22, 1993@11:44
ACKERTON, WILLIA	DALY, RICHARD (2222)	PHENYTOIN	JUN 22, 1993@11:48
ACKERTON, WILLIA	DALY, RICHARD (2222)	DEMECARIUM	JUN 22, 1993@12:00
ACKERTON, WILLIA	DALY, RICHARD (2222)	ASPIRIN	JUN 22, 1993@12:08
ACKERTON, WILLIA	DUCK, DONALD(6789)	PHENOBARBITAL	JUN 25, 1993@10:33
ACKERTON, WILLIA	DALY, RICHARD (2222)	PHENOBARBITAL	JUN 25, 1993@10:39
ACKERTON, WILLIA	LARD, BILL(9012)	CODEINE	JUN 30, 1993@08:55
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	THOR - PROM	AUG 11, 1993@10:35
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	IMMUNE GLOBULIN	AUG 18, 1993@10:02
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	CYCLOBENZAPRINE	JUL 11, 1994@14:11
ACKERTON, WILLIA	GORBACHEV, MIKE(1411)	SULFABENZAMIDE/S	JUL 11, 1994@14:14
ACKERTON, WILLIA	DUCK, DONALD(6789)	DUCK	JAN 06, 1995@11:13

Enter RETURN to continue or '^' to exit: ^

List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that the user will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered by the user. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN and provider. The room-bed will appear for current inpatients.

```
Select Reports Menu Option:  9  List by Location of Undocumented Allergies
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):  4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional):  T-180  (JUL 23, 1995)
Enter END Date (time optional):  T//  <RET>  (JAN 19, 1996)
```

The location prompt allows the user to select the ward or clinic that he/ she wants to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location:  ??
```

You may deselect from the list by typing a '-' followed by location name.
E.g. -3E would delete 3E from the list of locations already selected.
You may enter the word ALL to select all appropriate locations.

```
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
    1N
    1S
    GMC DR. PETIT
    PHYSICAL EXAM
```

```
Select Location:  1N
Another Location:  PHYSICAL EXAM <RET>
Another Location:  <RET>
```

```
QUEUE TO PRINT ON
DEVICE:  SELECT APPROPRIATE PRINTER
```

```
Requested Start Time: NOW//  <RET> (JAN 19, 1996@10:29:44)
```

```
Request queued...
```


List Autoverified Reaction Data

This option lists autoverified reaction data by date/time range, location and mechanism. It also displays previous sorting values that were used during this session. The first time that the user runs the report during this session, those previous values will be "not null." If the user runs the option again, the previous sorting values will display (e.g., *Previous Selection: Verification Date/Time from 1/1/96 to 1/31/96@24:00).

The header of this report contains the name of the report, the date it was run and the date range entered by the user. The body of the report contains the data sorted, first by ward location, then by mechanism, and finally by verification date. The report contains the patient's name, the last digits in the SSN, room-bed, the causative agent, the signs/symptoms, the name of the person who originated the entry and any comments entered by the originator.

Select Reports Menu Option: 10 List Autoverified Reaction Data

* Previous selection: VERIFICATION DATE/TIME not null

START WITH VERIFICATION DATE/TIME: FIRST// <RET>

* Previous selection: PATIENT:WARD LOCATION not null

START WITH WARD LOCATION: FIRST// <RET>

* Previous selection: MECHANISM not null

START WITH MECHANISM: FIRST// <RET>

DEVICE: HOME <RET> RIGHT MARGIN: 80// <RET>

01/29/96 LIST OF AUTOVERIFIED ALLERGIES FROM FIRST TO LAST Page: 1

PATIENT	ROOM-BED	REACTANT	VER. DATE
---------	----------	----------	-----------

WARD LOCATION: 1N

MECHANISM: UNKNOWN

TRAMLER, JOE (2345)	200-2	SIGN-OFF PROBLEM	JAN 11, 1996
---------------------	-------	------------------	--------------

ORIGIN.: TRAINER, FRANK

SIGNS: ITCHING, WATERING EYES

RASH

COMMENTS:

TRAMLER, JOE (2345)	200-2	ANIMAL HAIR	JAN 11, 1996
---------------------	-------	-------------	--------------

ORIGIN.: ACKERTAN, WILLIAM

SIGNS: ITCHING, WATERING EYES

RASH

COMMENTS:

Adverse Reaction Tracking Verifier Menu

01/29/96 LIST OF AUTOVERIFIED ALLERGIES FROM FIRST TO LAST Page: 2

PATIENT ROOM-BED REACTANT VER. DATE

WARD LOCATION: 1S

MECHANISM: UNKNOWN

LARD,BILL (9012) SIGN-OFF PROBLEM JAN 11,1996
ORIGIN.: TRAINER,FRANK
SIGNS: ITCHING,WATERING EYES
RASH
COMMENTS:

LARD,BILL (9012) POLLEN JAN 25,1996
ORIGIN.: TRAINER,FRANK
SIGNS: ITCHING,WATERING EYES
DRY MOUTH
RASH
COMMENTS: HAY FEVER SUFFERER

List by Location Not Verified Reactions

This is a new option. It prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient and reaction. The user can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV.

The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

Select Reports Menu Option: 11 List by Location Not Verified Reactions

DEVICE: HOME// <RET> HOME

Report Date: Jan 25, 1996 Page: 1

List of Unverified Reactions by Ward Location

Ward Location: 1N

Origination Date/Time	Originator	Reaction
200-1 JONES,SUE (111-12-4443)		
Jul 29, 1993@10:05	PETRI,DON	CYCLOSPORINE

Enter RETURN to continue or '^' to exit:

Report Date: Jan 25, 1996 Page: 2

List of Unverified Reactions by Ward Location

Ward Location: 1S

Origination Date/Time	Originator	Reaction
100-1 GORBACHEV,MIKAEL (411-41-1411)		
Aug 11, 1993@08:57	ACKERTON,WILLIAM	THEODUR (KEY PHARM)
Aug 13, 1993@12:44	MILLER,ROBERT	WARFARIN
Aug 09, 1994@14:06	ACKERTON,WILLIAM	DIAPERS
Aug 09, 1994@14:31	ACKERTON,WILLIAM	SPAM
100-2 NUDY,BAR (432-45-7677)		
Aug 03, 1994@10:50	ACKERTON,WILLIAM	IODINE CONTRAST DYE

Enter RETURN to continue or '^' to exit: ^

List by Location and Date all Signed Reactions

This is a new option. It prints a list of all patient reactions that have been signed off (completed) for a user supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on the user's terminal screen.

The header of the report contains the title, the date range selected by the user, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option: 12 List by Location and Date All Signed Reactions
Enter Start Date: T-120 (NOV 21, 1995)
Enter Ending Date: T (MAR 20, 1996)
```

```
DEVICE: HOME// <RET> HOME
```

One moment please...

```
Mar 20, 1996 Page: 1
```

```
List all Signed Patient Reactions for Ward Location 1N
From Nov 21, 1995 to Mar 20, 1996
```

```
Date Originator Type Causative Agent
```

```
-----
Patient: JONES,SUE (111-12-4443)
Jan 10, 1996@12:49 ASHTON,WILLIAM D AMPICILLIN
Jan 10, 1996@12:50 ASHTON,WILLIAM D GENTAMICIN
Feb 29, 1996@13:15 TRIMBLE,FRANK D TETRACYCLINE
Feb 29, 1996@13:13 TRIMBLE,FRANK DF ANTIRABIES SERUM
```

```
Patient: MILLER,BOBBY (111-00-0001)
Dec 15, 1995@16:02 BETFORD,TINA D SALT SUBSTITUTE
Feb 29, 1996@13:52 TRIMBLE,FRANK DF ANTIRABIES SERUM
```

```
Patient: TAYLOR,BOB (124-56-2345)
Feb 09, 1996@08:54 TRIMBLE,FRANK D FROG
Feb 09, 1996@12:57 ASHTON,WILLIAM D PATCHES
Feb 09, 1996@13:08 ASHTON,WILLIAM D HEARTBURN TABS
Mar 14, 1996@08:12 TRIMBLE,FRANK D PREDNISONE
Mar 14, 1996@09:10 TRIMBLE,FRANK D RELA
Mar 14, 1996@09:12 TRIMBLE,FRANK D MONOBENZONE
```

```
Enter RETURN to continue or '^' to exit: ^
```

List FDA Data by Report Date

This is a new option. It displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. The user must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that the user selected and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option:  13 List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date:  T-30  (DEC 26, 1995)
Enter Ending Date:  T   (JAN 25, 1996)
```

```
DEVICE: HOME//  <RET> HOME
```

```
Report Date: Jan 25, 1996
```

```
Page: 1
```

```
Adverse Reaction Tracking Report
From: 12/26/95 To: 1/25/96
```

Patient	Dates	Related Reaction
ACKERTON, BILL (333-54-2345) Loc: OUT PATIENT Obs:	Obs DT: 1/8/96 Trk DT: 1/8/96 ----- 0 Days Difference	SPAM
ACKERTON, BILL (333-54-2345) Loc: OUT PATIENT Obs:	Obs DT: 1/8/96 Trk DT: 1/8/96 ----- 0 Days Difference	FUZZEL
MILLER, BOB (111-00-0001) Loc: 1N Obs:	Obs DT: 1/8/96 Trk DT: 1/8/96 ----- 0 Days Difference	SALT SUBSTITUTE
TREVOR, BOB (124-56-2345) Loc: 1N Obs:	Obs DT: 1/9/96 Trk DT: 1/9/96 ----- 0 Days Difference	POLLEN

```
Enter RETURN to continue or '^' to exit:  ^
```


FDA Enter/Edit Menu (Verifier)

This menu should be given to people responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu will allow the user to edit the FDA data.

1. Enter/Edit FDA Report Data
2. Enter/Edit P&T Committee Data

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, the user may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), the user may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date and how the drug was given (SIG Code). The user can also enter a word processing type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), the user may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15 day report was completed and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows the user to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option:  1  Enter/Edit FDA Report Data

Select PATIENT NAME:  DALY,RICHARD          10-04-69      123122222      SC
                        VETERAN

Select CAUSATIVE AGENT:  ASPIRIN           10-04-69      123122222      SC
                        VETERAN
                        ASPIRIN

Select date reaction was OBSERVED (Time Optional):  T-10  (JAN 13, 1996)  JAN
13, 1996  (JAN 13, 1996)
Are you adding 'JAN 13, 1996' as
```

Adverse Reaction Tracking Verifier Menu

a new ADVERSE REACTION REPORTING? **Y** (Yes)

Indicate which FDA Report Sections to be completed:

1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): **1**

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

- 1 ANXIETY

Select Action (A)DD OR (D)ELETE: **A**

The following are the top ten most common signs/symptoms:

- | | |
|---------------------------|-------------------------|
| 1. ANXIETY | 7. HIVES |
| 2. ITCHING, WATERING EYES | 8. DRY MOUTH |
| 3. HYPOTENSION | 9. CHILLS |
| 4. DROWSINESS | 10. RASH |
| 5. CHEST PAIN | 11. OTHER SIGN/SYMP TOM |
| 6. DIARRHEA | |

Enter from the list above : **7**

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

- 1 ANXIETY
- 2 HIVES

Select Action (A)DD OR (D)ELETE: **<RET>**

Patient died?: **N** NO

Reaction treated with RX drug?: **N** NO

Life Threatening illness?: **N** NO

Required hospitalization?: **N** NO

Prolonged Hospitalization?: **N** NO

Resulted in permanent disability?: **N** NO

Is this event a Congenital Anomaly?: **N** NO

Did this event require intervention to prevent impairment/damage?: **N** NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT

Select Action (A/D/E): **ADD**

View Tx/Test from: JAN 13, 1996// **<RET>** (JAN 13, 1996)

To: JAN 13, 1996// **<RET>** (JAN 13, 1996)

LAB TEST:

Collection DT	Test Name	Specimen	Results	Hi/Low
---------------	-----------	----------	---------	--------

THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.

Select TEST: **??**

Choose from:

- 1,25-DIHYDROXYVIT D3
- 1/2HR LTT
- 1/2Hr.GTT
- 1/2Hr.GTT (URINE)
- 11-DEOXYCORTISOL
- 17-HYDROXYCORTICOSTEROIDS
- 17-HYDROXYPROGESTERONE
- 17-KETOGENIC STEROIDS
- 17-KETOSTEROIDS,TOTAL
- 1HR LTT
- 1Hr.GTT
- 1Hr.GTT (URINE)
- 25 OH VITAMIN D
- 2HR LTT
- 2Hr.GTT
- 2Hr.GTT (URINE)
- 3HR LTT
- 3Hr.GTT
- 3Hr.GTT (URINE)
- 4Hr.GTT
- 4Hr.GTT (URINE)

^

Select TEST: **1/2Hr.GTT (URINE)**

Are you adding '1/2Hr.GTT (URINE)' as
 a new RELEVANT TEST/LAB DATA (the 1ST for this ADVERSE REACTION
 REPORTING)? **Y** (Yes)

RESULTS: ??

This field will contain the results for the particular test.

RESULTS: Enter results here.

COLLECTION D/T: **T-10** (JAN 13, 1996)

Select TEST:

This patient has the following Test selected:

TEST/TX	RESULTS	DRAW DATE/TIME
1) 1/2Hr.GTT (URINE)	Enter results here.	01/13/96

Select Action (A/D/E):

Indicate which FDA Report Sections to be completed: **<RET>**

- 1. Reaction Information
- 2. Suspect Drug(s) Information
- 3. Concomitant Drugs and History
- 4. Manufacturer Information
- 5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): **<RET>**

Enter/Edit P&T Committee Data

This option will allow the user to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician. The user can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu:  2  Enter/Edit P&T Committee Data
Select PATIENT NAME:  DALY,RICHARD      10-04-69      123122222      SC
VETERAN

Select CAUSATIVE AGENT:  PENICILLIN      10-04-69      123122222      SC
VETERAN      PENICILLIN
Select date reaction was OBSERVED (Time Optional):  T  (JAN 24, 1996)  JAN
24, 1996  (JAN 24, 1996)
Are you adding 'JAN 24, 1996' as
a new ADVERSE REACTION REPORTING?  Y  (Yes)
```

P&T Report Completion

Serious ADR?: ??

This field determines if the reaction is considered serious.

Choose from:

y YES

n NO

Serious ADR?: y YES

ADR related to new drug? (Marketed within the last 2 yrs.): n NO

Unexpected ADR?: y YES

ADR related to therapeutic failure?: n NO

Dose related?: n NO

P&T ACTION FDA REPORT: ??

This field indicates if the P&T committee determined whether to send the report to FDA.

Choose from:

y YES

n NO

P&T ACTION FDA REPORT: n NO

P&T ACTION MFR REPORT: n NO

ADDENDUM:

1>ADD COMMENTS HERE

2>

EDIT Option: <RET>

Select PATIENT NAME: <RET>

Online Reference Card

This option provides the user with an online reference guide to the ART software. Users can browse through the text using the arrow keys on the keyboard. To exit the option, follow the screen text. For example, press the PF1 key and the letter E. The PF1 key is also labeled as "Num Lock" on some keyboards.

VA FileMan Browser DOCUMENT 1

INTRODUCTION

The purpose of the Adverse Reaction Tracking (ART) software, Version 4.0, is to permit clinical users to track and report adverse drug reactions. The Hines IRM Field Office developed this software and reference material to provide a "quick" reference for use with the ART software.

The intended users of this software are physicians, nurses, other clinicians, and clerks. Each VA site will designate persons to serve as verifiers. The primary function of verifiers is to confirm the correctness of the data entered in ART by users. The verifiers may be clinical pharmacists, dietitians, and other clinical personnel.

ORIENTATION AND HELPFUL HINTS

Throughout this manual, the carriage return or return key on the keyboard is represented as <RET>.

At any prompt in Adverse Reaction Tracking (ART), the user can enter ?? to get additional help.

Prompts that have the words "DATE/TIME" in them (e.g., Select DATE/TIME
Col> 1 | <PF1>H=Help <PF1>E=Exit | Line> 22 of 506 Screen> 1 of 23

Adverse Reaction Tracking Verifier Menu

P&T Committee Menu

The Patient & Therapeutic (P&T) Committee menu should be given to the P&T Committee members of Adverse Reaction Tracking as designated by the site. The options on this menu will allow the user to edit P&T data and print FDA data. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070.

1. Enter/Edit P&T Committee Data
2. Enter/Edit FDA Report Data
3. Reports Menu ...

Enter/Edit P&T Committee Data

This option will allow the user to edit P&T data. It allows for the evaluation of a suspected Advanced Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician.

```
Select P&T Committee Menu Option:  1  Enter/Edit P&T Committee Data

Select PATIENT NAME:  DALY,RICHARD          10-04-69      123122222      SC
VETERAN

Select CAUSATIVE AGENT:  PENICILLIN          10-04-69      123122222      SC
VETERAN          PENICILLIN

Select date reaction was OBSERVED (Time Optional):  T  (JAN 24, 1996)  JAN
24, 1996  (JAN 24, 1996)
Are you adding 'JAN 24, 1996' as
a new ADVERSE REACTION REPORTING?  Y  (Yes)
```

P&T Report Completion

Serious ADR?: ??

This field determines if the reaction is considered serious.

Choose from:

y YES

n NO

Serious ADR?: y YES

ADR related to new drug? (Marketed within the last 2 yrs.): n NO

Unexpected ADR?: y YES

ADR related to therapeutic failure?: n NO

Dose related?: n NO

P&T ACTION FDA REPORT: ??

This field indicates if the P&T committee determined whether to send the report to FDA.

Choose from:

y YES

n NO

P&T ACTION FDA REPORT: n NO

P&T ACTION MFR REPORT: n NO

ADDENDUM:

1>ADD COMMENTS HERE

2>

EDIT Option: <RET>

Select PATIENT NAME: <RET>

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, the user may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), the user may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date and how the drug was given (SIG Code). The user can also enter a word processing type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), the user may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15 day report was completed and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows the user to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select P&T Committee Menu Option:  2  Enter/Edit FDA Report Data

Select PATIENT NAME:  DALY,RICHARD          10-04-69      123122222      SC
                        VETERAN

Select CAUSATIVE AGENT:  ASPIRIN           10-04-69      123122222      SC
                        VETERAN
                        ASPIRIN

Select date reaction was OBSERVED (Time Optional):  T-10  (JAN 13, 1996)  JAN
13, 1996  (JAN 13, 1996)
Are you adding 'JAN 13, 1996' as
a new ADVERSE REACTION REPORTING?  Y  (Yes)
```

P&T Committee Menu

Indicate which FDA Report Sections to be completed:

1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): **1**

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

- 1 ANXIETY

Select Action (A)DD OR (D)ELETE: **A**

The following are the top ten most common signs/symptoms:

- | | |
|---------------------------|-----------------------|
| 1. ANXIETY | 7. HIVES |
| 2. ITCHING, WATERING EYES | 8. DRY MOUTH |
| 3. HYPOTENSION | 9. CHILLS |
| 4. DROWSINESS | 10. RASH |
| 5. CHEST PAIN | 11. OTHER SIGN/SYPTOM |
| 6. DIARRHEA | |

Enter from the list above : **7**

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

- 1 ANXIETY
- 2 HIVES

Select Action (A)DD OR (D)ELETE: **<RET>**

Patient died?: **N** NO

Reaction treated with RX drug?: **N** NO

Life Threatening illness?: **N** NO

Required hospitalization?: **N** NO

Prolonged Hospitalization?: **N** NO

Resulted in permanent disability?: **N** NO

Is this event a Congenital Anomaly?: **N** NO

Did this event require intervention to prevent impairment/damage?: **N** NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT

Select Action (A/D/E): **ADD**

View Tx/Test from: JAN 13, 1996// **<RET>** (JAN 13, 1996)

To: JAN 13, 1996// **<RET>** (JAN 13, 1996)

LAB TEST:

Collection DT	Test Name	Specimen	Results	Hi/Low
---------------	-----------	----------	---------	--------

THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.

Select TEST: **??**

Choose from:

1,25-DIHYDROXYVIT D3

- 1/2HR LTT
- 1/2Hr.GTT
- 1/2Hr.GTT (URINE)
- 11-DEOXYCORTISOL
- 17-HYDROXYCORTICOSTEROIDS
- 17-HYDROXYPROGESTERONE
- 17-KETOGENIC STEROIDS
- 17-KETOSTEROIDS, TOTAL
- 1HR LTT
- 1Hr.GTT
- 1Hr.GTT (URINE)
- 25 OH VITAMIN D
- 2HR LTT
- 2Hr.GTT
- 2Hr.GTT (URINE)
- 3HR LTT
- 3Hr.GTT
- 3Hr.GTT (URINE)
- 4Hr.GTT
- 4Hr.GTT (URINE)

^

Select TEST: **1/2Hr.GTT (URINE)**

Are you adding '1/2Hr.GTT (URINE)' as
a new RELEVANT TEST/LAB DATA (the 1ST for this ADVERSE REACTION
REPORTING)? **Y** (Yes)

RESULTS: ??

This field will contain the results for the particular test.

RESULTS: Enter results here.

COLLECTION D/T: **T-10** (JAN 13, 1996)

Select TEST:

This patient has the following Test selected:

TEST/TX	RESULTS	DRAW DATE/TIME
1) 1/2Hr.GTT (URINE)	Enter results here.	01/13/96

Select Action (A/D/E):

Indicate which FDA Report Sections to be completed: **<RET>**

1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): **<RET>**

Reports Menu (P&T)

This option is the menu of all reports that the Pharmacy and Therapeutics Committee can print. To view data for options 1 thru 12 below, please see the Reports Menu under the Verifier Menu (see Table of Contents for correct page numbers.) For options 13 thru 19, please continue on the following pages.

1. Print an FDA Report for a Patient
2. Print all FDA Events within D/T range
3. Print Patient FDA Exception Data
4. Print all FDA Exceptions within a D/T range
5. Patient Allergies Not Signed Off
6. Print Patient Reaction Data
7. Active Listing of Patient Reactions
8. List by Location of Undocumented Allergies
9. List Autoverified Reaction Data
10. List by Location Not Verified Reactions
11. List by Location and Date all Sign Reactions
12. List FDA Data by Report Date
13. List of Fatal Reaction Over a Date Range
14. Print Summary of Outcomes
15. Frequency Distribution of Causative Agents
16. Frequency Distribution of Drug Classes
17. Total Reported Reactions Over a Date Range
18. P&T Committee ADR Outcome Report
19. P&T Committee ADR Report

List of Fatal Reaction Over a Date Range

This option lists all fatal adverse drug reactions over a date range selected by the user.

The header of the report contains the name of the report, the date range selected by the user and the date that the report was printed. The body of the report contains the name of the patient, the last four digits of the patient's SSN, the date of the reaction, the name of the related reaction, and the date the patient died.

```
Select Reports Menu Option:  13  List of Fatal Reaction over a Date Range
Select an Observed date range for this report.
Enter Start Date:  T-365  (JAN 30, 1995)
Enter Ending Date:  T  (JAN 30, 1996)
```

```
DEVICE: HOME//  <RET>  HOME
```

```
Report Date: Jan 30, 1996                                     Page: 1
```

```
                List of Fatal Reaction over a date range
                From: 1/30/95 To: 1/30/96
```

Patient	Dates	Related Reaction	Date Died
DALY,RICHARD (D2222)	2/8/95	TYLOXAPOL	2/9/95

```
Enter RETURN to continue or '^' to exit:  <RET>
```

Print Summary of Outcomes

This option prints a summary report of patient outcomes for a date range selected by the user.

The header of the report contains the name of the report, the date range selected by the user and the date the report was run. The body of the report contains the outcome and number of times a user answered with a "Yes, No or No Response" to the outcome question. A total is printed for each column of responses. The number of records processed is printed, also. The sum of each Yes, No, and No Response column equals the number of records processed (e.g., 3+38+249=290).

Select Reports Menu Option: **14** Print Summary of Outcomes
 Select an Observed date range for this report.
 Enter Start Date: **T-365** (JAN 30, 1995)
 Enter Ending Date: **T** (JAN 30, 1996)

DEVICE: HOME// **<RET>** HOME

Report Date: Jan 30, 1996

Page: 1

Summary of Outcomes			
From: 1/30/95 To: 1/30/96			
	Yes	No	No Response

Patients that Died:	3	38	249
Reactions treated with RX drugs:	20	19	251
Life Threatening illness:	3	18	269
Required ER/MD visit:			290
Required hospitalization:	5	16	269
Prolonged Hospitalization:	7	32	251
Resulted in permanent disability:	1	37	252
Patient recovered:			290
Congenital Anomaly:		23	267
Required intervention:	5	18	267

Totals:	44	201	2655

Total number of records processed 290

Enter RETURN to continue or '^' to exit: **<RET>**

Frequency Distribution of Causative Agents

This options prints a report of the frequency distribution of causative agents for a date range selected by the user.

The header of the report contains the name of the report, the date range selected by the user and the date that the report was run. The body of the report contains the name of the causative agent and the number of times it was reported within the date range.

```
Select Reports Menu Option: 15 Frequency Distribution of Causative Agents
Select an Observed date range for this report.
Enter Start Date: T-365 (JAN 30, 1995)
Enter Ending Date: T (JAN 30, 1996)
```

```
DEVICE: HOME// <RET> HOME
```

```
Report Date: Jan 30, 1996 Page: 1
```

```
Frequency Distribution of Causative Agents
```

```
From: 1/30/95 To: 1/30/96
```

Causative Agents	Number
PENICILLIN	14
ASPIRIN	10
WATER	8
THOR - PROM	6
CODEINE	5
CYCLOSPORINE	5
HARBENTYL	5
PHENOBARBITAL	5
SALT SUBSTITUTE	5
TALC	5
DUST	4
TOMATO	4
BLOOD TEST	3
MILK	3
PENTAGASTRIN	3

```
Enter RETURN to continue or '^' to exit: <RET>
```

P&T Committee Menu

Report Date: Jan 30, 1996

Page: 2

Frequency Distribution of Causative Agents
From: 1/30/95 To: 1/30/96

Causative Agents	Number
TESTOSTERONE	3
WARFARIN	3
AMPICILLIN	2
DEMECARIUM	2
FUZZEL	2
IODIPAMIDE MEGLUMINE	2
MORPHINE	2
PEMOLINE	2
PSUEDOEPHEDRINE	2
SHRIMP	2
STRAWBERRIES	2
THORAZINE 10MG	2
THORAZINE 200MG	2

Total number of records processed 98

Enter RETURN to continue or '^' to exit: ^

Frequency Distribution of Drug Classes

This option prints a report of the frequency distribution of drug classes for a date range selected by the user.

The header of the report contains the name of the report, the date range selected by the user and the date the report was run. The body of the report contains the drug classification name followed by its code in parentheses and the number of times it was reported during the selected date range.

```
Select Reports Menu Option: 16 Frequency Distribution of Drug Classes
Select an Observed date range for this report.
Enter Start Date: T-365 (JAN 30, 1995)
Enter Ending Date: T (JAN 30, 1996)
```

```
DEVICE: HOME// <RET> HOME
```

```
Report Date: Jan 30, 1996 Page: 1
```

```

                Frequency Distribution of Drug Classes
                From: 1/30/95 To: 1/30/96
Drug Class                                     Number
-----
SALICYLATES,ANTIRHEUMATIC (MS101) :          9
  PARASYMPATHOLYTICS (AU350) :              5
PHENOTHIAZINE/RELATED ANTIPSYCH (CN701) :      4
  PHARMACEUTICAL AIDS/REAGENTS (PH000) :      4
    ANTIPSYCHOTICS (CN700) :                2
  DECONGESTANTS,SYSTEMIC (RE200) :            2
    PENICILLINS (AM050) :                   1
  NON-OPIOID ANALGESICS (CN103) :             1
    ANESTHETICS (CN200) :                   1
RADIOLOGICAL/CONTRAST MEDIA (DX100) :          1
  DIAGNOSTICS,OTHER (DX900) :               1
  IRRIGATION SOLUTIONS (IR100) :            1
  CONTACT LENS SOLUTIONS (OP400) :          1
    OPHTHALMICS,OTHER (OP900) :            1
  RESPIRATORY AGENTS,OTHER (RE900) :        1
IV SOLUTIONS WITH ELECTROLYTES (TN102) :      1
Enter RETURN to continue or '^' to exit:
```

P&T Committee Menu

Report Date: Jan 30, 1996

Page: 2

Frequency Distribution of Drug Classes
From: 1/30/95 To: 1/30/96

Drug Class	Number
ENTERAL NUTRITION (TN200)	1
IONIC CONTRAST MEDIA (DX102)	1
BRONCHODILATORS, XANTHINE-DERIV (RE104)	1
NASAL AND THROAT, TOPICAL, OTHER (NT900)	1
OXYTOCICS (GU600)	1
INTRODUCTION (AA000)	1
ANTIACNE AGENTS, TOPICAL (DE752)	1
ANTIHISTAMINE/DECONGESTANT/EXP (RE503)	1
DECONGESTANT/ANTITUSSIVE/EXPEC (RE513)	1
SODIUM (TN404)	1
BANDAGES/DRESSINGS, OTHER (XA199)	1

Total number of records processed 176

Enter RETURN to continue or '^' to exit: <RET>

Total Reported Reactions Over a Date Range

This option prints a report of the total number of reported reactions for a date range selected by the user.

The header of the report contains the title of the report and when it was run. The body of report contains the total number of actions reported for the date range listed.

```
Select Reports Menu Option:  17  Total Reported Reactions Over a Date Range
Select an Observed date range for this report.
Enter Start Date:  T-365  (JAN 30, 1995)
Enter Ending Date:  T  (JAN 30, 1996)
```

```
DEVICE: HOME//  <RET>  HOME
```

```
Report Date: Jan 30, 1996
```

```
Page: 1
```

```
Reported Reactions
```

```
-----
Total Number of Reported Reactions: 176
From: 1/30/95  To: 1/30/96
Enter RETURN to continue or '^' to exit:  <RET>
```

P&T Committee ADR Outcome Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range and a summary of the listed outcomes for those ADRs. The header of this report contains the name of the report, the date range selected by the user, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, whether the reaction required treatment (Req. Tx), whether the reaction required hospitalization (Req. Hosp), whether the reaction caused a permanent disability (Dis.), and did the patient die as a result of the reaction.

Select Reports Menu Option: **18** P&T Committee ADR Outcome Report
 Select an Observed date range for this report.
 Enter Start Date: **1/1/96** (JAN 01, 1996)
 Enter Ending Date: **1/31/96** (JAN 31, 1996)

DEVICE: HOME// **<RET>** HOME

Report Date: Feb 09, 1996 Page: 1
 P&T Committee ADR Outcome Report
 From: 1/1/96 To: 1/31/96

Obsv. Date	Causative agent	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
1/1/96	PSUEDOEPHEDRINE	HIVES ITCHING, WATERING EY NAUSEA, VOMITING DIARRHEA ANXIETY CHILLS DROWSINESS DRY MOUTH HYPOTENSION	Y			
1/8/96	SALT SUBSTITUTE	SWELLING (NON-SPECI NAUSEA, VOMITING	Y			
1/8/96	SPAM	ANXIETY				

Enter RETURN to continue or '^' to exit:

P&T Committee ADR Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range. The Sign/Symptoms, Mechanism, Severity and Comments are displayed for each ADR. This report should be queued to a printer that has a column width of 132 characters. The header of the report contains the name of the report, the date range selected by the user, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, the mechanism of the adverse reaction (i.e., A=Allergy, P=Pharmacologic, and U=Unknown), and any comments entered. The comments are identified by category (i.e., Observer, Verifier or Entered in Error).

```
Select Reports Menu Option:  19  P&T Committee ADR Report
Select an Observed date range for this report.
Enter Start Date:  1/1/96  (JAN 01, 1996)
Enter Ending Date:  1/31/96  (JAN 31, 1996)
```

This report required a 132 column printer.

```
DEVICE: HOME//  QUEUE TO PRINT ON
DEVICE: HOME//  SELECT APPROPRIATE PRINTER COMPUTER ROOM

Requested Start Time: NOW//  <RET> (FEB 06, 1996@11:23:22)

Request queued...
```

P&T Committee Menu

Report Date: Feb 06, 1996

Page: 1

P&T Committee ADR Report
From: 1/1/96 To: 1/31/96

Obsv. Date	Causative agent	Sign/Symptoms	ADR Mech	ADR Svr.	Comments
1/1/96	PSUEDOEPHEDRINE	HIVES ITCHING, WATERING EY NAUSEA, VOMITING DIARRHEA ANXIETY CHILLS DROWSINESS DRY MOUTH HYPOTENSION	U		OBSERVER COMMENTS: THIS IS A TEST
1/8/96	SALT SUBSTITUTE	SWELLING (NON-SPECI NAUSEA, VOMITING	U	MOD.	OBSERVER COMMENTS: Patient's swelling was observed by the nurse.
1/8/96	FUZZEL	HIVES ITCHING, WATERING EY NAUSEA, VOMITING DIARRHEA ANXIETY DROWSINESS DRY MOUTH DRY NOSE HYPOTENSION RASH	U		OBSERVER COMMENTS: THIS IS ANOTHER TEST ALLERGY
1/9/96	POLLEN	ITCHING, WATERING EY	U	MOD.	OBSERVER COMMENTS: the patient had a moderate reaction to some flowers.
1/10/96	ASPIRIN	NAUSEA, VOMITING DRY MOUTH	U		
1/10/96	ASPIRIN	NAUSEA, VOMITING	U	MOD.	
1/10/96	ASPIRIN	ITCHING, WATERING EY NAUSEA, VOMITING ANXIETY DROWSINESS HYPOTENSION	U	MILD	OBSERVER COMMENTS: THIS IS A TEST

Glossary

Adverse Reaction	Any condition precipitated by a drug which requires patient treatment, admission or transfer; prompts a specialty consultation; or causes injury or death. Every allergy is an adverse reaction, but every adverse reaction is not an allergy.
Adverse Reaction Only	Something that is an adverse reaction but not an allergy.
Adverse Reaction Tracking	The software package that stores and reports the patient allergy or adverse reaction data.
Allergy	A state of hypersensitivity induced by exposure to a certain agent.
Application	A system of computer programs and files that have been specifically developed to meet the requirements of a user or group of users. Examples of DHCP applications are the MAS and Nursing modules.
Application Coordinator	The person responsible for implementing a set of computer programs (application package) developed to support a specific functional area such as Nursing, MAS, etc.
ART	See Adverse Reaction Tracking.
Causative Agent	The name of the item which caused the patient to have a reaction (e.g., penicillin).
Date/Time Chart Marked	In ART, this field indicates when the patient's chart has been marked to indicate this allergy or adverse reaction.
Date/Time ID Band Marked	In ART, this field indicates when the patient ID band or bracelet has been marked to indicate this allergy or adverse reaction.

Glossary

Date/Time MD Notified	A field in ART that indicates when the primary physician has been alerted about a patient allergy or adverse reaction.
Dechallenge	Discontinuation/removal of allergen.
GMR Allergies File	A file of allergies/adverse reactions that are used by ART. The file number is 120.82.
GMRA MARK CHART bulletin	Warning that is generated when Date/Time Chart Marked field is left blank. This warning indicates that someone has to record this allergy or adverse reaction in the patient's chart.
GMRA MARK CHART mail group	This is the group of people who are charged with the responsibility to see that all data entered into ART gets recorded in the patient's chart.
GMRA VERIFY ALLERGY bulletin	Warning that an allergy or adverse reaction has been signed off (completed) by the originator and that it is ready for the verification process.
GMRA-VERIFY ALLERGY security key	Should be given to all verifiers in ART. Allows a verifier access to the verification process.
Historical	An allergy that has been stated by some source versus one that has actually been witnessed by some personnel at this facility.
Ingredient file	A file (#50.416) which contains generic drugs which are components of various drug products.
Likelihood	A measure of the probability that an allergy or adverse reaction was the cause of the patient problems indicated by the signs/symptoms. This field is calculated via an FDA algorithm.
Local Drug File	The list of medications used at a particular VA facility. This file is also sent out by the DHCP Pharmacy developers. The file number is 50.

Mechanism	In the context of ART, this is an indicator of whether the data for a patient is an adverse reaction only, or an allergy. See also adverse reaction and allergy.
National Drug File	This file is a list of drug products available which includes specific information for each product. Information included for the products are trade name, NDC number, manufacturer, VA Drug Class code, dosage form, route of administration, strength and units, ingredients, ingredient strength and units, package code, package size, package type, VA product name and VA generic name.
Observed	An allergy or adverse reaction that has actually been witnessed by some personnel at this facility.
Patient Allergies File	The file where the patient allergy/adverse reaction data is stored in ART. The file number of this file is 120.8.
Rechallenge	Reintroduction of allergen after dechallenge.
Severity	This is an index of how the allergy/adverse reaction affected the patient.
Sign/Symptom	Something that could be subjectively or objectively measured that indicates an allergy or adverse reaction.
Sign/Symptoms File	A list of signs/symptoms that can be selected for a patient allergy or adverse reaction. The file number is 120.83.
Top Ten Signs/Symptoms	A site configurable set of indicators of an allergy or adverse reaction that is used to expedite data entry of these indicators.
Treatment	This is some lab test or drug intervention that was performed as a result of an allergy or adverse reaction.
True Allergy	Something that is an allergy, which implies that it is also an adverse reaction.
VA Drug Classification System file	A file (#50.605) which contains the VA Drug Classification codes and their descriptions. Each drug product in the National Drug file is assigned a primary code which is part of the information stored for each drug product in the National Drug file.

Glossary

Verification	The process of reviewing and approving the data entered by some clinical user. This process is done by a verifier.
Verifier	A person who has the GMRA-VERIFY ALLERGY security key. This person can perform verification of patient data in ART.

Appendix 1

National GMR Allergies (120.82) File Entries

ADHESIVE TAPE
ALCOHOL
ANIMAL HAIR
ANISE OIL
ANTIRABIES SERUM
ASCORBIC ACID
ASPARTAME
ASPIRIN
AUROTHIOGLUCOSE (SESAME OIL)
BANANA
BCG VACCINE
BENZALKONIUM CHLORIDE
BISMUTH SUBSALICYLATE
BOTULISM ANTITOXIN
BROAD BEANS
BUTTERSCOTCH FLAVORING
CAFFEINE
CALCITONIN, SALMON
CAPSAICIN
CARROTS
CETYLPYRIDINIUM
CHEESE
CHICKEN
CHOCOLATE
CINNAMON OIL
CITRATED CAFFEINE
CITRUS
CLOVE OIL
COCOA
COD LIVER OIL
CORN
COTTONSEED OIL
DAIRY PRODUCTS
DIGOXIN IMMUNE FAB (OVINE)
DIPHThERIA ANTITOXIN, EQUINE
DIPHThERIA TOXOID
DUST
EGGS

ESTRADIOL CYPIONATE
F D & C BLUE #2
F D & C GREEN #6
F D & C RED #3
F D & C RED #40
F D & C RED #40 LAKE
F D & C YELLOW #6
F D & C YELLOW #6 LAKE
FAT EMULSIONS
FIGS
FISH
FLUPHENAZINE DECANOATE
FOOD PRESERVATIVES
FOOD STARCH, MODIFIED
GELATIN
GOLD SODIUM THIOMALATE
HEPARIN SODIUM (BEEF LUNG)
HEPARIN SODIUM (PORK)
HERRING
HORSE SERUM
INSULIN
IODINE
IRON FILLINGS
LACTOSE
LICORICE
MALTOSE
METHYL SALICYLATE
METHYLCELLULOSE
MILK
MOLD
MONOSODIUM GLUTAMATE
NAFARELIN ACETATE
NANDROLONE, ETC
NUTS
OTHER ALLERGY/ADVERSE REACTION
PARA-AMINOBENZOIC ACID
PARABEN
PEACHES
PEANUT OIL
PEPPERMINT
PINEAPPLE
PLUMS
POLLEN
POLYSORBATE

PORK
POTASSIUM IODIDE
POTATO
POULTRY
POVIDONE IODINE
PSYLLIUM
RABIES IMMUNE GLOBULIN
RED FOOD DYE
SACCHARIN
SAFFLOWER OIL
SALICYLAMIDE
SALICYLIC ACID
SESAME OIL
SHELL FISH
SHRIMP
SOY BEANS
SOY SAUCE
STRAWBERRIES
SULFITES
SUNFLOWER OIL
TARTARIC ACID
TESTOSTERONE
TOMATO
VANILLA
VASOPRESSIN TANNATE (IN OIL)
WHEAT
YEAST
YOGURT

Appendix 1

Appendix 2

National Sign/Symptoms (120.83) File Entries

AGITATION
AGRANULOCYTOSIS
ALOPECIA
ANAPHYLAXIS
ANEMIA
ANOREXIA
ANXIETY
APNEA
APPETITE, INCREASED
ARRHYTHMIA
ASTHENIA
ASTHMA
ATAXIA
ATHETOSIS
BRACHYCARDIA
BREAST ENGORGEMENT
BRONCHOSPASM
CARDIAC ARREST
CHEST PAIN
CHILLS
COMA
CONFUSION
CONGESTION, NASAL
CONJUNCTIVAL CONGESTION
CONSTIPATION
COUGHING
DEAFNESS
DELIRIUM
DELUSION
DEPRESSION
DEPRESSION, MENTAL
DEPRESSION, POSTICTAL
DERMATITIS
DERMATITIS, CONTACT
DERMATITIS, PHOTOALLERGENIC
DIAPHORESIS
DIARRHEA
DIPLOPIA

DISTURBED COORDINATION
DIZZINESS
DREAMING, INCREASED
DROWSINESS
DRY MOUTH
DRY NOSE
DRY THROAT
DYSPNEA
DYSURIA
ECCHYMOSIS
ECG CHANGES
ECZEMA
EDEMA
EPIGASTRIC DISTRESS
EPISTAXIS
ERYTHEMA
EUPHORIA
EXCITATION
EXTRASYSTOLE
FACE FLUSHED
FACIAL DYSKINESIA
FAINTNESS
FATIGUE
FEELING OF WARMTH
FEVER
GALACTORRHEA
GENERALIZED RASH
GI REACTION
GLAUCOMA
GYNECOMASTIA
HALLUCINATIONS
HEADACHE
HEART BLOCK
HEMATURIA
HEMOGLOBIN, INCREASED
HIVES
HYPERSENSITIVITY
HYPERTENSION
HYPOTENSION
IMPAIRMENT OF ERECTION
IMPOTENCE
INAPPROPRIATE PENILE ERECTION
INSOMNIA
IRRITABILITY

ITCHING, WATERING EYES
JUNCTIONAL RHYTHM
LABYRINTHITIS, ACUTE
LACRIMATION
LDH, INCREASED
LETHARGY
LEUKOCYTE COUNT, DECREASED
LIBIDO, DECREASED
LIBIDO, INCREASED
MIOSIS
MYOCARDIAL INFARCTION
NAUSEA, VOMITING
NERVOUSNESS, AGITATION
NEUTROPHIL COUNT, DECREASED
NIGHTMARES
OPTIC ATROPHY
ORGASM, INHIBITED
ORONASALPHARYNGEAL IRRITATION
OTHER REACTION
PAIN, JOINT
PALPITATIONS
PANCYTOPENIA
PARESTHESIA
PARKINSONIAN-LIKE SYNDROME
PHOTOSENSITIVITY
POSSIBLE REACTION
PRIAPISM
PROLONGED PENILE ERECTION
PRURITIS
PTOSIS
PURPURA
RALES
RASH
RASH, PAPULAR
RESPIRATORY DISTRESS
RETROGRADE EJACULATION
RHINITIS
RHINORRHEA
RHONCHUS
S-T CHANGES, TRANSIENT
SEIZURES
SEIZURES, TONIC-CLONIC
SELF-DEPRECATATION
SEVERE RASH

Appendix 2

SHORTNESS OF BREATH
SINUS BRACHYCARDIA
SNEEZING
SOMNOLENCE
SPEECH DISORDER
SWELLING (NON-SPECIFIC)
SWELLING-EYES
SWELLING-LIPS
SWELLING-THROAT
SYNCOPE
TACHYCARDIA
THROMBOCYTOPENIA
TREMORS
URINARY FLOW, DELAYED
URINARY FREQUENCY
URINARY FREQUENCY, INCREASED
URINARY RETENTION
URTICARIA
UVEITIS
VERTIGO
VISION,BLURRED
VISUAL DISTURBANCES
VOMITING
WEAKNESS
WEIGHT GAIN
WHEEZING



Department of Veterans Affairs
Decentralized Hospital Computer Program

**ADVERSE REACTION TRACKING
(ART)
USER MANUAL**

Version 4.0

March 1996

Hines IRM Field Office
Hines, IL

Preface

This manual was developed to assist the clinical users of Adverse Reaction Tracking (ART). This manual shows how the Adverse Reaction Tracking software appears to the clinical user, and gives basic instructions on its use. The objective of the software is to track and report patient allergy and adverse reaction data. The software contains parameter fields that the site can use to customize the use of the software to the site's needs.

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