



RESOURCE AND PATIENT MANAGEMENT SYSTEM

Adverse Reaction Tracking

(GMRA)

User Manual

Version 4.0 Patch 1001
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Office of Information Technology (OIT)
Division of Information Resource Management
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Preface

This user manual describes the functional characteristics of the Adverse Reaction Tracking 4.0 through patch 1002. It is intended for all users of the package. 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 Resource and Patient Management System (RPMS) is presumed for most users. Package coordinators should have more than a basic knowledge of RPMS and the needs of a clinical environment.

Use of Adverse Reaction Tracking within the Electronic Health Record (EHR) is primarily described in the EHR documentation, but some examples are provided in this manual.

1.0 Introduction

The objective of Adverse Reaction Tracking (ART) is to track and report patient allergy and adverse reaction data.

Recent modifications are aimed at standardizing data stored in the package. When data is to be shared between facilities or in central repositories, it is essential that it can cross from system to system, but also that it retains the same meaning.

The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) have been standardized. As a result of standardization, sites will no longer be allowed to add or edit entries in either of these files. In addition, users will no longer be able to add “free text” reactants or signs/symptoms.

2.0 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 RPMS is presumed for most users of the software. The Application Coordinator should have more than a basic knowledge of RPMS and the needs of a clinical environment.

2.1 Security Keys

The software does contain several security keys. Users should contact the Application Coordinator or IT personnel if they feel they require one of these keys.

2.1.1 GMRA-ALLERGY VERIFY

This key is needed to verify allergy/adverse reactions. It is also one of two requirements for the user to receive EHR notifications of reactions needing verification.

2.1.2 GMRA-SUPERVISOR

This key should be give ONLY to those users who have the authority to override the software's security in order to edit data.

2.1.3 GMRA-CLINIC

This key is needed to access the Adverse Reaction Tracking Clinician menu.

2.1.4 GMRA-USER

This key is needed for all users who will be documenting adverse reactions in any setting, and to access the Adverse Reaction Tracking User Menu.

2.1.5 GMRA-PT

This key is needed to access the Adverse Reaction Tracking P&T Committee menu.

2.2 GMRA Update Resource

ADI (Allergy Domain Implementation/Data Standardization) uses a resource device to control the updating of existing patient allergies/adverse reactions. When changes are made to existing allergy definitions in file 120.82, all associated patient allergies/adverse reactions in file 120.8 are updated to match the new definition of the entry from 120.82. The resource device controls the updating process. Because of the way the updates are implemented, the resource device needs to manage the updates one at a time. As a result, the resource slots field is set to ONE and should NOT be changed.

2.3 Mail Bulletins and Groups

The software generates mail bulletins when certain events happen and sends a bulletin to a specified mail group. Users should contact the Application Coordinator or IT personnel if they feel they should be a member of one of the mail groups.

2.3.1 Mail Bulletins

2.3.1.1 GMRA ENTERED IN ERROR

This bulletin is generated when a reaction has been marked as “entered in error”.

This bulletin is intended to be sent to both the verifiers and the chart marking groups so that the reaction can be corrected on the patient record.

In addition, if the reactant is an observed drug reaction, the P&T Committee members will also be notified.

2.3.1.2 GMRA MARK CHART

This bulletin will alert the appropriate users to mark the chart and/or ID band for the patient and allergy/adverse reaction specified in the bulletin.

2.3.1.3 GMRA P&T COMMITTEE FDA

This bulletin will be issued when an agent is both observed and a drug and has been signed off.

2.3.1.4 GMRA SIGNS/SYMPTOMS UPDATE

This bulletin is to be sent to the P&T Committee if a reaction has had the Signs/Symptoms changed at any time.

2.3.1.5 GMRA VERIFY ALLERGY

This bulletin will indicate that an allergy/adverse reaction needs to be verified.

It is also the second of two requirements for the user to receive EHR notifications of reactions needing verification.

2.3.2 Mail Groups

2.3.2.1 **GMRA MARK CHART**

This group contains a list of users who will need to be notified that the ID Band needs to be updated. The new message reads “The ID Band for the following patient needs to indicate that the following Allergy/Adverse reaction has been reported”.

2.3.2.2 **GMRA VERIFY DRUG ALLERGY**

This group contains a list of all verifiers who will need to be sent drug reaction information.

2.3.2.3 **GMRA VERIFY FOOD ALLERGY**

This group contains a list of all verifiers who will need to be sent food reaction information.

2.3.2.4 **GMRA VERIFY OTHER ALLERGY**

This group contains a list of all verifiers who will need to be sent other types of reaction information (i.e. not food or drug).

2.3.2.5 **GMRA P&T COMMITTEE FDA**

This group contains a list of the members of the Pharmacy and Therapeutic (P&T) Committee.

2.3.2.6 **GMRA REQUEST NEW REACTANT**

This group contains a list of users who will need to be sent information when a user has attempted to enter a reactant that is not currently in the system.

The group GMRA VERIFY DRUG ALLERGY will be added to this group by default. Site Managers may remove or add to this group as needed.

3.0 Package Operation

3.1 Adverse Reaction Tracking (GMRAMGR)

This is the main menu and contains all the options of the Adverse Reaction Tracking System. It is usually given to the package coordinator and/or the Information Technology support personnel.

1. Enter/Edit Site Configurable Files ... [GMRA SITE FILE MENU]
2. Adverse Reaction Tracking User Menu ... [GMRA USER MENU]
3. Adverse Reaction Tracking Clinician Menu ... [GMRA CLINICIAN MENU]
4. Adverse Reaction Tracking Verifier Menu ... [GMRA VERIFIER MENU]
5. P&T Committee Menu ... [GMRA P&T MENU]

3.2 Enter/Edit Site Configurable Files (GMRA SITE FILE MENU)

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 package coordinator or Information Technology personnel.

NOTE: the GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) have been standardized. As a result of standardization, sites are no longer allowed to add or edit entries in either of these files. In addition, users will no longer be able to add free-text signs/symptoms or reactants.

Additional terms have been added to the GMR ALLERGY file, and more will be added with upcoming patch releases. Sites may request new reactants or signs/symptoms through the IHS RPMS Feedback website at <http://www.ihs.gov/RPMS/index.cfm?module=feedback&option=add&newquery=1>. Sites should select the RPMS Application “Pharmacy – New Reactant/Symptom Request (PRSR)” to ensure these requests are reviewed without delay.

The options on this menu are still available, but will not allow entries; this was done to further emphasize the changes to the application.

1. Edit Allergy File
2. Enter/Edit Signs/Symptoms Data
3. Enter/Edit Site Parameters
4. Sign/Symptoms List
5. Allergy File List
6. Allergy clean up utility

3.2.1 Edit Allergy File

The GMR ALLERGIES file (120.82) has been standardized. As a result, sites are no longer allowed to add or edit entries in this file. In addition, users will no longer be able to add “free text” reactants.

Users attempting to edit this file will see the following warning text:

“In support of national standardization of the contents of this file, local site addition and modification functions are no longer available. If you wish to request a new term or modify an existing term, please request through the IHS RPMS Feedback web site located at <http://www.ihs.gov/RPMS>. Once at the IHS RPMS Feedback page, select the RPMS Application ‘Pharmacy - New Reactant/Symptom Request (PRSR)’ to ensure these are reviewed in a timely manner. If you have any questions regarding this new term request process, please contact your local Adverse Reaction Tracking package coordinator.”

3.2.2 Enter/Edit Signs/Symptoms Data

The SIGNS/SYMPTOMS file (120.83) has been standardized. As a result, sites are no longer allowed to add or edit entries in this file. In addition, users will no longer be able to add “free text” signs or symptoms.

Users attempting to edit this file will see the following warning text:

“In support of national standardization of the contents of this file, local site addition and modification functions are no longer available. If you wish to request a new term or modify an existing term, please request through the IHS RPMS Feedback web site located at <http://www.ihs.gov/RPMS>. Once at the IHS RPMS Feedback page, select the RPMS Application ‘Pharmacy - New Reactant/Symptom Request (PRSR)’ to ensure these are reviewed in a timely manner. If you have any questions regarding this new term request process, please contact your local Adverse Reaction Tracking package coordinator.”

3.2.3 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 should ensure that each of the site’s divisions are listed in the site parameters. This can be checked by entering a single question mark at the “Select Division” prompt.

Sites utilizing a unified database may elect to use additional site names to achieve different parameters for each division. In this case, the divisions will be matched to a site name based on the desired parameter set up (e.g., divisions A and B do not wish to Autoverify, but division C wishes to Autoverify food reactions only; in this case two sites may be set up, with divisions A and B in the first site name with Autoverify turned off and division C in the second site name with Autoverify Food Only turned on).

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 you will see. Note that this list is used **ONLY** in the RPMS package and not in the Electronic Health Record component. Sites are strongly cautioned against removing entries completely, as future enhancements will require a full list to be in place.
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 on (completes) it. The site can determine which 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 reactions may also need to be verified. 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. **NOTE:** the “Reporter” data fields contain the site’s default values that will appear on the FDA adverse reaction reports. This information may be left blank. You will be prompted for the reporter information when creating an FDA report.
6. Whether to allow comments to be added to the reaction data that is entered in error. This allows you to indicate why the data is incorrect.

Example:

```
Select Enter/Edit Site Configurable Files Option: 3  Enter/Edit Site Parameters
Select GMR ALLERGY SITE PARAMETERS NAME: ?
```

```
Answer with GMR ALLERGY SITE PARAMETERS NAME:
HOSPITAL
```

```
You may enter a new GMR ALLERGY SITE PARAMETERS, if you wish
Answer must be 3-30 characters in length.
```

```
Select GMR ALLERGY SITE PARAMETERS NAME: HOSPITAL
NAME: HOSPITAL// (No editing)
Select DIVISION: DEMO INDIAN HOSPITAL// ?
```

```
Answer with DIVISION:
DEMO INDIAN HOSPITAL
```

```
You may enter a new DIVISION, if you wish
```

```
Answer with INSTITUTION NAME, or STATUS, or STATION NUMBER, or
OFFICIAL VA NAME, or CURRENT LOCATION, or CODING SYSTEM/ID PAIR, or
NPI, or STATUS, or NAME (CHANGED FROM), or CODING SYSTEM
Do you want the entire INSTITUTION List? N (No)
Select DIVISION: DEMO INDIAN HOSPITAL//
```

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

- | | |
|----------------------------|----------------|
| 1. ANXIETY | 6. DIARRHEA |
| 2. ITCHING | 7. HIVES |
| 3. SWELLING (NON-SPECIFIC) | 8. DYSPEPSIA |
| 4. DROWSINESS | 9. ANAPHYLAXIS |
| 5. NAUSEA,VOMITING | 10. RASH |

```
Enter the number of the sign/symptom that you would like to edit:
```

```
AUTOVERIFY FOOD/DRUG/OTHER: NO AUTOVERIFY//
AUTOVERIFY OBSERVED/HISTORICAL: NO AUTOVERIFY//
AUTOVERIFY LOGICAL OPERATOR: AND//
REQUIRE ORIGINATOR COMMENTS: NO//
MARK ID BAND FLAG: NO//
METHOD OF NOTIFICATION: BULLETIN//
ALERT ID BAND/CHART MARK: NO//
SEND CHART MARK BULLETIN FOR NEW ADMISSIONS:
FDA DATA REQUIRED: NO//
ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: YES
//
```

```
REPORTER NAME: PHARMACIST,PHARMACIST
ADDRESS: DEMO INDIAN MEDICAL CENTER
100 S. MAIN
CITY: ANYTOWN
STATE: OKLAHOMA
ZIP: 74464
PHONE: 555-123-4567
OCCUPATION: PHARMACY
```

```
Do you want to edit Reporter Information shown above? No// (No)
```

3.2.4 Signs/Symptoms List

This option lets the user 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 Application Coordinators in maintaining the Sign/Symptom file.

Example:

```

Select Enter/Edit Site Configurable Files Option: 4  Sign/Symptoms List
START WITH NAME: FIRST//
DEVICE: HOME  VIRTUAL TERMINAL      Right Margin: 80//
SIGN/SYMPTOMS LIST                    APR 26,2011 09:30  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
...

```

3.2.5 Allergy 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. You 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 maintaining the GMR ALLERGIES file.

Example:

```

Select Enter/Edit Site Configurable Files Option: 5  Allergies File List
START WITH NAME: FIRST//
DEVICE: HOME VIRTUAL TERMINAL      Right Margin: 80//
GMR ALLERGIES LIST                  APR 26,2011  10:04  PAGE 1
-----

NAME: ABALONE                        ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ACRYLIC FIBER                  ALLERGY TYPE: OTHER
EFFECTIVE DATE/TIME: APR 19, 2011@12:34:59
  STATUS: INACTIVE

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

NAME: ADHESIVES                      ALLERGY TYPE: OTHER
  NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ALBUTEROL                      ALLERGY TYPE: DRUG
SYNONYM: PROVENTIL
VA DRUG CLASSES: RE100
DRUG INGREDIENT: ALBUTEROL
EFFECTIVE DATE/TIME: APR 19, 2011@12:34:59
  STATUS: INACTIVE

...

```

3.2.6 Allergy clean up utility

This option was distributed with patch GMRA 4.0 1001 to help sites identify and fix adverse reaction entries that have free-text reactants, or reactions that are pointed to the Drug Ingredients file (50.416) or VA Drug Class file (50.605).

After installing this patch, free-text entries were no longer allowed from within the ART package, or from the Electronic Health Record.

Lower-case entries are also no longer allowed. Previously, lower-case entries could be added to the GMR ALLERGIES file (120.82). A previous patch post-install routine identified any local entries and updated them to upper case. Synonyms were also checked and converted to upper case, if required.

This utility does NOT automatically match any entry to a “better” entry, nor does it suggest better entries. It is simply a tool for identifying allergies that may be problematic and allows the user to take action on them.

When the user selects a free-text reactant, a list of currently existing free-text entries is displayed in alphabetical order. This list may take a few minutes to generate, as all existing entries need to be evaluated to determine which are “free text”. The list shows the name of the reactant, and the number of entries for that reactant.

When entering the utility, any users who are currently working in the utility are listed. If users are listed as working with the utility, the next user will not be allowed to update the list. In other words, only one user can be updating the list at any given time.

Once the list is displayed, the user can either:

1. Mark the entry as entered in error
2. Update the record so that it points to a reactant selected from GMR Allergy file or one of the National Drug files.

****IMPORTANT****

Please keep the GMRA UPDATE resource device slot set at 1. If this has been changed, updates to the Allergies files could occur out of order. If this has been changed, please contact the OIT Help Desk to assess the implications at your site.

3.2.6.1 Free Text

Example:

```

1      Edit Allergy File
2      Enter/Edit Signs/Symptoms Data
3      Enter/Edit Site Parameters
4      Sign/Symptoms List
5      Allergies File List
6      Allergy clean up utility

Select Enter/Edit Site Configurable Files Option: 6  Allergy clean up utility

      Select one of the following:

          1      Free Text
          2      Ingredient
          3      Drug Class

Select the list you wish to work with: 1  Free Text
Building list of free text allergies...this may take a few minutes

Allergy Tracking Update   Apr 26, 2011 10:33:16   Page: 1 of 18
Allergy Tracking Free Text Entries

```

Reactant	# Active Entries
1 AC I/ARB	1
2 ACEI	3
3 ACTIFED	1
4 ADVERSE DRUG REACTION H202	1
5 AKE: ACI	1
6 ALBUTEROL	22
7 ALENDRONATE	7
8 ALL ANTIBIOTIC UNKNOWN	1
9 ALL DYES	1
10 ALL EYE DROPS	1
11 ALL NSAIDS	1
12 ALL TAPES	1
13 ALLERGIC TO DYE	1

```

14 AMITRIPTYLINE                24
15 AMLODIPINE                   30
16 AMOXICILLIN                  700
17 AMPICILLIN                   110
+       Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display             UR Update to new reactant
Select Item(s): Next Screen//

```

NOTE: If the list had been built previously, the user will see the following alternative text:

```

Select the list you wish to work with: 1 Free Text
The free text list was last built on Apr 26, 2011
Do you want to rebuild the list? NO// YES

```

Detailed Display: The detailed display window shows the patient name and the list of currently active reactions, separated by a tilde (~). This way, the user can quickly look to see if the patient already had an active reaction that is the same as the free-text entry. In this case, the user would mark the free-text entry as entered in error.

The “free text detailed display” action lets the user see the FileMan inquiry-style listing of the free text entry for the selected patient. The user will see the comments, reactions, and other associated information for the entry that is being fixed.

1. Select the Free text option from the Allergy Clean Up utility.
2. Select the number of the reactant and then select DD to see details about the reactant (alternatively, DD can be selected first and then the reactant). **NOTE:** for detailed display, only one group can be selected at a time.

Example:

```

Allergy Tracking Update   Apr 26, 2011 10:34:42   Page:  1  of  18
Allergy Tracking Free Text Entries
  Reactant                                # Active Entries
1  AC I/ARB                                1
2  ACEI                                    3
3  ACTIFED                                 1
4  ADVERSE DRUG REACTION H202             1
5  AKE: ACI                                1
6  ALBUTEROL                              22
7  ALENDRONATE                             7
8  ALL ANTIBIOTIC UNKNOWN                 1
9  ALL DYES                                1
10 ALL EYE DROPS                           1
11 ALL NSAIDS                              1
12 ALL TAPES                               1
13 ALLERGIC TO DYE                         1
14 AMITRIPTYLINE                           24
15 AMLODIPINE                               30
16 AMOXICILLIN                             700
17 AMPICILLIN                              110
+       Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display             UR Update to new reactant
Select Item(s): Next Screen// 6

```

Allergy Tracking Update Apr 26, 2011 10:35:06 Page: 1 of 18
 Allergy Tracking Free Text Entries

Reactant	# Active Entries
1 AC I/ARB	1
2 ACEI	3
3 ACTIFED	1
4 ADVERSE DRUG REACTION H202	1
5 AKE: ACI	1
6 ALBUTEROL	22
7 ALENDRONATE	7
8 ALL ANTIBIOTIC UNKNOWN	1
9 ALL DYES	1
10 ALL EYE DROPS	1
11 ALL NSAIDS	1
12 ALL TAPES	1
13 ALLERGIC TO DYE	1
14 AMITRIPTYLINE	24
15 AMLODIPINE	30
16 AMOXICILLIN	700
17 AMPICILLIN	110

+ Select one or more entries
 AE Add/Edit Allergy File EE Mark entered in error
 DD Detailed Display UR Update to new reactant
 Select Item(s): Next Screen// DD

Reactant Detailed Display Apr 26, 2011 12:07:29 Page: 1 of 3

Patient listing for reactant ALBUTEROL

Patient Name	Last 4
1 DEMO,PATIENT MAE	9654
Allergies: ALBUTEROL~IODINE~CIPROFLOXACIN	
2 DEMO,PATIENT LEE	5900
Allergies: ALBUTEROL	
3 DEMO,PATIENT KEITH	9160
Allergies: PENICILLIN~RAPAMUNE~ACETAMINOPHEN/HYDROCODONE~ALBUTEROL	
4 DEMO,PATIENT TINA	9321
Allergies: BECLMETHASONE INHALER~BACTRIM~ALBUTEROL	
5 DEMO,PATIENT MARYJANE	6233
Allergies: ATENOLOL~CAPTOPRIL~FOSINOPRIL~STEROIDS~ALBUTEROL~SIMVASTATIN	
6 DEMO,PATIENT LARRY	2934
Allergies: ERYTHROMYCIN~ALBUTEROL	
7 DEMO,PATIENT HEATHER	4540
Allergies: ALBUTEROL	
8 DEMO,PATIENT NICOLE	9851
Allergies: PENICILLIN~ALBUTEROL	

+ Select a patient >>>
 EE Entered in Error PR Add/Edit Patient Reaction
 UR Update to new reactant DD Allergy Detailed Display
 AE Add/Edit Allergy File
 Select Item(s): Next Screen//1

Reactant Detailed Display Apr 26, 2011 12:07:54 Page: 1 of 3

Patient listing for reactant ALBUTEROL

Patient Name	Last 4
1 DEMO,PATIENT MAE	9654
Allergies: ALBUTEROL~IODINE~CIPROFLOXACIN	
2 DEMO,PATIENT LEE	5900
Allergies: ALBUTEROL	
3 DEMO,PATIENT KEITH	9160
Allergies: PENICILLIN~RAPAMUNE~ACETAMINOPHEN/HYDROCODONE~ALBUTEROL	
4 DEMO,PATIENT TINA	9321

```

Allergies: BECLOMETHASONE INHALER~BACTRIM~ALBUTEROL
5 DEMO,PATIENT MARYJANE 6233
Allergies: ATENOLOL~CAPTOPRIL~FOSINOPRIL~STEROIDS~ALBUTEROL~SIMVASTATIN
6 DEMO,PATIENT LARRY 2934
Allergies: ERYTHROMYCIN~ALBUTEROL
7 DEMO,PATIENT HEATHER 4540
Allergies: ALBUTEROL
8 DEMO,PATIENT NICOLE 9851
Allergies: PENICILLIN~ALBUTEROL
+ Select a patient >>>
EE Entered in Error PR Add/Edit Patient Reaction
UR Update to new reactant DD Allergy Detailed Display
AE Add/Edit Allergy File
Select Item(s): Next Screen// DD Allergy Detailed Display

PATIENT: DEMO,PATIENT MAE REACTANT: ALBUTEROL
GMR ALLERGY: OTHER ALLERGY/ADVERSE REACTION
ORINATION DATE/TIME: JUL 12, 2004@17:24
ORIGINATOR: WOFFORD-FARRIS,JAMES CLIFTON III
OBSERVED/HISTORICAL: HISTORICAL ORIGINATOR SIGN OFF: YES
MECHANISM: UNKNOWN VERIFIED: YES
VERIFICATION DATE/TIME: JUL 12, 2004@17:25:41
VERIFIER: WOFFORD-FARRIS,JAMES CLIFTON III
ALLERGY TYPE: DRUG
DRUG INGREDIENT: ALBUTEROL
VA DRUG CLASS: ANTIASHTMA/BRONCHODILATORS
DATE/TIME: JUL 12, 2004@17:27:02
USER ENTERING: WOFFORD-FARRIS,JAMES CLIFTON III

Press return to continue or '^' to stop:

```

Mark Entered in Error: The user can mark an entire group as entered in error from this opening screen, however, it is recommended that the user first view the detailed display to review the entries in a group before doing a mass update.. Upon marking the reaction as entered in error, a check is made to see if there are still active reactions for the patient. If there are not any, then the user is prompted to enter and updated assessment for the patient.

1. Select the Free Text option from the Allergy Clean Up utility.
2. Select the number of the reactant(s) you wish to mark as entered in error. Alternatively, the user can select the action, and then select the number of the reactant(s).
3. Type EE for Mark Entered in Error, and then answer YES to confirm ALL allergies are to be marked as entered in error.

Example:

```

Allergy Tracking Update Apr 26, 2011 10:41:45 Page: 1 of 18
Allergy Tracking Free Text Entries
  Reactant # Active Entries
1 AC I/ARB 1
2 ACEI 2
3 ACTIFED 1
4 ADVERSE DRUG REACTION H202 1

```

```

5  AKE: ACI 1
6  ALBUTEROL 22
7  ALENDRONATE 7
8  ALL ANTIBIOTIC UNKNOWN 1
9  ALL DYES 1
10 ALL EYE DROPS 1
11 ALL NSAIDS 1
12 ALL TAPES 1
13 ALLERGIC TO DYE 1
14 AMITRIPTYLINE 24
15 AMLODIPINE 30
16 AMOXICILLIN 700
17 AMPICILLIN 110
+      Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Next Screen// EE
Select Entries from list: 2

```

You are about to mark ALL allergies with the selected reactant as entered in error.

ARE YOU SURE? NO//YES

Allergy Tracking Update Apr 26, 2011 10:42:59 Page: 1 of 18
Allergy Tracking Free Text Entries

Reactant	# Active Entries
1 AC I/ARB	1
2 ACEI	** FIXED **
3 ACTIFED	1
4 ADVERSE DRUG REACTION H202	1
5 AKE: ACI	1
6 ALBUTEROL	22
7 ALENDRONATE	7
8 ALL ANTIBIOTIC UNKNOWN	1
9 ALL DYES	1
10 ALL EYE DROPS	1
11 ALL NSAIDS	1
12 ALL TAPES	1
13 ALLERGIC TO DYE	1
14 AMITRIPTYLINE	24
15 AMLODIPINE	30
16 AMOXICILLIN	700
17 AMPICILLIN	110

```

+      Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Next Screen//

```

Update to New Reactant: The user may select and update groups of entries from the opening menu, however, it is recommended that the user first view the detailed display to review the entries in a group before doing a mass update. **CHANGES CANNOT BE UNDONE!** When the entry is updated, a comment is stored in the PATIENT ALLERGY file indicating who made the change, date/time of change, and a comment that indicates what the previous value was and what the new value is. In addition, the new reactant is compared against current orders and order checking information is returned, if appropriate. When a new reactant is selected, checks are made for duplicate entries and previously entered-in-error information. When updating a reactant, the utility will search through the applicable files in the same order used when entering a new reaction: GMR ALLERGIES (#120.82), National Drug File – Generic Names (#50.6), National Drug File – Trade Names (#50.67), DRUG INGREDIENT (#50.416), and VA DRUG CLASS (#50.605). The user should select the best match from the most appropriate file (e.g., foods and substances from the GMR ALLERGIES file, drugs from the National Drug File, etc.).

When performing a group update or selecting multiple patients for updating from the detailed display listing, the reactant selected for the first patient will become the default for the remaining patients. The exception to that would be if the user decides to not accept the default while updating one of the patients. In that case, the last chosen reactant will become the default for the next patient. The default only holds while working with a particular group. Once you select a new reactant group or a new group of patients, the user must re-select the reactant. This should cut down on the amount of time needed in selecting the reactant for each patient.

NOTE: Due to the way the order checking software works, the user may get “false positives.” In other words, if the patient currently has an allergy order check for some other order not related to this new reactant, you may still see the order check.

Example: (note that although it appear to read the same, the old reactant was from the GMR ALLERGIES file (#120.82) and the new is from the National Drug – Generic Names file (#50.6) and will behave properly for order checks as a result.)

Allergy Tracking Update Apr 26, 2011 12:38:47 Page: 1 of 18		
Allergy Tracking Free Text Entries		
Reactant		# Active Entries
1	AC I/ARB	1
2	ACTIFED	1
3	ADVERSE DRUG REACTION H202	1
4	AKE: ACI	1
5	ALBUTEROL	21
6	ALENDRONATE	7
7	ALL ANTIBIOTIC UNKNOWN	1
8	ALL DYES	1
9	ALL EYE DROPS	1
10	ALL NSAIDS	1
11	ALL TAPES	1
12	ALLERGIC TO DYE	1
13	AMITRIPTYLINE	24
14	AMLODIPINE	30

```

15 AMOXICILLIN                700
16 AMPICILLIN                 110
17 ANESTHESIA MEDS            1
+      Select one or more entries
AE Add/Edit Allergy File EE  Mark entered in error
DD Detailed Display          UR  Update to new reactant
Select Item(s): Next Screen// 5

Allergy Tracking Update   Apr 26, 2011 12:41:42   Page: 1 of 18
Allergy Tracking Free Text Entries
  Reactant                                # Active Entries
1  AC I/ARB                                1
2  ACTIFED                                1
3  ADVERSE DRUG REACTION H202             1
4  AKE: ACI                                1
5  ALBUTEROL                              21
6  ALENDRONATE                            7
7  ALL ANTIBIOTIC UNKNOWN                 1
8  ALL DYES                                1
9  ALL EYE DROPS                          1
10 ALL NSAIDS                              1
11 ALL TAPES                               1
12 ALLERGIC TO DYE                         1
13 AMITRIPTYLINE                          24
14 AMLODIPINE                              30
15 AMOXICILLIN                             700
16 AMPICILLIN                              110
17 ANESTHESIA MEDS                          1
+      Select one or more entries
AE Add/Edit Allergy File EE  Mark entered in error
DD Detailed Display          UR  Update to new reactant
Select Item(s): Next Screen// UR

You should use the detailed display option to review entries in
this group before doing a mass update.  CHANGES CANNOT BE UN-DONE!
Press enter to continue:

You are about to update ALL allergies with the selected reactant
to a new reactant.

ARE YOU SURE? NO// YES

Updating ALBUTEROL reactions

For patient DEMO,PATIENT LEE

Enter Causative Agent: ALBUTEROL

Checking GMR ALLERGIES (#120.82) file for matches...

You selected ALBUTEROL
Is this correct? Y// NO

Now checking the National Drug File - Generic Names (#50.6)

  1  ALBUTEROL
  2  ALBUTEROL/IPRATROPIUM
CHOOSE 1-2: 1  ALBUTEROL

You selected ALBUTEROL
Is this correct? Y// ES

```

```

Performing order checking...patient has no active orders.

For patient DEMO,PATIENT KEITH

Use reactant ALBUTEROL? Y// ES
Performing order checking...patient has no active orders.
...

```

Update/Entered in Error from Detailed Display: The user may elect to mark a reactant as entered-in-error or update a reactant from the detailed display view. When updating a reactant, the utility will search through the applicable files in the same order used when entering a new reaction: GMR ALLERGIES (#120.82), National Drug File – Generic Names (#50.6), National Drug File – Trade Names (#50.67), DRUG INGREDIENT (#50.416), and VA DRUG CLASS (#50.605). The user should select the best match from the most appropriate file (e.g., foods and substances from the GMR ALLERGIES file, drugs from the National Drug File, etc.).

Example: (Note: in the following example, each file searched in the update process was shown to emphasize the files and order searched. Users would not necessarily need to run through each file this way.)

```

Reactant Detailed Display   Apr 26, 2011 12:08:36   Page:   1 of 3
Patient listing for reactant ALBUTEROL
  Patient Name                Last 4
1  DEMO,PATIENT MAE           9654
Allergies: ALBUTEROL~IODINE~CIPROFLOXACIN
2  DEMO,PATIENT LEE           5900
Allergies: ALBUTEROL
3  DEMO,PATIENT KEITH         9160
Allergies: PENICILLIN~RAPAMUNE~ACETAMINOPHEN/HYDROCODONE~ALBUTEROL
4  DEMO,PATIENT TINA           9321
Allergies: BECLOMETHASONE INHALER~BACTRIM~ALBUTEROL
5  DEMO,PATIENT MARYJANE       6233
Allergies: ATENOLOL~CAPTOPRIL~FOSINOPRIL~STEROIDS~ALBUTEROL~SIMVASTATIN
6  DEMO,PATIENT LARRY          2934
Allergies: ERYTHROMYCIN~ALBUTEROL
7  DEMO,PATIENT HEATHER        4540
Allergies: ALBUTEROL
8  DEMO,PATIENT NICOLE         9851
Allergies: PENICILLIN~ALBUTEROL
+      Select a patient                >>>
EE  Entered in Error                PR  Add/Edit Patient Reaction
UR  Update to new reactant           DD  Allergy Detailed Display
AE  Add/Edit Allergy File
Select Item(s): Next Screen// 1

```

```

Reactant Detailed Display   Apr 26, 2011 12:09:04   Page:   1 of 3
Patient listing for reactant ALBUTEROL
  Patient Name                Last 4
1  DEMO,PATIENT MAE           9654
Allergies: ALBUTEROL~IODINE~CIPROFLOXACIN
2  DEMO,PATIENT LEE           5900
Allergies: ALBUTEROL
3  DEMO,PATIENT KEITH         9160
Allergies: PENICILLIN~RAPAMUNE~ACETAMINOPHEN/HYDROCODONE~ALBUTEROL
4  DEMO,PATIENT TINA           9321

```

```

Allergies: BECLOMETHASONE INHALER~BACTRIM~ALBUTEROL
5 DEMO,PATIENT MARYJANE 6233
Allergies: ATENOLOL~CAPTOPRIL~FOSINOPRIL~STEROIDS~ALBUTEROL~SIMVASTATIN
6 DEMO,PATIENT LARRY 2934
Allergies: ERYTHROMYCIN~ALBUTEROL
7 DEMO,PATIENT HEATHER 4540
Allergies: ALBUTEROL
8 DEMO,PATIENT NICOLE 9851
Allergies: PENICILLIN~ALBUTEROL
+ Select a patient >>>
EE Entered in Error PR Add/Edit Patient Reaction
UR Update to new reactant DD Allergy Detailed Display
AE Add/Edit Allergy File
Select Item(s): Next Screen// UR

```

You are about to update the selected patient's
ALBUTEROL allergy to a new reactant.

ARE YOU SURE? NO// YES

For patient DEMO,PATIENT MAE

Enter Causative Agent: ALBUTEROL

Checking GMR ALLERGIES (#120.82) file for matches...

You selected ALBUTEROL
Is this correct? Y// NO

Now checking the National Drug File - Generic Names (#50.6)

- 1 ALBUTEROL
- 2 ALBUTEROL/IPRATROPIUM

CHOOSE 1-2:

Now checking the National Drug File - Trade Names (#50.67)

Choose from the following 38 matches:

- 1 ALBUTEROL
 - 2 ALBUTEROL 0.083% INHAL SOLN
 - 3 ALBUTEROL 0.083% SOLN
 - 4 ALBUTEROL 0.83% SOLN
 - 5 ALBUTEROL 2 MG TABLETS
 - 6 ALBUTEROL 90MCG INHALER
 - 7 ALBUTEROL HFA
 - 8 ALBUTEROL INHALATION AEROSOL
 - 9 ALBUTEROL SO4 0.5% 5ML
 - 10 ALBUTEROL SO4 2MG TABLET
 - 11 ALBUTEROL SO4 2MG/5ML SYRUP
 - 12 ALBUTEROL SO4 4MG TABLET
 - 13 ALBUTEROL SOLUTION
 - 14 ALBUTEROL SULFATE
 - 15 ALBUTEROL SULFATE 0.083% SOLN,INHL
 - 16 ALBUTEROL SULFATE 0.5% INHALATION SOL
 - 17 ALBUTEROL SULFATE 0.5% SOLN
 - 18 ALBUTEROL SULFATE 2MG TABLET
- Press <return> to see more, or ^ to stop ...
- 19 ALBUTEROL SULFATE 2MG TABS
 - 20 ALBUTEROL SULFATE 2MG/5ML SYRUP
 - 21 ALBUTEROL SULFATE 4MG ER TABLET
 - 22 ALBUTEROL SULFATE 4MG TAB

```

23  ALBUTEROL SULFATE 4MG TABS
24  ALBUTEROL SULFATE 8MG ER TABLET
25  ALBUTEROL SULFATE POWDER
26  ALBUTEROL SULFATE SOLUTION FOR INHALATION
27  ALBUTEROL SULFATE SYRUP
28  ALBUTEROL SULFATE TABLETS
29  ALBUTEROL SULFATE TABLETS 2MG
30  ALBUTEROL SULFATE TABLETS 4MG
31  ALBUTEROL SULFATE TABLETS, 2MG
32  ALBUTEROL SULFATE TABLETS, 4MG
33  ALBUTEROL SULFATE TABS
34  ALBUTEROL SULFATE,USP
35  ALBUTEROL SYRUP
36  ALBUTEROL TABLET
37  ALBUTEROL TABLETS
Press <return> to see more, or ^ to stop ...
38  ALBUTEROL TABS
Select 1-38:

Now checking INGREDIENT (#50.416) file for matches...

    ...OK? Yes// N (No)

Now checking VA DRUG CLASS (#50.605) file for matches...

Could not find ALBUTEROL in any files.
Please try again (check spelling, etc).
If you need to add a new reactant, use the AE option.
Enter Causative Agent: ALBUTEROL

Checking GMR ALLERGIES (#120.82) file for matches...

You selected ALBUTEROL
Is this correct? Y// NO

Now checking the National Drug File - Generic Names (#50.6)

    1  ALBUTEROL
    2  ALBUTEROL/IPRATROPIUM
CHOOSE 1-2: 1  ALBUTEROL

You selected ALBUTEROL
Is this correct? Y//YES

Reactant Detailed Display    Apr 26, 2011 12:23:55    Page: 1 of 3
Patient listing for reactant ALBUTEROL
  Patient Name                Last 4
1  DEMO,PATIENT LEE           5900
Allergies: ALBUTEROL
2  DEMO,PATIENT KEITH        9160
Allergies: PENICILLIN~RAPAMUNE~ACETAMINOPHEN/HYDROCODONE~ALBUTEROL
3  DEMO,PATIENT TINA         9321
Allergies: BECLOMETHASONE INHALER~BACTRIM~ALBUTEROL
4  DEMO,PATIENT MARYJANE     6233
Allergies: ATENOLOL~CAPTOPRIL~FOSINOPRIL~STEROIDS~ALBUTEROL~SIMVASTATIN
5  DEMO,PATIENT LARRY        2934
Allergies: ERYTHROMYCIN~ALBUTEROL
6  DEMO,PATIENT HEATHER      4540
Allergies: ALBUTEROL
7  DEMO,PATIENT NICOLE       9851
Allergies: PENICILLIN~ALBUTEROL

```

```

8 DEMO,PATIENT LATRICIA 5423
Allergies: ALBUTEROL~ERYTHROMYCIN
+ Select a patient >>>
EE Entered in Error PR Add/Edit Patient Reaction
UR Update to new reactant DD Allergy Detailed Display
AE Add/Edit Allergy File
Select Item(s): Next Screen//

Allergy Tracking Update Apr 26, 2011 10:34:42 Page: 1 of 18
Allergy Tracking Free Text Entries
  Reactant # Active Entries
1 AC I/ARB 1
2 ACEI 3
3 ACTIFED 1
4 ADVERSE DRUG REACTION H202 1
5 AKE: ACI 1
6 ALBUTEROL 22
7 ALENDRONATE 7
8 ALL ANTIBIOTIC UNKNOWN 1
9 ALL DYES 1
10 ALL EYE DROPS 1
11 ALL NSAIDS 1
12 ALL TAPES 1
13 ALLERGIC TO DYE 1
14 AMITRIPTYLINE 24
15 AMLODIPINE 30
16 AMOXICILLIN 700
17 AMPICILLIN 110
+ Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Next Screen// 2

Allergy Tracking Update Apr 26, 2011 10:35:06 Page: 1 of 18
Allergy Tracking Free Text Entries
  Reactant # Active Entries
1 AC I/ARB 1
2 ACEI 3
3 ACTIFED 1
4 ADVERSE DRUG REACTION H202 1
5 AKE: ACI 1
6 ALBUTEROL 22
7 ALENDRONATE 7
8 ALL ANTIBIOTIC UNKNOWN 1
9 ALL DYES 1
10 ALL EYE DROPS 1
11 ALL NSAIDS 1
12 ALL TAPES 1
13 ALLERGIC TO DYE 1
14 AMITRIPTYLINE 24
15 AMLODIPINE 30
16 AMOXICILLIN 700
17 AMPICILLIN 110
+ Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Next Screen// DD

Reactant Detailed Display Apr 26, 2011 10:36:27 Page: 1 of 1
Patient listing for reactant ACEI
Patient Name Last 4

```

```
1 DEMO,PATIENT LYNN 7968
Allergies: ACE INHIBITORS~ACEI
2 PATIENT,CRSAG
Allergies: ACEI~ARBUTAMINE HYDROCHLORIDE~ARB
3 PATIENT,CRSFC
Allergies: ACEI~ANGIOTENSIN II INHIBITOR~TDAP
```

```
          Select a patient >>>
EE Entered in Error          PR Add/Edit Patient Reaction
UR Update to new reactant    DD Allergy Detailed Display
AE Add/Edit Allergy File
Select Item(s): Quit// 1
```

```
Reactant Detailed Display Apr 26, 2011 10:38:15 Page: 1 of 1
Patient listing for reactant ACEI
  Patient Name          Last 4
1 DEMO,PATIENT LYNN 7968
Allergies: ACE INHIBITORS~ACEI
2 PATIENT,CRSAG
Allergies: ACEI~ARBUTAMINE HYDROCHLORIDE~ARB
3 PATIENT,CRSFC
Allergies: ACEI~ANGIOTENSIN II INHIBITOR~TDAP
```

```
          Select a patient >>>
EE Entered in Error          PR Add/Edit Patient Reaction
UR Update to new reactant    DD Allergy Detailed Display
AE Add/Edit Allergy File
Select Item(s): Quit// EE
```

You are about to mark the selected patient's
ACEI allergy as entered in error.

ARE YOU SURE? NO// Y (YES)

```
Reactant Detailed Display Apr 26, 2011 10:40:34 Page: 1 of 1
Patient listing for reactant ACEI
  Patient Name          Last 4
1 PATIENT,CRSAG
Allergies: ACEI~ARBUTAMINE HYDROCHLORIDE~ARB
2 PATIENT,CRSFC
Allergies: ACEI~ANGIOTENSIN II INHIBITOR~TDAP
```

```

                Select a patient                                >>>
EE  Entered in Error                                         PR  Add/Edit Patient Reaction
UR  Update to new reactant                                   DD  Allergy Detailed Display
AE  Add/Edit Allergy File
Select Item(s): Quit//
```

Add/Edit Patient Reaction: This option can be used to add additional reactions for the patient. This option should be used to add NEW reactions only. If existing entries are marked as entered in error from within this option it will not update the utility's display until the list is rebuilt upon re-entry of this option. This could cause confusion as the list will no longer be accurate.

Add/Edit Allergy File: The addition of local reactants and signs/symptoms is no longer allowed. Requests for new terms should be made through the RPMS Feedback page.

3.2.6.2 Ingredient

See section 3.2.6.1. This option is used to identify reactions linked to the DRUG INGREDIENTS file. Sites may choose to update these reactions to entries from the NATIONAL DRUG file. For now, reactions associated with the DRUG INGREDIENTS file will still order check, though this may change in the future. Sites are encouraged to review future patch notes carefully.

3.2.6.3 Drug Class

See section 3.2.6.1. This option is used to identify reactions linked to the VA DRUG CLASS file. Sites may choose to update these reactions to link to the NATIONAL DRUG file. For now, reactions associated with the VA DRUG CLASS file will still order check, though this may change in the future. Sites are encouraged to review future patch notes carefully.

3.3 Adverse Reaction Tracking User Menu (GMRA USER MENU)

This menu is assigned to all users of Adverse Reaction Tracking who are not clinicians, verifiers, or Application Coordinators. The options in 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

3.3.1 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, the source of the information, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction and the source, the date and time the sign/symptom occurred, the SNOMED event type, any appropriate comments concerning the entry, and whether the patient's ID Band/Chart is marked for the reaction.

Selecting a Patient: The user may select a patient by name or portion of name (last name, first name; a comma must follow the last name and no space after the comma), IHS chart number (e.g. 12345), date of birth (e.g., 01-22-66 or 01/22/66 or Jan 22, 1966), ward location (e.g., PEDIATRICS), or Room-Bed (e.g., 101-2).

Assessing the Patient: If the selected patient does not have any allergies/adverse reactions stored in the ART database, the user is asked "Does this patient have any known allergies or adverse reactions?". A Yes response will allow the user to make an entry. A No response will mark the patient as "No Known Allergies" and return to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient, the software will not ask the 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 (drug, food, other, or a combination), any signs/symptoms and the source, the mechanism (allergy or pharmacologic), whether it was observed or historical, and whether or not it was verified.

It is now possible to delete an assessment of "No Known Allergies" or NKA from within the ART package. When a patient is selected that has no active allergies in file, the question will be presented in one of two ways. If there has been no assessment, there is no default answer. If the patient has been assessed as "No Known Allergies", the default will be NO. In the case where the default answer is NO (meaning the patient is NKA), the user may enter "@" (the "at" sign) to indicate the assessment should be deleted and the patient should be returned to the "not assessed" state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

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 will have the opportunity to edit the data concerning that entry.
2. If the response is not part of that patient's entry or the user does not want to edit and 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,
 - b. NATIONAL DRUG (50.6) – this file contains the names of available drug products including trade names and manufacturer,
 - c. NATIONAL DRUG, Trade Names (50.67) – this file contains the trade names for the NATIONAL DRUG file
 - d. DRUG INGREDIENTS (50.416) – this file contains the names of individual generic drugs and other agents that are components of various drug products,
 - e. VA DRUG CLASS (50.605) – this file contains the names of the various drug classes.
3. If the reactant is not found after steps 1 and 2, then the user is asked “Would you like to send an email requesting (the reactant) be added as a causative agent?” If the answer is NO, the user will be returned to the reactant lookup; if the answer is YES, the user will see the message

“You may now add any comments you may have to the message that is going to be sent with the request to add this reactant. You may add things like signs/symptoms, observed or historical, etc., that may be useful to the reviewer.

Enter RETURN to continue or “^” to exit:”

If enter is pressed, the user is allowed to enter comments, and when the comments are saved, the user will see the message

“Message sent – NOTE: This reactant was NOT added for this patient.

Enter another Causative Agent? YES//”

If the answer is YES, the user is returned to the reactant lookup prompt; if the answer is NO, the user is returned to the patient lookup prompt. A mailman message is generated to the user making the request and to the Mail Group GMRA REQUEST NEW REACTANT, containing the comment entered, the user name and contact information, patient, and the reactant.

Source: The user is able to select the source of the reactant information. Available choices are Chart Review, External Source, Family, Friend, Medical Provider, Other Source, Patient, or Spouse.

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 person entering the data), the severity of the reaction (i.e., mild, moderate, or severe), and the date a medical doctor was notified. The user will only see these prompts if they hold the GMRA-ALLERGY VERIFY key. Also, the user may edit the date and time of the observation.

Signs/Symptoms: The user may choose to assign one or more signs/symptoms to the reaction. The site should have a "top 10" list of symptoms and the option to choose one not on the main list. The Signs/Symptoms file is no longer editable locally, and the user is no longer allowed to enter a free text sign/symptom. Once a sign/symptom has been chosen, the user may enter the date the sign/symptom occurred, and the source of the information about the sign/symptom. The time of day may be entered, but it is optional.

SNOMED Event Code: The user is prompted to choose a SNOMED Event code. This event code along with the Type (Nature of Reaction) will be used to map to the old Mechanism; neither Type nor Mechanism will be user selectable. The table below shows the Event Codes available, and the Mechanism and Type (Nature of Reaction) they are mapped to.

The Mechanism is the way the reaction is mediated. The options are Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent due to an immune-mediated response. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to a drug or drug ingredient due to a non-immune mediated response. Unknown is used for non-medication reactions or when the user is unsure of the mechanism. NOTE: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

The Type (Nature of Reaction) is what type of substance causes the reaction. The options are Food, Drug, Other, or combinations of the three types. These are set in the GMR ALLERGIES file or other files used to link to the causative agent. These are no longer editable by the user.

SNOMED Event	Type (Nature of Reaction)	Mechanism
Allergy to Substance	Other Drug, Food Drug, Other Food, Other	Unknown
Drug Allergy	Drug	Allergy
Drug Intolerance	Drug	Pharmacologic
Food Allergy	Food	Allergy
Food Intolerance	Food	Unknown
Propensity to Adverse Reactions	Other Drug, Food Drug, Other Food, Other	Unknown
Propensity to Adverse Reaction to Substance	Other	Unknown
Propensity to Adverse Reaction to Drug	Drug	Pharmacologic
Propensity to Adverse Reaction to Food	Food	Unknown

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 for reactions designated as observed. If the entry is being edited and any existing comments exist for this causative agent, the software will display those comments and their author (the originator of the entry, a verifier, or a person who marked the entry as entered in error). This is only true for OBSERVED type reactions. Comments entered for reactions designated as historical are optional. NOTE: sites are strongly encouraged to enter comments for reactions marked entered in error for auditing purposes.

FDA Data: When the type of 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 they hold 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 sites 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 GMRA-ALLERGY VERIFY key, 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.

Signing off on an Entry: Signing off (i.e. answering YES to “Is this 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.

Previous versions of the software allowed users to leave entries in a “not signed off” state. Although not complete, the allergy became part of the patient’s record, even though the user was told it would not be. Depending on how the entry was made, an alert might not be sent indicating that the entry needed to be signed off. Ultimately, an unfinished entry might never be finished, but still appear in the patient’s record.

A change has been made so that no new entry can be left in a “not signed off” state. Upon entering a new reaction, if the user enters an “^” at any point during the data gathering process, the entry will be deleted. Upon completing the new entry, the user will be asked if the entry is okay. If the answer is NO, the user will be given the opportunity to edit or delete the entry. The entry must then be deleted or accepted before exiting the process. As a result, no new entries will be allowed to be in an unsigned state.

NOTE: sites should run the “Patient Allergies Not Signed Off” option to identify all existing entries that have not yet been completed. Each entry should be reviewed and marked as entered in error or completed by entering the required information. Once these entries are cleaned up, then no unsigned entries should appear in the patient’s record. The user is not required to update these entries as data may not be available, but the user should review them and take action if possible. The post-installation routine will also list any reactions that are observed, have been signed off, but are missing either an observed date or a sign/symptom. These entries should also be reviewed and updated if possible.

Example:

```
Select Adverse Reaction Tracking Option: 2  Adverse Reaction Tracking User Menu
```

- 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

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

Select PATIENT NAME: DEMO

1	DEMO,ALLERGY CHARLES	<A>	M	11-02-1969	XXX-XX-5701	WW	104836
2	DEMO,ALLERGY CONNIE	<A>	F	10-24-1933	XXX-XX-4127	WW	110211
3	DEMO,ALLERGY LEANN	<A>	F	12-04-1946	XXX-XX-9435	WW	150673
4	DEMO,AMILYA PEARL		F	06-30-2008	XXX-XX-0821	WW	106735
5	DEMO,AUSTIN WAYNE		M	** SENSITIVE **		WW	192640

ENTER '^' TO STOP, OR

CHOOSE 1-5: 2

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
-----	-----	----	-----	-----	-----
BEN-GAY		YES	UNKNOWN	HIST	DRUG

Enter Causative Agent: IBUPROFEN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

IBUPROFEN OK? Yes// N (No)

Now checking the National Drug File - Generic Names (#50.6)

1	IBUPROFEN
2	IBUPROFEN/PSEUDOEPHEDRINE

CHOOSE 1-2: 1 IBUPROFEN

IBUPROFEN OK? Yes// (Yes)

SOURCE: ?

Only allow items designates as a source of information

Answer with BEH ALLERGY VALUES NAME

Do you want the entire BEH ALLERGY VALUES List? Y (Yes)

Choose from:

- CHART REVIEW
- EXTERNAL SOURCE
- FAMILY
- FRIEND
- MEDICAL PROVIDER
- OTHER SOURCE
- PATIENT
- SPOUSE

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

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

- | | |
|----------------------------|------------------------|
| 1. ANXIETY | 7. HIVES |
| 2. ITCHING | 8. DYSPEPSIA |
| 3. SWELLING (NON-SPECIFIC) | 9. ANAPHYLAXIS |
| 4. DROWSINESS | 10. RASH |
| 5. NAUSEA,VOMITING | 11. OTHER SIGN/SYMPTOM |
| 6. DIARRHEA | |

Enter from the list above : 11

Select SIGN/SYMPTOMS NAME: GI REACTION NATIONAL SIGN/SYMPTOM

Select SIGN/SYMPTOMS NAME:

Date(Time Optional) of appearance of Sign/Symptom(s): 4-4-1973 (APR 04, 1973)

Select source: ?

Answer with BEH ALLERGY VALUES NAME

Do you want the entire BEH ALLERGY VALUES List? Y (Yes)

Choose from:

CHART REVIEW
EXTERNAL SOURCE
FAMILY
FRIEND
MEDICAL PROVIDER
OTHER SOURCE
PATIENT
SPOUSE

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

Signs/Symptoms	Date Observed

1 GI REACTION	Apr 04, 1973

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

SNOMED EVENT: ??

Choose from:

ALLERGY TO SUBSTANCE
DRUG ALLERGY
DRUG INTOLERANCE
FOOD ALLERGY
FOOD INTOLERANCE
PROPENSITY TO ADVERSE REACTIONS
PROPENSITY TO ADVERSE REACTIONS TO DRUG
PROPENSITY TO ADVERSE REACTIONS TO FOOD
PROPENSITY TO ADVERSE REACTIONS TO SUBSTANCE

COMMENTS:

No existing text

Currently you have verifier access.

Would you like to verify this Causative Agent now? Yes// N (No)

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE

BEN-GAY		YES	UNKNOWN	HIST	DRUG
IBUPROFEN	SPOUSE	NO	PHARM	HIST	DRUG

Reactions: GI REACTION(Source: SPOUSE)

Enter Causative Agent: PENICILLIN

```

Checking existing PATIENT ALLERGIES (#120.8) file for matches...
Now checking GMR ALLERGIES (#120.82) file for matches...

    PENICILLIN    OK? Yes//    (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: O  OBSERVED
Select date reaction was OBSERVED (Time Optional):  6-23-2001  (JUN 23, 2001)
JUN 23, 2001  (JUN 23, 2001)
  Are you adding 'JUN 23, 2001' as

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

The following are the top ten most common signs/symptoms:
  1. ANXIETY                7. HIVES
  2. ITCHING                8. DYSPEPSIA
  3. SWELLING (NON-SPECIFIC) 9. ANAPHYLAXIS
  4. DROWSINESS            10. RASH
  5. NAUSEA,VOMITING       11. OTHER SIGN/SYMPTOM
  6. DIARRHEA

Enter from the list above :  9
Date(Time Optional) of appearance of Sign/Symptom(s): Jun 23, 2001//  (JUN 23, 2001)

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

      Signs/Symptoms                Date Observed
-----
  1  ANAPHYLAXIS                    Jun 23, 2001

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

COMMENTS:
  No existing text

Complete the observed reaction report? Yes//  (Yes)
DATE/TIME OF EVENT: JUN 23,2001//
OBSERVER: DEMO,DOCTOR
SEVERITY: ?

MILD      - Requires minimal therapeutic intervention such as
            discontinuation of drug(s).
MODERATE  - Requires active treatment of adverse reaction, or
            further testing or evaluation to assess
            extent of non-serious outcome (see SEVERE for
            definition of serious).
SEVERE    - Includes any serious outcome, resulting in life or organ
            threatening situation or death, significant or permanent
            disability, requiring intervention to prevent permanent
            impairment or damage, or requiring/prolonging
            hospitalization.

Choose from:
  1      MILD
  2      MODERATE
  3      SEVERE
SEVERITY: SEV  SEVERE
DATE MD NOTIFIED: Jun 23,2001//  (JUN 23, 2001)
Complete the FDA data? Yes//  (Yes)
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//

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

Signs/Symptoms

1 ANAPHYLAXIS

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

Patient died?: N NO
 Reaction treated with RX drug?: Y YES
 Life Threatening illness?: Y YES
 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?: YES

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

Select Action (A/D/E): ?

ENTER A TO ADD NEW LAB DATA, D TO DELETE LAB DATA OR
 E TO EDIT LAB DATA ON FILE FOR THIS PATIENT

Select one of the following:

A	ADD
D	DELETE
E	EDIT

Select Action (A/D/E):

This patient has the following Drugs selected:

PENICILLIN

Select Action (A/D/E):

THIS PATIENT HAS NO CONCOMITANT DRUGS ON FILE

Select Action (A/D/E):

OTHER RELATED HISTORY:

No existing text

REPORTER NAME: PHARMACIST,PHARMACIST Replace

REPORTER ADDRESS1: DEMO INDIAN MEDICAL CENTER

REPORTER ADDRESS2: 100 S. MAIN//

REPORTER ADDRESS3:

REPORTER CITY: ANYTOWN//

REPORTER STATE: OKLAHOMA//

REPORTER ZIP: 74464//

REPORTER PHONE: 555-123-4567//

IS REPORTER A HEALTH CARE PROVIDER?: Y YES

Do you want the identity disclosed to the manufacturer?: N NO

OCCUPATION: PHARMACIST//

Currently you have verifier access.

Would you like to verify this Causative Agent now? Yes// N (No)

Causative Agent Data edited this Session:
ADVERSE REACTION

1) IBUPROFEN

Obs/Hist: HISTORICAL
Signs/Symptoms: GI REACTION (4/4/73)

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:38:44

User: NIESEN, MARY ANN

Title: PHARMACIST

SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
ALL NSAIDS

2) PENICILLIN

Obs/Hist: OBSERVED
Obs d/t: Jun 23, 2001
Signs/Symptoms: ANAPHYLAXIS (6/23/01)

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:40:11

User: NIESEN, MARY ANN

Title: PHARMACIST

REACTION WAS SEEN AND TREATED IN THE ER BUT NOT ADDED TO
ADVERSE REACTIONS

Are ALL these correct? NO// YES

This session you have CHOSEN:

IBUPROFEN
PENICILLIN

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

Select PATIENT NAME: demo

1	DEMO, ALLERGY CHARLES	<A>	M	11-02-1969	XXX-XX-5701	WW	104836
2	DEMO, ALLERGY CONNIE	<A>	F	10-24-1933	XXX-XX-4127	WW	110211
3	DEMO, ALLERGY LEA	<A>	F	12-04-1946	XXX-XX-9435	WW	150673
4	DEMO, AMILYA PEARL		F	06-30-2008	XXX-XX-0821	WW	106735
5	DEMO, AUSTIN WAYNE		M	** SENSITIVE **		WW	192640

ENTER '^' TO STOP, OR

CHOOSE 1-5: 1

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
AMOXICILLIN	PATIENT	NO	ALLERGY	HIST	DRUG
WALNUTS		NO	UNKNOWN	HIST	FOOD
Reactions: GI REACTION(Source:)					
BEE STINGS		AUTO	UNKNOWN	HIST	OTHER

Enter Causative Agent: SPONGEBOB

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

Now checking the National Drug File - Generic Names (#50.6)

```

Now checking the National Drug File - Trade Names (#50.67)
Now checking the INGREDIENTS (#50.416) file for matches...
Now checking VA DRUG CLASS (50.605) file for matches...
Could not find SPONGEBOB in any files.

Before sending an email requesting the addition of a new reactant, please
try entering the first 3 or 4 letters of the reactant to search for
the desired entry.

Would you like to send an email requesting SPONGEBOB
be added as a causative agent?
Send email? NO// YES

You may now add any comments you may have to the message that
is going to be sent with the request to add this reactant.
You may want to add things like sign/symptoms, observed or historical, etc
that may be useful to the reviewer.

Enter RETURN to continue or '^' to exit:

==[ WRAP ]==[ INSERT ]=====< >===== [ <PF1>H=Help ]====
THIS PATIENT REPORTS A VIOLENT REACTION TO WATCING SPONGEBOB.

<=====T=====T=====T=====T=====T=====T=====T=====T=====T=====>=====

Message sent - NOTE: This reactant was NOT added for this patient.

Enter another Causative Agent? YES// NO

```

Mark a Reaction Entered in Error/Inactivate a reaction: A user may mark a reaction as entered in error. “Entered in Error” should *only* be used if the information is truly in error on the patient (i.e., entered on the wrong patient or using the wrong causative agent). Inactivation should be used for previous reactions that are no longer an issue for the patient (i.e., ibuprofen caused a GI upset reaction but the patient has found a variety of ibuprofen that is tolerable and now takes it routinely).

The user may select a patient, and a listing of the existing reaction entries will be shown. The user may select a reaction, and at the prompt "Is the reaction information correct?", select NO. The user will then see the prompt "Mark this reaction as 'Entered-in-Error'?" and may answer YES to make the reaction entered in error. Answering this question NO will bring the user to a second prompt "Inactivate this reaction?" Answer YES to make the reaction inactive. The user will be required to enter an inactivation reason. Options are NO LONGER ALLERGIC or REACTION IS TOLERABLE.

Example:

```

Select Adverse Reaction Tracking Option: 2  Adverse Reaction Tracking User Menu

 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

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

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
 2 DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
 3 DEMO,ALLERGY LEANN <A>  F 12-04-1946 XXX-XX-9435  WW 150673
 4 DEMO,AMILYA PEARL      F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE     M  ** SENSITIVE **          WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT                SOURCE          VER.   MECH.   OBS/
-----                -
BEN-GAY                  YES           UNKNOWN HIST   DRUG
IBUPROFEN                SPOUSE        NO      PHARM   HIST   DRUG
  Reactions: GI REACTION(Source: SPOUSE)
PENICILLIN                CHART REVIEW  NO      ALLERGY OBS    DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)
WALNUTS                   PATIENT       NO      UNKNOWN HIST   FOOD
  Reactions: HIVES(Source: PATIENT)

Enter Causative Agent: BEN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

                <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  BEN-GAY
  BEN-GAY  OK? Yes//  (Yes)

  PATIENT: DEMO,ALLERGY CONNIE CAUSATIVE AGENT: BEN-GAY
  INGREDIENTS:                VA DRUG CLASSES:

  ORIGINATOR: DAVIS,MARY J      ORIGINATED: Jul 15, 2004@09:00
  SIGN OFF: YES                 OBS/HIST: HISTORICAL

```

ID BAND MARKED: CHART MARKED: Jul 15, 2004@09:00:32

MECHANISM: UNKNOWN

VERIFIER: DAVIS, MARY J VERIFIED: JUL 20, 2004@10:59:19

Is the reaction information correct? Yes// N (No)

Mark this reaction as 'Entered-in-Error'? YES

COMMENTS:

No existing text

Edit? NO// YES

==[WRAP]==[INSERT]===== < COMMENTS > =====[<PF1>H=Help]====
 THIS REACTION IS NOT FOR THIS PATIENT, ACCIDENTALLY ENTERED ON
 WRONG PATIENT.

<=====T=====T=====T=====T=====T=====T=====T=====T=====T>=====

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
IBUPROFEN	SPOUSE	NO	PHARM	HIST	DRUG
Reactions: GI REACTION(Source: SPOUSE)					
PENICILLIN	CHART REVIEW	NO	ALLERGY	OBS	DRUG
Reactions: ANAPHYLAXIS(Source: CHART REVIEW)					
WALNUTS	PATIENT	NO	UNKNOWN	HIST	FOOD
Reactions: HIVES(Source: PATIENT)					

Enter Causative Agent: WALN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

<A> F 10-24-1933 XXX-XX-4127 WW 110211
 WALNUTS
 WALNUTS OK? Yes// (Yes)

PATIENT: DEMO, ALLERGY CONNIE CAUSATIVE AGENT: WALNUTS

SOURCE OF INFORMATION: PATIENT
 ORIGINATOR: NIESEN, MARY ANN ORIGINATED: Apr 27, 2011@09:58
 SIGN OFF: YES OBS/HIST: HISTORICAL
 EVENT: FOOD INTOLERANCE CODE: 235719002

```

ID BAND MARKED:                                CHART MARKED: Apr 27, 2011@09:59:49

SIGNS/SYMPTOMS: HIVES (Jan 29, 2010) SOURCE: PATIENT

      MECHANISM: UNKNOWN
Is the reaction information correct? Yes// N (No)
Mark this reaction as 'Entered-in-Error'? NO
Inactivate this reaction? YES
Select reason: ??

Choose from:
NO LONGER ALLERGIC
REACTION IS TOLERABLE

Select reason: NO LONGER ALLERGIC
Enter another Causative Agent? YES// NO

```

3.3.2 Active listing of Patient Reactions

This option will give a brief listing of the active (i.e., data that is signed off and not inactive or 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, IHS chart number, 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, SNOMED event and code, 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 assessed for reactions, the body of the report will display a message stating that there is no reaction data on file.

Example:

```

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

Select PATIENT: DEMO
 1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
 2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
 3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
 4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
 5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211

DEVICE: HOME// VIRTUAL TERMINAL

ACTIVE ALLERGY/ADVERSE REACTION LISTING
Run Date/Time: 4/27/11 1:43:36 pm

```

ADVERSE REACTION	VERIFIED	OBS/ HIST

TYPE: DRUG		
=====		
IBUPROFEN	NO	HIST
EVENT: DRUG INTOLERANCE		
SNOMED CODE: 59037007		
Reactions: GI REACTION (Apr 04, 1973)		
PENICILLIN	NO	OBS
EVENT: DRUG ALLERGY		
SNOMED CODE: 416098002		
Reactions: ANAPHYLAXIS (Jun 23, 2001)		
Enter RETURN to continue or '^' to exit:		

3.3.3 Edit Chart and ID Band

This option allows sites to update the ID Band marking status. All questions and displays regarding chart marking have been removed, since the entry of a reaction into ART is the marking of the chart.

The user may select a patient, and is then shown a list of reactions for that patient (active and inactive). The user may select one or more reactions. When done selecting reactions, the system will automatically change these to indicate the ID Band has been marked.

Example:

Select Adverse Reaction Tracking User Menu Option: 3 Edit Chart and ID Band			
Select Patient: demo			
1	DEMO,ALLERGY CHARLES	<A> M 11-02-1969 XXX-XX-5701	WW 104836
2	DEMO,ALLERGY CONNIE	<A> F 10-24-1933 XXX-XX-4127	WW 110211
3	DEMO,ALLERGY LEANN	<A> F 12-04-1946 XXX-XX-9435	WW 150673
4	DEMO,AMILYA PEARL	F 06-30-2008 XXX-XX-0821	WW 106735
5	DEMO,AUSTIN WAYNE	M ** SENSITIVE **	WW 192640
ENTER '^' TO STOP, OR			
CHOOSE 1-5: 2			
CHOOSE FROM:			
IBUPROFEN			
PENICILLIN			
WALNUTS (Inactive)			
Select CAUSATIVE AGENT: IBUPROF			
	<A>	F 10-24-1933 XXX-XX-4127	WW 110211
IBUPROFEN			
Select another CAUSATIVE AGENT: PEN			
	<A>	F 10-24-1933 XXX-XX-4127	WW 110211
PENICILLIN			
Select another CAUSATIVE AGENT: WALN			
	<A>	F 10-24-1933 XXX-XX-4127	WW 110211

```

WALNUTS

Select another CAUSATIVE AGENT:
This session you have CHOSEN:
  IBUPROFEN
  PENICILLIN
  WALNUTS

```

3.3.4 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 of ID bands marked. 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). This applies to Inpatients only. When entering a reaction on an Outpatient, the option to indicate if the ID Band had been marked is not available or displayed.

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, IHS chart number, name of the causative agent, and whether the patient ID band, chart, or both were unmarked.

Example:

```

Select Adverse Reaction Tracking User Menu Option: 4 List by Location of Unmark
ed 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):1
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, or TEAM
Do you want the entire HOSPITAL LOCATION List? y (Yes)
Choose from:
  ICU
  MEDICALSURGICAL
  NEWBORN
  OBSTETRICS

Select Location: ICU
Another Location: MEDICALSURGICAL
Another Location: NEWBORN
Another Location: OBSTETRICS
Another Location:

DEVICE: HOME// VIRTUAL TERMINAL

Apr 27,2011 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1
CURRENT INPATIENTS

```

PATIENT	SSN	ALLERGY	UNMARKED

WARD: ICU			
DEMO, TAMMY LYNN	18-73-35	PENICILLIN AMOXICILLIN	CHART CHART
Apr 27, 2011	PATIENTS WITH UNMARKED ID BAND/CHART		PAGE 2
CURRENT INPATIENTS			

WARD: MEDICALSURGICAL			
DEMO, LAVELDA WAPSKINEH	10-33-24	MORPHINE	CHART
DEMO, DOROTHY ROSE	99-99-99	COTTONSEED OIL	CHART
		WINE	CHART
DEMO, TAMBRA ANNETTE	17-27-79	SULFA	CHART
		ENALAPRIL	CHART
		GATIFLOXACIN	CHART
Apr 27, 2011	PATIENTS WITH UNMARKED ID BAND/CHART		PAGE 3
CURRENT INPATIENTS			

WARD: NEWBORN			
* No Patients for this Ward *			
Apr 27, 2011	PATIENTS WITH UNMARKED ID BAND/CHART		PAGE 4
CURRENT INPATIENTS			

WARD: OBSTETRICS			
DEMO, CRYSTAL ANN	19-73-28	DOXYCYCLINE	CHART

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

Example:

```
Select Adverse Reaction Tracking User Menu Option: 4 List by Location of Unmark
ed 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):1
Select Location: ALL
Do you mean ALL Locations? Yes// (Yes)
Another Location:
```

3.3.5 Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients who have not been signed off (completed) by the user entering the 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 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 IHS chart number, the causative agent, and the date/time the entry was made.

Example:

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

DEVICE: HOME// VIRTUAL TERMINAL

ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 4/27/11 2:08:19 pm

ORIGINATOR          PATIENT          ALLERGY          ORIGINATION DATE/TIME
-----
ADAIR,PETER DEMO,BABY(99-99-95) PENICILLIN      DEC 15, 2009@14:00
BARREL,SCOT A DEMO,DANIEL(13-34-45) IOD              JAN 14, 2004@09:53
BARREL,SCOT A DEMO,JUDY LY(13-80-30) PENICILLIN      MAR 24, 2004@10:15
BOWTIE,JEFF W DEMO,SARA(11-05-92) CLARITIN D     JUL 13, 2004@17:16
BOWTIE,JEFF W DEMO,SARA(11-05-92) UNKNOWN           JUL 13, 2004@17:17
BOWTIE,JEFF W DEMO,MARTA (11-06-54) SULFA             JUL 13, 2004@17:24
BOWTIE,JEFF W DEMO,ANNA JA(11-06-90) PENICILLIN      JUL 13, 2004@17:32
BOWTIE,JEFF W DEMO,KELSIE(11-07-01) CODEINE           JUL 13, 2004@17:38
BOWTIE,JEFF W DEMO,CAITLI (11-10-56) CECLOR           JUL 13, 2004@18:29
BOWTIE,JEFF W DEMO,JORDAN (11-11-22) CODEINE           JUL 13, 2004@18:39
BOWTIE,JEFF W DEMO,CHRYST(11-19-16) IBUPROFEN        JUL 13, 2004@19:54
BOWTIE,JEFF W DEMO,ALBE(11-62-28) CODEINE             JUL 13, 2004@20:07
BOWTIE,JEFF W DEMO,ROBERT (11-67-78) NONE             JUL 13, 2004@20:53
BOWTIE,JEFF W DEMO,TIERRA(11-68-30) ERTYTHROMYCIN    JUL 13, 2004@20:57
BOWTIE,JEFF W DEMO,BYRON G(11-69-67) VISTERIL        JUL 13, 2004@21:23
```

3.3.6 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 reactions. 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, IHS chart number, and provider. The room-bed will appear for current inpatients.

NOTE: This report will show patients as not having received an assessment if the assessment was entered after the end date of the range. For this reason, it is recommended to end the range with today. This can be done with an entry of "T" (for "Today") and the "Enter END Date (time optional): T//" prompt.

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

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

Example:

```
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.

Please note! This report will show patients as not having received an
assessment if the assessment was entered after the end date of
the range. For this reason, it is recommended to end the range
with today. This can be done with an entry of 'T' (for Today) at
the 'Enter END Date (time optional): T//' prompt.

Enter START Date (time optional): -90 (JAN 27, 2011)
Enter END Date (time optional): T// (APR 27, 2011)
Select Location: ALL
Do you mean ALL Locations? Yes// (Yes)
Another Location:

QUEUE TO PRINT ON
DEVICE: Home VIRTUAL TERMINAL [YOU CAN NOT SELECT A VIRTUAL TERMINAL]

Previously, you have selected queueing.
Do you STILL want your output QUEUED? Yes// N (No)
DEVICE: Home VIRTUAL TERMINAL

Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 1
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00

PATIENT SSN
-----

CLINIC: MED CLINIC
* No Patients for this Clinic *

Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 2
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00
```

PATIENT	SSN	PROVIDER

WARD: ICU		
DEMO,ALICIA LOUISE Room/Bed: 3011-1	160758	ASHLY, BARBARA A
DEMO, LOIS JEANNETTE	180836	JOE, HOWARD
DEMO, ADRIAN Room/Bed: 3012-1	212735	SMITH, GRETA LOUISE
ROADKILL, BUBBIT	253614	DEMO, DOCTOR

3.3.7 Print Patient Reaction Data

This option will allow the user to produce 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, IHS Chart number, date of birth, and age. The body of the report contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the source of the data, 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, the SNOMED Event and code, whether the patient ID band or chart is marked, a list of signs/symptoms, the mechanism, and additional comments made by the originator. For Inactive reactions it will also contain the inactive date, reason, and person who inactivated. A line of dots appears in the body of the report between the various reaction entries.

Example:

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

Select PATIENT: DEMO
 1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
 2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
 3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
 4 DEMO,AMILLYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
 5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1-3
Select 1:ACTIVE, 2:ENTERED IN ERROR, 3:INACTIVE
Which would you like to see?: (1-3): 1-3
```

DEVICE: HOME// VIRTUAL TERMINAL

ALLERGY/ADVERSE REACTION REPORTS

Run Date/Time: 4/27/11 2:16:22 pm

DEMO,ALLERGY CO 110211 OCT 24,1933 (77)

STATUS: ACTIVE

TYPE: DRUG
=====

AGENT: IBUPROFEN
INGREDIENTS: IBUPROFEN VA DRUG CLASSES: NONSALICYLATE NSAIs,A

SOURCE OF INFORMATION: SPOUSE
ORIGINATOR: NIESEN,MARY ANN ORIGINATED: Apr 27, 2011@07:37
SIGN OFF: YES OBS/HIST: HISTORICAL
EVENT: DRUG INTOLERANCE CODE: 59037007

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:38:44 User: NIESEN,MARY ANN
Title: PHARMACIST

SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
ALL NSAIDS

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973) SOURCE: SPOUSE

MECHANISM: PHARMACOLOGIC

.....
AGENT: PENICILLIN
INGREDIENTS: PENICILLIN VA DRUG CLASSES: (INACTIVE) PENICILLIN
PENICILLINS,AMINO DER

SOURCE OF INFORMATION: CHART REVIEW
ORIGINATOR: NIESEN,MARY ANN ORIGINATED: Apr 27, 2011@07:39
SIGN OFF: YES OBS/HIST: OBSERVED
EVENT: DRUG ALLERGY CODE: 416098002
SEVERITY: SEVERE OBS D/T: Jun 23, 2001

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:40:11 User: NIESEN,MARY ANN
Title: PHARMACIST

REACTION WAS SEEN AND TREATED IN THE ER BUT NOT ADDED TO
ADVERSE REACTIONS

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: ANAPHYLAXIS (Jun 23, 2001) SOURCE: CHART REVIEW

MECHANISM: ALLERGY

.....
STATUS: E/E

```

-----
TYPE: DRUG
=====

AGENT: BEN-GAY
INGREDIENTS: VA DRUG CLASSES:

ORIGINATOR: DAVIS,MARY J ORIGINATED: Jul 15, 2004@09:00
SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED: Jul 15, 2004@09:00:32

MECHANISM: UNKNOWN

VERIFIER: DAVIS,MARY J VERIFIED: JUL 20, 2004@10:59:19

USER ENTERING D/T ENTERED
IN ERROR: NIESEN,MARY ANN IN ERROR: APR 27, 2011@12:00:44

ENTERED IN ERROR
COMMENTS:
Date: Apr 27, 2011@12:00:44 User: NIESEN,MARY ANN
Title: PHARMACIST
THIS REACTION IS NOT FOR THIS PATIENT, ACCIDENTALLY
ENTERED ON WRONG PATIENT.

.....
STATUS: INACTIVE
-----
TYPE: FOOD
=====

AGENT: WALNUTS

SOURCE OF INFORMATION: PATIENT
ORIGINATOR: NIESEN,MARY ANN ORIGINATED: Apr 27, 2011@09:58
SIGN OFF: YES OBS/HIST: HISTORICAL
EVENT: FOOD INTOLERANCE CODE: 235719002

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

INACTIVE: APR 27, 2011@12:01:50
REASON: NO LONGER ALLERGIC BY: NIESEN,MARY ANN

SIGNS/SYMPTOMS: HIVES (Jan 29, 2010) SOURCE: PATIENT

MECHANISM: UNKNOWN

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

```

3.3.8 Online Reference Card

This option provides a very brief overview of entering patient reaction data. Users may navigate through the document using the up and down arrows on the keyboard:



Users may exit the online reference using the F1 key quickly followed by the E key:



3.4 Adverse Reaction Tracking Clinician Menu (GMRA CLINICIAN MENU)

This menu is assigned to all clinicians of Adverse Reaction Tracking who are not verifiers or Application Coordinators. The options on this menu allow users 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 ID band.

This menu should only be given to the clinicians of ART. This menu contains the following options:

1. Enter/Edit Patient Reaction Data
2. FDA Enter/Edit Menu...
3. Reports Menu...
4. Edit Chart and ID Band
5. Online Reference Card
6. Reactivate Reaction/Allergy
7. Unable to assess allergies

3.4.1 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, the source of the information, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction and the source, the date and time the sign/symptom occurred, the SNOMED event type, any appropriate comments concerning the entry, and whether the patient's ID Band/Chart is marked for the reaction.

Selecting a Patient: The user may select a patient by name or portion of name (last name, first name; a comma must follow the last name and no space after the comma), IHS chart number (e.g. 12345), date of birth (e.g., 01-22-66 or 01/22/66 or Jan 22, 1966), ward location (e.g., PEDIATRICS), or Room-Bed (e.g., 101-2).

Assessing the Patient: If the selected patient does not have any allergies/adverse reactions stored in the ART database, the user is asked “Does this patient have any known allergies or adverse reactions?”. A Yes response will allow the user to make an entry. A No response will mark the patient as “No Known Allergies” and return to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient, the software will not ask the 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 (drug, food, other, or a combination), any signs/symptoms and the source, the mechanism (allergy or pharmacologic), whether it was observed or historical, and whether or not it was verified.

It is now possible to delete an assessment of “No Known Allergies” or NKA from within the ART package. When a patient is selected that has no active allergies in file, the question will be presented in one of two ways. If there has been no assessment, there is no default answer. If the patient has been assessed as “No Known Allergies”, the default will be NO. In the case where the default answer is NO (meaning the patient is NKA), the user may enter “@” (the “at” sign) to indicate the assessment should be deleted and the patient should be returned to the “not assessed” state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

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 will have the opportunity to edit the data concerning that entry.
2. If the response is not part of that patient’s entry or the user does not want to edit and 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,
 - b. NATIONAL DRUG (50.6) – this file contains the names of available drug products including trade names and manufacturer,
 - c. NATIONAL DRUG, Trade Names (50.67) – this file contains the trade names for the NATIONAL DRUG file
 - d. DRUG INGREDIENTS (50.416) – this file contains the names of individual generic drugs and other agents that are components of various drug products,

- e. VA DRUG CLASS (50.605) – this file contains the names of the various drug classes.
- 3. If the reactant is not found after steps 1 and 2, then the user is asked “Would you like to send an email requesting (the reactant) be added as a causative agent?” If the answer is NO, the user will be returned to the reactant lookup; if the answer is YES, the user will see the message

“You may now add any comments you may have to the message that is going to be sent with the request to add this reactant. You may add things like signs/symptoms, observed or historical, etc., that may be useful to the reviewer.

Enter RETURN to continue or “^” to exit:”

If enter is pressed, the user is allowed to enter comments, and when the comments are saved, the user will see the message

“Message sent – NOTE: This reactant was NOT added for this patient.

Enter another Causative Agent? YES//”

If the answer is YES, the user is returned to the reactant lookup prompt; if the answer is NOE, the user is returned to the patient lookup prompt. A mailman message is generated to the user making the request and to the Mail Group GMRA REQUEST NEW REACTANT, containing the comment entered, the user name and contact information, patient, and the reactant.

Source: The user is able to select the source of the reactant information. Available choices are Chart Review, External Source, Family, Friend, Medical Provider, Other Source, Patient, or Spouse.

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 person 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 they hold the GMRA-ALLERGY VERIFY key.

Signs/Symptoms: The user may choose to assign one or more signs/symptoms to the reaction. The site should have a “top 10” list of symptoms and the option to choose one not on the main list. The Signs/Symptoms file is no longer editable locally, and the user is no longer allowed to enter a free text sign/symptom. Once a sign/symptom has been chosen, the user may enter the date the sign/symptom occurred, and the source of the information about the sign/symptom. The time of day may be entered, but it is optional.

SNOMED Event Code: The user is prompted to choose a SNOMED Event code. This event code along with the Type (Nature of Reaction) will be used to map to the old Mechanism; neither Type nor Mechanism will be user selectable. The table below shows the Event Codes available, and the Mechanism and Type (Nature of Reaction) they are mapped to.

The Mechanism is the way the reaction is mediated. The options are Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent due to an immune-mediated response. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to a drug or drug ingredient due to a non-immune mediated response. Unknown is used for non-medication reactions or when the user is unsure of the mechanism. NOTE: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

The Type (Nature of Reaction) is what type of substance causes the reaction. The options are Food, Drug, Other, or combinations of the three types. These are set in the GMR ALLERGIES file or other files used to link to the causative agent. These are no longer editable by the user.

SNOMED Event	Type (Nature of Reaction)	Mechanism
Allergy to Substance	Other Drug, Food Drug, Other Food, Other	Unknown
Drug Allergy	Drug	Allergy
Drug Intolerance	Drug	Pharmacologic
Food Allergy	Food	Allergy
Food Intolerance	Food	Unknown
Propensity to Adverse Reactions	Other Drug, Food Drug, Other Food, Other	Unknown
Propensity to Adverse Reaction to Substance	Other	Unknown

SNOMED Event	Type (Nature of Reaction)	Mechanism
Propensity to Adverse Reaction to Drug	Drug	Pharmacologic
Propensity to Adverse Reaction to Food	Food	Unknown

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 for reactions designated as observed. If the entry is being edited and any existing comments exist for this causative agent, the software will display those comments and their author (the originator of the entry, a verifier, or a person who marked the entry as entered in error). This is only true for OBSERVED type reactions. Comments entered for reactions designated as historical are optional. NOTE: sites are strongly encouraged to enter comments for reactions marked entered in error for auditing purposes.

FDA Data: When the type of 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 they hold 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 sites 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 GMRA-ALLERGY VERIFY key, 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.

Signing off on an Entry: Signing off (i.e. answering YES to “Is this 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.

Previous versions of the software allowed users to leave entries in a “not signed off” state. Although not complete, the allergy became part of the patient’s record, even though the user was told it would not be. Depending on how the entry was made, an alert might not be sent indicating that the entry needed to be signed off. Ultimately, an unfinished entry might never be finished, but still appear in the patient’s record.

A change has been made so that no new entry can be left in a “not signed off” state. Upon entering a new reaction, if the user enters an “^” at any point during the data gathering process, the entry will be deleted. Upon completing the new entry, the user will be asked if the entry is okay. If the answer is NO, the user will be given the opportunity to edit or delete the entry. The entry must then be deleted or accepted before exiting the process. As a result, no new entries will be allowed to be in an unsigned state.

NOTE: sites should run the “Patient Allergies Not Signed Off” option to identify all existing entries that have not yet been completed. Each entry should be reviewed and marked as entered in error or completed by entering the required information. Once these entries are cleaned up, then no unsigned entries should appear in the patient’s record. The user is not required to update these entries as data may not be available, but the user should review them and take action if possible. The post-installation routine will also list any reactions that are observed, have been signed off, but are missing either an observed date or a sign/symptom. These entries should also be reviewed and updated if possible.

Example:

```
Select Adverse Reaction Tracking Clinician Menu Option: 1  Enter/Edit Patient Re

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
 2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
 3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
 4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
 5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT SOURCE VER. MECH. OBS/
-----
BEN-GAY YES UNKNOWN HIST DRUG

Enter Causative Agent: IBUPROFEN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

IBUPROFEN OK? Yes// N (No)

Now checking the National Drug File - Generic Names (#50.6)
```

```

1  IBUPROFEN
2  IBUPROFEN/PSEUDOEPHEDRINE
CHOOSE 1-2: 1  IBUPROFEN
IBUPROFEN  OK? Yes//  (Yes)

SOURCE: ?
    Only allow items designates as a source of information
Answer with BEH ALLERGY VALUES NAME
Do you want the entire BEH ALLERGY VALUES List? Y  (Yes)
Choose from:
CHART REVIEW
EXTERNAL SOURCE
FAMILY
FRIEND
MEDICAL PROVIDER
OTHER SOURCE
PATIENT
SPOUSE

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

The following are the top ten most common signs/symptoms:
1. ANXIETY                7. HIVES
2. ITCHING                8. DYSPEPSIA
3. SWELLING (NON-SPECIFIC) 9. ANAPHYLAXIS
4. DROWSINESS            10. RASH
5. NAUSEA,VOMITING       11. OTHER SIGN/SYMPATOM
6. DIARRHEA

Enter from the list above : 11
Select SIGN/SYMPATOMS NAME: GI REACTION          NATIONAL SIGN/SYMPATOM
Select SIGN/SYMPATOMS NAME:
Date(Time Optional) of appearance of Sign/Symptom(s): 4-4-1973  (APR 04, 1973)
Select source: ?
Answer with BEH ALLERGY VALUES NAME
Do you want the entire BEH ALLERGY VALUES List? Y  (Yes)
Choose from:
CHART REVIEW
EXTERNAL SOURCE
FAMILY
FRIEND
MEDICAL PROVIDER
OTHER SOURCE
PATIENT
SPOUSE

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

      Signs/Symptoms                Date Observed
-----
1  GI REACTION                      Apr 04, 1973

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

Choose from:
ALLERGY TO SUBSTANCE
DRUG ALLERGY
DRUG INTOLERANCE
FOOD ALLERGY
FOOD INTOLERANCE

```

PROPENSITY TO ADVERSE REACTIONS
 PROPENSITY TO ADVERSE REACTIONS TO DRUG
 PROPENSITY TO ADVERSE REACTIONS TO FOOD
 PROPENSITY TO ADVERSE REACTIONS TO SUBSTANCE

COMMENTS:

No existing text

Currently you have verifier access.

Would you like to verify this Causative Agent now? Yes// N (No)

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
BEN-GAY		YES	UNKNOWN	HIST	DRUG
IBUPROFEN	SPOUSE	NO	PHARM	HIST	DRUG

Reactions: GI REACTION(Source: SPOUSE)

Enter Causative Agent: PENICILLIN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

PENICILLIN OK? Yes// (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: 0 OBSERVED

Select date reaction was OBSERVED (Time Optional): 6-23-2001 (JUN 23, 2001)

JUN 23, 2001 (JUN 23, 2001)

Are you adding 'JUN 23, 2001' as

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

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

- | | |
|----------------------------|-------------------------|
| 1. ANXIETY | 7. HIVES |
| 2. ITCHING | 8. DYSPEPSIA |
| 3. SWELLING (NON-SPECIFIC) | 9. ANAPHYLAXIS |
| 4. DROWSINESS | 10. RASH |
| 5. NAUSEA,VOMITING | 11. OTHER SIGN/SYMP TOM |
| 6. DIARRHEA | |

Enter from the list above : 9

Date(Time Optional) of appearance of Sign/Symptom(s): Jun 23, 2001// (JUN 23, 2001)

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

Signs/Symptoms	Date Observed
1 ANAPHYLAXIS	Jun 23, 2001

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

COMMENTS:

No existing text

Complete the observed reaction report? Yes// (Yes)

DATE/TIME OF EVENT: JUN 23,2001//

OBSERVER: DEMO,DOCTOR

SEVERITY: ?

MILD - Requires minimal therapeutic intervention such as

```

discontinuation of drug(s).
MODERATE - Requires active treatment of adverse reaction, or
          further testing or evaluation to assess
          extent of non-serious outcome (see SEVERE for
          definition of serious).
SEVERE   - Includes any serious outcome, resulting in life or organ
          threatening situation or death, significant or permanent
          disability, requiring intervention to prevent permanent
          impairment or damage, or requiring/prolonging
          hospitalization.
Choose from:
  1      MILD
  2      MODERATE
  3      SEVERE
SEVERITY: SEV SEVERE
DATE MD NOTIFIED: Jun 23,2001// (JUN 23, 2001)
Complete the FDA data? Yes// (Yes)
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//

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

Signs/Symptoms
-----
1 ANAPHYLAXIS

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

Patient died?: N NO
Reaction treated with RX drug?: Y YES
Life Threatening illness?: Y YES
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?: YES

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

ENTER A TO ADD NEW LAB DATA, D TO DELETE LAB DATA OR
E TO EDIT LAB DATA ON FILE FOR THIS PATIENT

Select one of the following:

  A      ADD
  D      DELETE
  E      EDIT

Select Action (A/D/E):

This patient has the following Drugs selected:

PENICILLIN
Select Action (A/D/E):

THIS PATIENT HAS NO CONCOMITANT DRUGS ON FILE

```

Select Action (A/D/E):

OTHER RELATED HISTORY:

No existing text

REPORTER NAME: PHARMACIST,PHARMACIST Replace

REPORTER ADDRESS1: DEMO INDIAN MEDICAL CENTER

REPORTER ADDRESS2: 100 S. MAIN//

REPORTER ADDRESS3:

REPORTER CITY: ANYTOWN//

REPORTER STATE: OKLAHOMA//

REPORTER ZIP: 74464//

REPORTER PHONE: 555-123-4567//

IS REPORTER A HEALTH CARE PROVIDER?: Y YES

Do you want the identity disclosed to the manufacturer?: N NO

OCCUPATION: PHARMACIST//

Currently you have verifier access.

Would you like to verify this Causative Agent now? Yes// N (No)

Causative Agent Data edited this Session:

ADVERSE REACTION

1) IBUPROFEN

Obs/Hist: HISTORICAL

Signs/Symptoms: GI REACTION (4/4/73)

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:38:44

User: NIESEN,MARY ANN

Title: PHARMACIST

SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
ALL NSAIDS

2) PENICILLIN

Obs/Hist: OBSERVED

Obs d/t: Jun 23, 2001

Signs/Symptoms: ANAPHYLAXIS (6/23/01)

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:40:11

User: NIESEN,MARY ANN

Title: PHARMACIST

REACTION WAS SEEN AND TREATED IN THE ER BUT NOT ADDED TO
ADVERSE REACTIONS

Are ALL these correct? NO// YES

This session you have CHOSEN:

IBUPROFEN

PENICILLIN

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

Select PATIENT NAME: demo

1	DEMO,ALLERGY CHARLES	<A>	M	11-02-1969	XXX-XX-5701	WW	104836
2	DEMO,ALLERGY CONNIE	<A>	F	10-24-1933	XXX-XX-4127	WW	110211
3	DEMO,ALLERGY LEA	<A>	F	12-04-1946	XXX-XX-9435	WW	150673
4	DEMO,AMILYA PEARL		F	06-30-2008	XXX-XX-0821	WW	106735
5	DEMO,AUSTIN WAYNE		M	** SENSITIVE **		WW	192640

ENTER '^' TO STOP, OR
CHOOSE 1-5: 1

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
AMOXICILLIN	PATIENT	NO	ALLERGY	HIST	DRUG
WALNUTS		NO	UNKNOWN	HIST	FOOD
Reactions: GI REACTION(Source:)					
BEE STINGS		AUTO	UNKNOWN	HIST	OTHER

Enter Causative Agent: SPONGEBOB

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

Now checking the National Drug File - Generic Names (#50.6)

Now checking the National Drug File - Trade Names (#50.67)

Now checking the INGREDIENTS (#50.416) file for matches...

Now checking VA DRUG CLASS (50.605) file for matches...

Could not find SPONGEBOB in any files.

Before sending an email requesting the addition of a new reactant, please try entering the first 3 or 4 letters of the reactant to search for the desired entry.

Would you like to send an email requesting SPONGEBOB be added as a causative agent?
Send email? NO// YES

You may now add any comments you may have to the message that is going to be sent with the request to add this reactant. You may want to add things like sign/symptoms, observed or historical, etc that may be useful to the reviewer.

Enter RETURN to continue or '^' to exit:

==[WRAP]==[INSERT]===== < >===== [<PF1>H=Help]====
THIS PATIENT REPORTS A VIOLENT REACTION TO WATCING SPONGEBOB.

```
<=====T=====T=====T=====T=====T=====T=====T=====T=====T=====T>=====
```

```
Message sent - NOTE: This reactant was NOT added for this patient.
Enter another Causative Agent? YES// NO
```

Mark a Reaction Entered in Error/Inactivate a reaction: A user may mark a reaction as entered in error. “Entered in Error” should *only* be used if the information is truly in error on the patient (i.e., entered on the wrong patient or using the wrong causative agent). Inactivation should be used for previous reactions that are no longer an issue for the patient (i.e., ibuprofen caused a GI upset reaction but the patient has found a variety of ibuprofen that is tolerable and now takes it routinely).

The user may select a patient, and a listing of the existing reaction entries will be shown. The user may select a reaction, and at the prompt “Is the reaction information correct?”, select NO. The user will then see the prompt “Mark this reaction as ‘Entered-in-Error?’” and may answer YES to make the reaction entered in error. Answering this question NO will bring the user to a second prompt “Inactivate this reaction?” Answer YES to make the reaction inactive. The user will be required to enter an inactivation reason. Options are NO LONGER ALLERGIC or REACTION IS TOLERABLE.

Example:

```
Select Adverse Reaction Tracking Option: 2 Adverse Reaction Tracking User Menu

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

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

```

Select PATIENT NAME: DEMO
  1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
  2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
  3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
  4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
  5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT SOURCE VER. MECH. OBS/
-----
BEN-GAY YES UNKNOWN HIST DRUG
IBUPROFEN SPOUSE NO PHARM HIST DRUG
  Reactions: GI REACTION(Source: SPOUSE)
PENICILLIN CHART REVIEW NO ALLERGY OBS DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)
WALNUTS PATIENT NO UNKNOWN HIST FOOD
  Reactions: HIVES(Source: PATIENT)

Enter Causative Agent: BEN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

          <A> F 10-24-1933 XXX-XX-4127 WW 110211
    BEN-GAY
    BEN-GAY OK? Yes// (Yes)

    PATIENT: DEMO,ALLERGY CONNIE CAUSATIVE AGENT: BEN-GAY
    INGREDIENTS: VA DRUG CLASSES:

    ORIGINATOR: DAVIS,MARY J ORIGINATED: Jul 15, 2004@09:00
    SIGN OFF: YES OBS/HIST: HISTORICAL

    ID BAND MARKED: CHART MARKED: Jul 15, 2004@09:00:32

    MECHANISM: UNKNOWN

    VERIFIER: DAVIS,MARY J VERIFIED: JUL 20, 2004@10:59:19
    Is the reaction information correct? Yes// N (No)
    Mark this reaction as 'Entered-in-Error'? YES

    COMMENTS:
    No existing text
    Edit? NO// YES

    ==[ WRAP ]==[ INSERT ]=====< COMMENTS >===== [ <Pfl>H=Help ]=====
    THIS REACTION IS NOT FOR THIS PATIENT, ACCIDENTALLY ENTERED ON
    WRONG PATIENT.

```

```
<=====T=====T=====T=====T=====T=====T=====T=====T=====T=====T>=====
```

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
IBUPROFEN	SPOUSE	NO	PHARM	HIST	DRUG
Reactions: GI REACTION(Source: SPOUSE)					
PENICILLIN	CHART REVIEW	NO	ALLERGY	OBS	DRUG
Reactions: ANAPHYLAXIS(Source: CHART REVIEW)					
WALNUTS	PATIENT	NO	UNKNOWN	HIST	FOOD
Reactions: HIVES(Source: PATIENT)					

Enter Causative Agent: WALN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

```

                                <A>   F 10-24-1933 XXX-XX-4127   WW 110211
WALNUTS
WALNUTS   OK? Yes//   (Yes)

```

PATIENT: DEMO,ALLERGY CONNIE CAUSATIVE AGENT: WALNUTS

```

SOURCE OF INFORMATION: PATIENT
ORIGINATOR: NIESEN,MARY ANN           ORIGINATED: Apr 27, 2011@09:58
SIGN OFF: YES                         OBS/HIST: HISTORICAL
EVENT: FOOD INTOLERANCE                CODE: 235719002

```

ID BAND MARKED: CHART MARKED: Apr 27, 2011@09:59:49

SIGNS/SYMP TOMS: HIVES (Jan 29, 2010) SOURCE: PATIENT

```

MECHANISM: UNKNOWN
Is the reaction information correct? Yes// N (No)
Mark this reaction as 'Entered-in-Error'? NO
Inactivate this reaction? YES
Select reason: ??

```

```

Choose from:
NO LONGER ALLERGIC
REACTION IS TOLERABLE

```

```

Select reason: NO LONGER ALLERGIC
Enter another Causative Agent? YES// NO

```

3.4.2 FDA Enter/Edit Menu ...

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 allow users to enter and edit the FDA data.

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

3.4.2.1 Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning and 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 give, 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 refill 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 (e.g., Initial).

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

Example:

1	Enter/Edit FDA Report Data
2	Enter/Edit P&T Committee Data
Select FDA Enter/Edit Menu Option: 1 Enter/Edit FDA Report Data	
Select PATIENT NAME: DEMO	

```

1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
IBUPROFEN
PENICILLIN

Select CAUSATIVE AGENT: PENICIL
<A> F 10-24-1933 XXX-XX-4127 WW 110211
PENICILLIN
Select date reaction was OBSERVED (Time Optional): ??

Choose from:
JUN 23, 2001

Select date reaction was OBSERVED (Time Optional): 6/23/2001 (JUN 23, 2001)
...OK? Yes// (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): 1-5

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

Signs/Symptoms
-----
1 ANAPHYLAXIS

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

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

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

This patient has the following Drugs selected:

PENICILLIN
Select Action (A/D/E):

THIS PATIENT HAS NO CONCOMITANT DRUGS ON FILE
Select Action (A/D/E):

```

```
OTHER RELATED HISTORY:
  No existing text
  Edit? NO//

MANUFACTURER NAME: LEDERLE
  1  LEDERLE LABS
  2  LEDERLE PARENTE
  3  LEDERLE PIPCILL
CHOOSE 1-3: 1  LEDERLE LABS
MFR ADDRESS #1: PO Box 8299
MFR ADDRESS #2:
MFR ADDRESS #3:
MFR CITY: PHILADELPHIA
MFR STATE: PA  PENNSYLVANIA
MFR ZIP: 19101
IND/NDA # FOR SUPPORT DRUG:
MFR CONTROL #: ??
      This is the control number used by the manufacturer.

MFR CONTROL #: 234FD67
DATE RECEIVED BY MFR:
Select SOURCE: ?
      You may enter a new REPORT SOURCE, if you wish
  Choose from:
    f  FOREIGN
    h  HEALTH PROFESSIONAL
    s  STUDY
    l  LITERATURE
    c  CONSUMER

Select SOURCE: H (h  HEALTH PROFESSIONAL)
  Are you adding 'HEALTH PROFESSIONAL' as a new SOURCE (the 1ST for this ADVERSE
  REACTION REPORTING)? No// Y (Yes)
Select SOURCE:
15 DAY REPORT: ??
      This field is to determine if the 15 Day Report has been completed.

  Choose from:
    y  YES
    n  NO
15 DAY REPORT: N NO
REPORT TYPE: ??
      This is the type of report issued.

  Choose from:
    i  INITIAL
    f  FOLLOWUP

REPORTER NAME: PHARMACIST,PHARMACIST  Replace
REPORTER ADDRESS1: DEMO INDIAN MEDICAL CENTER  Replace
REPORTER ADDRESS2: 100 S. MAIN//
REPORTER ADDRESS3:
REPORTER CITY: ANYTOWN//
REPORTER STATE: OKLAHOMA//
REPORTER ZIP: 74464//
REPORTER PHONE: 555-123-4567//
IS REPORTER A HEALTH CARE PROVIDER?: YES//
Do you want the identity disclosed to the manufacturer?: NO
  //
```

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):

3.4.2.2 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.

Example:

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

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
 2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
 3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
 4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE   <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
  IBUPROFEN
  PENICILLIN

Select CAUSATIVE AGENT: PENI
                                <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  PENICILLIN
Select date reaction was OBSERVED (Time Optional): ??

  Choose from:
  JUN 23, 2001

Select date reaction was OBSERVED (Time Optional): 6/23/2001  (JUN 23, 2001)
  ...OK? Yes//  (Yes)

P&T Report Completion
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?: Y  YES
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: Y  YES
DATE REPORTED TO FDA: 4/26/2011  (APR 26, 2011)
P&T ACTION MFR REPORT: ??
      This field tells if the P&T committee determined whether to send the report to
      the manufacturer.

      Choose from:
      Y          YES
      n          NO
P&T ACTION MFR REPORT: Y  YES
DATE OF PATIENT CONSENT TO MFR: 4/26/2011  (APR 26, 2011)
DATE SENT TO MFR: 4/26/2011  (APR 26, 2011)

ADDENDUM:
  No existing text
  Edit? NO//

```

3.4.3 Reports Menu ...

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 Signed Reactions
9. List FDA data by Report Date

3.4.3.1 Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not inactive or entered in error) allergy/adverse reaction data for a particular patient. This report may be sent to 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, IHS chart number, 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, SNOMED event and code, 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 assessed for reactions, the body of the report will display a message stating that there is no reaction data on file.

Example:

```
Select Reports Menu Option: 1  Active Listing of Patient Reactions

Select PATIENT: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE    <A>  F 10-24-1933 XXX-XX-4127  WW 110211

DEVICE: HOME//  VIRTUAL TERMINAL

ACTIVE ALLERGY/ADVERSE REACTION LISTING
Run Date/Time: 4/27/11 1:43:36 pm
DEMO,ALLERGY CO          110211          OCT 24,1933 (77)

-----
ADVERSE REACTION                                VERIFIED      OBS/
-----
                                         HIST

TYPE: DRUG
=====
IBUPROFEN                                         NO             HIST
EVENT: DRUG INTOLERANCE
SNOMED CODE: 59037007
Reactions: GI REACTION (Apr 04, 1973)
PENICILLIN                                         NO             OBS
EVENT: DRUG ALLERGY
SNOMED CODE: 416098002
Reactions: ANAPHYLAXIS (Jun 23, 2001)
Enter RETURN to continue or '^' to exit:
```

3.4.3.2 Print Patient Reaction Data

This option will allow the user to produce 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, IHS Chart number, date of birth, and age. The body of the report contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the source of the data, 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, the SNOMED Event and code, whether the patient ID band or chart is marked, a list of signs/symptoms, the mechanism, and additional comments made by the originator. For Inactive reactions it will also contain the inactive date, reason, and person who inactivated. A line of dots appears in the body of the report between the various reaction entries.

Example:

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

Select PATIENT: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE    <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1-3
Select 1:ACTIVE, 2:ENTERED IN ERROR, 3:INACTIVE
Which would you like to see?: (1-3): 1-3

DEVICE: HOME//  VIRTUAL TERMINAL

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 4/27/11 2:16:22 pm
DEMO,ALLERGY CO          110211          OCT 24,1933 (77)
-----

STATUS: ACTIVE
-----
TYPE: DRUG
=====

AGENT: IBUPROFEN
INGREDIENTS: IBUPROFEN  VA DRUG CLASSES: NONSALICYLATE NSAIs,A

SOURCE OF INFORMATION: SPOUSE
ORIGINATOR: NIESEN,MARY ANN  ORIGINATED: Apr 27, 2011@07:37
SIGN OFF: YES  OBS/HIST: HISTORICAL
EVENT: DRUG INTOLERANCE  CODE: 59037007

ORIGINATOR
COMMENTS:
  Date: Apr 27, 2011@07:38:44  User: NIESEN,MARY ANN
                               Title: PHARMACIST

SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
ALL NSAIDS
```

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973) SOURCE: SPOUSE

MECHANISM: PHARMACOLOGIC

.....
 AGENT: PENICILLIN
 INGREDIENTS: PENICILLIN VA DRUG CLASSES: (INACTIVE) PENICILLIN
 PENICILLINS,AMINO DER

SOURCE OF INFORMATION: CHART REVIEW
 ORIGINATOR: NIESEN,MARY ANN ORIGINATED: Apr 27, 2011@07:39
 SIGN OFF: YES OBS/HIST: OBSERVED
 EVENT: DRUG ALLERGY CODE: 416098002
 SEVERITY: SEVERE OBS D/T: Jun 23, 2001

ORIGINATOR
 COMMENTS:

Date: Apr 27, 2011@07:40:11 User: NIESEN,MARY ANN
 Title: PHARMACIST

REACTION WAS SEEN AND TREATED IN THE ER BUT NOT ADDED TO
 ADVERSE REACTIONS

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: ANAPHYLAXIS (Jun 23, 2001) SOURCE: CHART REVIEW

MECHANISM: ALLERGY

.....
 STATUS: E/E

 TYPE: DRUG
 =====

AGENT: BEN-GAY
 INGREDIENTS: VA DRUG CLASSES:

ORIGINATOR: DAVIS,MARY J ORIGINATED: Jul 15, 2004@09:00
 SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED: Jul 15, 2004@09:00:32

MECHANISM: UNKNOWN

VERIFIER: DAVIS,MARY J VERIFIED: JUL 20, 2004@10:59:19

USER ENTERING D/T ENTERED
 IN ERROR: NIESEN,MARY ANN IN ERROR: APR 27, 2011@12:00:44

ENTERED IN ERROR
 COMMENTS:

Date: Apr 27, 2011@12:00:44 User: NIESEN,MARY ANN
 Title: PHARMACIST

THIS REACTION IS NOT FOR THIS PATIENT, ACCIDENTALLY
 ENTERED ON WRONG PATIENT.

.....
 STATUS: INACTIVE

```

-----
TYPE: FOOD
=====

AGENT: WALNUTS

SOURCE OF INFORMATION: PATIENT
ORIGINATOR: NIESEN,MARY ANN      ORIGINATED: Apr 27, 2011@09:58
SIGN OFF: YES                     OBS/HIST: HISTORICAL
EVENT: FOOD INTOLERANCE          CODE: 235719002

ID BAND MARKED:                  CHART MARKED: Apr 27, 2011@14:07:39

INACTIVE: APR 27, 2011@12:01:50
REASON: NO LONGER ALLERGIC      BY: NIESEN,MARY ANN

SIGNS/SYMPTOMS: HIVES (Jan 29, 2010)      SOURCE: PATIENT

MECHANISM: UNKNOWN

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

```

3.4.3.3 Print an FDA report for a Patient

This option allows you 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 data into the system. The report should be queued to run on a printer with a 132-column width.

Example:

```

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

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
 2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
 3 DEMO,ALLERGY LEANN  <A>  F 12-04-1946 XXX-XX-9435  WW 150673
 4 DEMO,AMILYA PEARL   F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE   M  ** SENSITIVE **          WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select CAUSATIVE AGENT: PENI
                        <A>  F 10-24-1933 XXX-XX-4127  WW 110211
                        PENICILLIN
Select date reaction was OBSERVED (Time Optional): ??

Choose from:
JUN 23, 2001

Select date reaction was OBSERVED (Time Optional): 6/23/2001 (JUN 23, 2001)
...OK? Yes// (Yes)

THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.

```

```
QUEUE TO PRINT ON
DEVICE: Home VIRTUAL TERMINAL [YOU CAN NOT SELECT A VIRTUAL TERMINAL]

Previously, you have selected queueing.
Do you STILL want your output QUEUED? Yes// N (No)
DEVICE: SL SLAVE SLAVE
```

Report example on next page

=====	DEMO INDIAN MEDICAL CENTER 100 S. MAIN
Mail to: MedWatch or FAX to:	ANYTOWN, OKLAHOMA 74464 555-123-4567
5600 Fishers Lane 1-800-FDA-0178	-----
mfr.	2. Health professional? 3. Occupation 4. Reported to
Rockville, MD 20852-9787	[YES] PHARMACIST [NO]

Manufacturer,	5. If you don't want your identity disclosed to the
	place an "X" in the box.[X]
FDA Form 3500	
=====	
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.	

3.4.3.4 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 of ID bands marked. 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). This applies to Inpatients only. When entering a reaction on an Outpatient, the option to indicate if the ID Band had been marked is not available or displayed.

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, IHS chart number, name of the causative agent, and whether the patient ID band, chart, or both were unmarked.

Example:

```
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):1
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, or TEAM
Do you want the entire HOSPITAL LOCATION List? y (Yes)
Choose from:
ICU
MEDICALSURGICAL
NEWBORN
OBSTETRICS

Select Location: ICU
Another Location: MEDICALSURGICAL
Another Location: NEWBORN
Another Location: OBSTETRICS
Another Location:

DEVICE: HOME// VIRTUAL TERMINAL

Apr 27,2011 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1
CURRENT INPATIENTS

PATIENT SSN ALLERGY UNMARKED
-----
          WARD: ICU
DEMO,TAMMY LYNN 18-73-35 PENICILLIN CHART
                   AMOXICILLIN CHART

Apr 27,2011 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 2
CURRENT INPATIENTS
```

PATIENT	SSN	ALLERGY	UNMARKED

WARD: MEDICALSURGICAL			
DEMO,LAVELDA WAPSKINEH	10-33-24	MORPHINE	CHART
DEMO,DOROTHY ROSE	99-99-99	COTTONSEED OIL	CHART
		WINE	CHART
DEMO,TAMBRA ANNETTE	17-27-79	SULFA	CHART
		ENALAPRIL	CHART
		GATIFLOXACIN	CHART
Apr 27,2011	PATIENTS WITH UNMARKED	ID BAND/CHART	PAGE 3
CURRENT INPATIENTS			
PATIENT	SSN	ALLERGY	UNMARKED

WARD: NEWBORN			
* No Patients for this Ward *			
Apr 27,2011	PATIENTS WITH UNMARKED	ID BAND/CHART	PAGE 4
CURRENT INPATIENTS			
PATIENT	SSN	ALLERGY	UNMARKED

WARD: OBSTETRICS			
DEMO,CRYSTAL ANN	19-73-28	DOXYCYCLINE	CHART

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

Example:

```
Select Adverse Reaction Tracking User Menu Option: 4 List by Location of Unmark
ed 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):1
Select Location: ALL
Do you mean ALL Locations? Yes// (Yes)
Another Location:
```

3.4.3.5 Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients who have not been signed off (completed) by the user entering the 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 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 IHS chart number, the causative agent, and the date/time the entry was made.

Example:

```
Select Reports Menu Option: 5 Patient Allergies Not Signed Off

DEVICE: HOME// VIRTUAL TERMINAL

ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 4/27/11 2:08:19 pm

ORIGINATOR          PATIENT          ALLERGY          ORIGINATION DATE/TIME
-----
ADAIR,PETER DEMO,BABY(99-99-95) PENICILLIN      DEC 15, 2009@14:00
BARREL,SCOT A DEMO,DANIEL(13-34-45) IOD              JAN 14, 2004@09:53
BARREL,SCOT A DEMO,JUDY LY(13-80-30) PENICILLIN      MAR 24, 2004@10:15
BOWTIE,JEFF W DEMO,SARA(11-05-92) CLARITIN D     JUL 13, 2004@17:16
BOWTIE,JEFF W DEMO,SARA(11-05-92) UNKNOWN           JUL 13, 2004@17:17
BOWTIE,JEFF W DEMO,MARTA (11-06-54) SULFA            JUL 13, 2004@17:24
BOWTIE,JEFF W DEMO,ANNA JA(11-06-90) PENICILLIN      JUL 13, 2004@17:32
BOWTIE,JEFF W DEMO,KELSIE(11-07-01) CODEINE           JUL 13, 2004@17:38
BOWTIE,JEFF W DEMO,CAITLI (11-10-56) CECLOR           JUL 13, 2004@18:29
BOWTIE,JEFF W DEMO,JORDAN (11-11-22) CODEINE           JUL 13, 2004@18:39
BOWTIE,JEFF W DEMO,CHRYST(11-19-16) IBUPROFEN        JUL 13, 2004@19:54
BOWTIE,JEFF W DEMO,ALBE(11-62-28) CODEINE             JUL 13, 2004@20:07
BOWTIE,JEFF W DEMO,ROBERT (11-67-78) NONE             JUL 13, 2004@20:53
BOWTIE,JEFF W DEMO,TIERRA(11-68-30) ERTYTHROMYCIN    JUL 13, 2004@20:57
BOWTIE,JEFF W DEMO,BYRON G(11-69-67) VISTERIL        JUL 13, 2004@21:23
```

3.4.3.6 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 reactions. 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, IHS chart number, and provider. The room-bed will appear for current inpatients.

NOTE: This report will show patients as not having received and assessment if the assessment was entered after the end date of the range. For this reason, it is recommended to end the range with today. This can be done with an entry of "T" (for "Today") and the "Enter END Date (time optional): T/" prompt.

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

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

Example:

```
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.
```

```
Please note! This report will show patients as not having received an
assessment if the assessment was entered after the end date of
the range. For this reason, it is recommended to end the range
with today. This can be done with an entry of 'T' (for Today) at
the 'Enter END Date (time optional): T//' prompt.
```

```
Enter START Date (time optional): -90 (JAN 27, 2011)
Enter END Date (time optional): T// (APR 27, 2011)
Select Location: ALL
Do you mean ALL Locations? Yes// (Yes)
Another Location:
```

```
QUEUE TO PRINT ON
DEVICE: Home VIRTUAL TERMINAL [YOU CAN NOT SELECT A VIRTUAL TERMINAL]
```

```
Previously, you have selected queueing.
Do you STILL want your output QUEUED? Yes// N (No)
DEVICE: Home VIRTUAL TERMINAL
```

```
Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 1
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00
```

```
PATIENT SSN
-----
```

```
CLINIC: MED CLINIC
* No Patients for this Clinic *
```

```
Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 2
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00
```

```
PATIENT SSN PROVIDER
-----
```

```
WARD: ICU
DEMO,ALICIA LOUISE 160758 ASHLY,BARBARA A
Room/Bed: 3011-1
DEMO,LOIS JEANNETTE 180836 JOE,HOWARD
DEMO,ADRIAN 212735 SMITH,GRETA LOUISE
Room/Bed: 3012-1
ROADKILL,BUBBIT 253614 DEMO,DOCTOR
```

3.4.3.7 List by Location Not Verified Reactions

This option 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 the Application Coordinator or IT personnel 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 locations. The body contains the patient's name and IHS chart number, the causative agent, the name of the originator of the reaction, and the date/time the data originated. The Room-Bed is also displayed for each inpatient.

Example:

```

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

DEVICE: HOME// VIRTUAL TERMINAL
Report Date: Apr 28, 2011 Page: 1
List of Unverified Reactions by Ward Location
Ward Location: ICU
  Origination Date/Time      Originator      Reaction
-----
3013-1 DEMO,JEREMY PAUL (20-23-08)
      Nov 13, 2008@14:38      JONES,CARLA      AMPICILLIN

Report Date: Apr 28, 2011 Page: 2
List of Unverified Reactions by Ward Location
Ward Location: MEDICALSURGICAL
  Origination Date/Time      Originator      Reaction
-----
3309-2 DEMO,DOROTHY ROSE (99-99-99)
      Apr 27, 2011@10:01      SMITH,MARY      WALNUTS
3319-1 DEMO,LAVELDA WAPSKINEH (10-33-24)
      Apr 17, 2008@10:35      JONES,CARLA      MORPHINE

Report Date: Apr 28, 2011 Page: 3
List of Unverified Reactions by Ward Location
Ward Location: OUTPATIENT
  Origination Date/Time      Originator      Reaction
-----
DEMO,BROOKE ANN EESHAHA (19-79-56)
      Aug 05, 2004@17:40      WILLIAMS,JOHN J      SULFA
DEMO,CAITLIN TIANA (11-10-56)
      Jul 13, 2004@18:29      BOWTIE,JEFF W      CECLOR
DEMO,WANDA CARROL (18-29-00)
      Aug 04, 2004@19:42      WILLIAMS,JOHN J      FOSINOPRIL
DEMO,JEREMY MICHAEL (17-59-45)
      Aug 04, 2004@19:55      FISHER,MARTHA A      SULFA
DEMO,MARIAH HOPE (19-75-66)
      Aug 05, 2004@18:32      WILLIAMS,JOHN J      PENICILLIN
      Aug 05, 2004@18:32      WILLIAMS,JOHN J      AMPICILLIN
DEMO,AMOS LYNN (17-57-76)
      Aug 04, 2004@20:40      FISHER,MARTHA A      NAPROXEN
DEMO,SUE ELLEN (10-05-06)
      Jul 27, 2004@09:48      BOWTIE,JEFF W      SERTRALINE
DEMO,JORDAN LAY (12-99-01)

```

Jul 21, 2004@17:46

BOWTIE,JEFF W

PENICILLIN

3.4.3.8 List by Location and Date all Signed Reactions

This option 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 terminal screen.

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

Example:

```
Select Reports Menu Option: 8 List by Location and Date All Signed Reactions
Enter Start Date: -30 (MAR 29, 2011)
Enter Ending Date: t (APR 28, 2011)

DEVICE: HOME// VIRTUAL TERMINAL

One moment please...
Apr 28, 2011 Page: 1
List all Signed Patient Reactions for Ward Location MEDICALSURGICAL
From Mar 29, 2011 to Apr 28, 2011@24:00
Date Originator Type Causative Agent
-----
Patient: DEMO,DOROTHY ROSE (99-99-99)
Apr 27, 2011@10:01 SMITH,MARY F WALNUTS

Apr 28, 2011 Page: 2
List all Signed Patient Reactions for Out Patients
From Mar 29, 2011 to Apr 28, 2011@24:00
Date Originator Type Causative Agent
-----
Patient: DEMO,CRYSTAL LYNN (16-06-13)
Mar 29, 2011@11:18 ROZINSKI,DAVID D TDAP

Patient: DEMO,ALLERGY CHARLES (10-48-36)
Apr 20, 2011@09:01 SMITH,MARY D AMOXICILLIN
Apr 18, 2011@11:23 SMITH,MARY F WALNUTS

Patient: DEMO,ALLERGY CONNIE (11-02-11)
Apr 27, 2011@07:37 SMITH,MARY D IBUPROFEN
Apr 27, 2011@07:39 SMITH,MARY D PENICILLIN
Apr 27, 2011@09:58 SMITH,MARY F WALNUTS

Patient: DEMO,JOHN (00-00-55)
Apr 27, 2011@10:19 SMITH,MARY D PENICILLIN

Patient: DEMO,DUSTIN KEE (20-20-97)
Apr 04, 2011@13:32 ROZINSKI,DAVID D INFLUENZA
Apr 28, 2011 Page: 3
List all Signed Patient Reactions for Out Patients
```

```

From Mar 29, 2011 to Apr 28, 2011@24:00
Date          Originator          Type Causative Agent
-----
Patient: DEMO,AMBER DAWN (10-15-65)
Apr 26, 2011@10:03:28HIMS,BARBARA          DF PEANUTS
Patient: PATIENT,CRSFC (90-01-58)
Mar 29, 2011@11:40  ROZINSKI,DAVID          D  TDAP
Patient: DEMO,GEOFFREY MICHAEL (20-07-13)
Apr 04, 2011@11:23  ROZINSKI,DAVID          D  HEPATITIS A
Patient: TEST,CATHY (00-00-03)
Apr 06, 2011@15:21  ROZINSKI,DAVID          D  CIPROFLOXACIN
Enter RETURN to continue or '^' to exit:

```

3.4.3.9 List FDA data by Report Date

This option 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 displayed on the terminal screen.

The header of the report contains the title of the report, the date range selected, and the date the report was run. The body of the report contains the patient's name and IHS chart number, 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.

Example:

```

Select Reports Menu Option: 9 List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: -14 (APR 14, 2011)
Enter Ending Date: T (APR 28, 2011)

DEVICE: HOME// VIRTUAL TERMINAL
Report Date: Apr 28, 2011 Page: 1
Adverse Reaction Tracking Report
From: 4/14/11 To: 4/28/11
Patient          Dates          Related Reaction
-----
DEMO,ALLERGY CONNIE          Obs DT: 4/23/11 PENICILLIN
(11-02-11)          Trk DT: 4/27/11
Loc: OUT PATIENT          -----
Obs: SMITH,MARY          5 Days Difference

DEMO,JOHN          Obs DT: 4/26/11 PENICILLIN
(00-00-55)          Trk DT: 4/27/11
Loc: OUT PATIENT          -----
Obs: SMITH,MARY          1 Days Difference

Enter RETURN to continue or '^' to exit:

```

3.4.4 Edit Chart and ID Band

This option allows sites to update the ID Band marking status. All questions and displays regarding chart marking have been removed, since the entry of a reaction into ART is the marking of the chart.

The user may select a patient, and is then shown a list of reactions for that patient (active and inactive). The user may select one or more reactions. When done selecting reactions, the user must enter once more to get to the ID Band question. At the “Has the ID Band been marked or unmarked for this (these) CAUSATIVE AGENT(S)?” the user may select YES to indicate the band has been marked, or NO to indicate the band has not been marked.

Example:

```
Select Adverse Reaction Tracking Clinician Menu Option: 4  Edit Chart and ID Band
Select Patient: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

CHOOSE FROM:
  IBUPROFEN
  PENICILLIN
  WALNUTS (Inactive)

Select CAUSATIVE AGENT: IBUPROF
                        <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  IBUPROFEN

Select another CAUSATIVE AGENT: PEN
                        <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  PENICILLIN

Select another CAUSATIVE AGENT: WALN
                        <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  WALNUTS

Select another CAUSATIVE AGENT:
This session you have CHOSEN:
  IBUPROFEN
  PENICILLIN
  WALNUTS
```

3.4.5 Online Reference Card

This option provides a very brief overview of entering patient reaction data. Users may navigate through the document using the up and down arrows on the keyboard:



Users may exit the online reference using the F1 key quickly followed by the E key:



Reactivate Reaction/Allergy

This option is used to reactivate a previously inactivated reaction. The user may select a patient with inactivated reactions. Selecting a patient without inactivated reactions results in the user being brought immediately back to the menu screen.

A list of the patient's inactivated reactions will be displayed, and the user may select one to reactivate. The software will check existing entries for duplication, and then verify that this reaction should be reactivated. Answering YES at the prompt will reactivate the reaction.

Example:

```
Select Adverse Reaction Tracking Clinician Menu Option: 6  Reactivate Reaction/A

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
 2 DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
 3 DEMO,ALLERGY LEANN <A>  F 12-04-1946 XXX-XX-9435  WW 150673
 4 DEMO,AMILYA PEARL      F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE      M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT          SOURCE          VER.   MECH.   OBS/
-----          -
WALNUTS          PATIENT          NO    UNKNOWN HIST  FOOD
  Reactions: HIVES(Source: PATIENT)
  Inactive: APR 27, 2011@12:01:50( NO LONGER ALLERGIC )

Enter Item to Reactivate: WALNUTS

Checking existing PATIENT ALLERGIES (#120.8) file for matches...
                                <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  WALNUTS
  WALNUTS  OK? Yes//  (Yes)
```

Reaction has been reactivated

3.4.6 Unable to Assess Allergies

This option allows the user to document the inability to assess the patient's reactions. This is intended to be used when circumstances are such that the user is unable to determine if the existing data in the database is correct and complete, or if no assessment has been done but circumstances prevent the gathering of this data.

The user may select a patient, and a current listing of active reaction will be shown. The user will be asked if the patient should be marked as being unable to assess for allergies. Answering YES will mark the patient, and the user will be required to enter a reason. The choices are ALTERED MENTAL STATUS, CAREGIVER DOES NOT KNOW, LANGUAGE BARRIER, OTHER, PATIENT DOES NOT KNOW, or UNCONSCIOUS. Selecting OTHER as the reason will allow the user to enter a brief explanation. NOTE: it is strongly recommended that this free text explanation be entered in mixed case, and to be limited to 30 characters or less to avoid display issues in the EHR.

Multiple instances of "unable to assess" may be entered during a stay/visit at the facility. The "unable to assess" will be removed when activity is performed on the patient's record: marking "no known" reactions, adding or editing a reaction, etc.

Example:

```
Select Adverse Reaction Tracking Clinician Menu Option: 7  Unable to assess alle
Select PATIENT NAME: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT                SOURCE          VER.   MECH.   OBS/
-----                -
IBUPROFEN              SPOUSE          NO     PHARM   HIST   DRUG
  Reactions: GI REACTION(Source: SPOUSE)
PENICILLIN              CHART REVIEW   NO     ALLERGY OBS    DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)
WALNUTS                 PATIENT        YES    UNKNOWN HIST   FOOD
  Reactions: HIVES(Source: PATIENT)
  Inactive: APR 27, 2011@12:01:50( NO LONGER ALLERGIC )
  Reactivated: APR 28, 2011@16:33:19
Do you want to mark this patient as being unable to assess for allergies?? NO//Y
ES
Select reason: ??

Choose from:
```

ALTERED MENTAL STATUS
 CAREGIVER DOES NOT KNOW
 LANGUAGE BARRIER
 OTHER
 PATIENT DOES NOT KNOW
 UNCONSCIOUS

Select reason: UNCONSCIOUS
 Patient has been marked unassessable

Select Adverse Reaction Tracking Clinician Menu Option: 1 Enter/Edit Patient Re

Select PATIENT NAME: DEMO

1	DEMO,ALLERGY CHARLES	<A>	M	11-02-1969	XXX-XX-5701	WW	104836
2	DEMO,ALLERGY CONNIE	<A>	F	10-24-1933	XXX-XX-4127	WW	110211
3	DEMO,ALLERGY LEANN	<A>	F	12-04-1946	XXX-XX-9435	WW	150673
4	DEMO,AMILYA PEARL		F	06-30-2008	XXX-XX-0821	WW	106735
5	DEMO,AUSTIN WAYNE		M	** SENSITIVE **		WW	192640

ENTER '^' TO STOP, OR

CHOOSE 1-5: 2

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
-----	-----	----	-----	----	----
IBUPROFEN	SPOUSE	NO	PHARM	HIST	DRUG
Reactions: GI REACTION(Source: SPOUSE)					
PENICILLIN	CHART REVIEW	NO	ALLERGY	OBS	DRUG
Reactions: ANAPHYLAXIS(Source: CHART REVIEW)					
WALNUTS	PATIENT	YES	UNKNOWN	HIST	FOOD
Reactions: HIVES(Source: PATIENT)					
Inactive: APR 27, 2011@12:01:50(NO LONGER ALLERGIC)					
Reactivated: APR 28, 2011@16:33:19					

Patient has been marked as unassessable for allergies

Reason given is UNCONSCIOUS

Can this pt. now be assessed? YES//

Select PATIENT NAME: DEMO

1	DEMO,ALLERGY CHARLES	<A>	M	11-02-1969	XXX-XX-5701	WW	104836
2	DEMO,ALLERGY CONNIE	<A>	F	10-24-1933	XXX-XX-4127	WW	110211
3	DEMO,ALLERGY LEANN	<A>	F	12-04-1946	XXX-XX-9435	WW	150673
4	DEMO,AMILYA PEARL		F	06-30-2008	XXX-XX-0821	WW	106735
5	DEMO,AUSTIN WAYNE		M	** SENSITIVE **		WW	192640

ENTER '^' TO STOP, OR

CHOOSE 1-5: 2

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
-----	-----	----	-----	----	----
IBUPROFEN	SPOUSE	NO	PHARM	HIST	DRUG
Reactions: GI REACTION(Source: SPOUSE)					
PENICILLIN	CHART REVIEW	NO	ALLERGY	OBS	DRUG
Reactions: ANAPHYLAXIS(Source: CHART REVIEW)					
WALNUTS	PATIENT	YES	UNKNOWN	HIST	FOOD
Reactions: HIVES(Source: PATIENT)					
Inactive: APR 27, 2011@12:01:50(NO LONGER ALLERGIC)					
Reactivated: APR 28, 2011@16:33:19					

3.5 Adverse Reaction Tracking Verifier Menu (GMRA 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
7. Reactivate Reaction/Allergy
8. Unable to assess allergies

3.5.1 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, the source of the information, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction and the source, the date and time the sign/symptom occurred, the SNOMED event type, any appropriate comments concerning the entry, and whether the patient's ID Band/Chart is marked for the reaction.

Selecting a Patient: The user may select a patient by name or portion of name (last name, first name; a comma must follow the last name and no space after the comma), IHS chart number (e.g. 12345), date of birth (e.g., 01-22-66 or 01/22/66 or Jan 22, 1966), ward location (e.g., PEDIATRICS), or Room-Bed (e.g., 101-2).

Assessing the Patient: If the selected patient does not have any allergies/adverse reactions stored in the ART database, the user is asked "Does this patient have any known allergies or adverse reactions?". A Yes response will allow the user to make an entry. A No response will mark the patient as "No Known Allergies" and return to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient, the software will not ask the 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 (drug, food, other, or a combination), any signs/symptoms and the source, the mechanism (allergy or pharmacologic), whether it was observed or historical, and whether or not it was verified.

It is now possible to delete an assessment of “No Known Allergies” or NKA from within the ART package. When a patient is selected that has no active allergies in file, the question will be presented in one of two ways. If there has been no assessment, there is no default answer. If the patient has been assessed as “No Known Allergies”, the default will be NO. In the case where the default answer is NO (meaning the patient is NKA), the user may enter “@” (the “at” sign) to indicate the assessment should be deleted and the patient should be returned to the “not assessed” state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

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 will have the opportunity to edit the data concerning that entry.
2. If the response is not part of that patient’s entry or the user does not want to edit and 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,
 - b. NATIONAL DRUG (50.6) – this file contains the names of available drug products including trade names and manufacturer,
 - c. NATIONAL DRUG, Trade Names (50.67) – this file contains the trade names for the NATIONAL DRUG file
 - d. DRUG INGREDIENTS (50.416) – this file contains the names of individual generic drugs and other agents that are components of various drug products,
 - e. VA DRUG CLASS (50.605) – this file contains the names of the various drug classes.
3. If the reactant is not found after steps 1 and 2, then the user is asked “Would you like to send an email requesting (the reactant) be added as a causative agent?” If the answer is NO, the user will be returned to the reactant lookup; if the answer is YES, the user will see the message

“You may now add any comments you may have to the message that is going to be sent with the request to add this reactant. You may add things like signs/symptoms, observed or historical, etc., that may be useful to the reviewer.

Enter RETURN to continue or “^” to exit:”

If enter is pressed, the user is allowed to enter comments, and when the comments are saved, the user will see the message

“Message sent – NOTE: This reactant was NOT added for this patient.

Enter another Causative Agent? YES//”

If the answer is YES, the user is returned to the reactant lookup prompt; if the answer is NOE, the user is returned to the patient lookup prompt. A mailman message is generated to the user making the request and to the Mail Group GMRA REQUEST NEW REACTANT, containing the comment entered, the user name and contact information, patient, and the reactant.

Source: The user is able to select the source of the reactant information. Available choices are Chart Review, External Source, Family, Friend, Medical Provider, Other Source, Patient, or Spouse.

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 person 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 they hold the GMRA-ALLERGY VERIFY key.

Signs/Symptoms: The user may choose to assign one or more signs/symptoms to the reaction. The site should have a “top 10” list of symptoms and the option to choose one not on the main list. The Signs/Symptoms file is no longer editable locally, and the user is no longer allowed to enter a free text sign/symptom. Once a sign/symptom has been chosen, the user may enter the date the sign/symptom occurred, and the source of the information about the sign/symptom. The time of day may be entered, but it is optional.

SNOMED Event Code: The user is prompted to choose a SNOMED Event code. This event code along with the Type (Nature of Reaction) will be used to map to the old Mechanism; neither Type nor Mechanism will be user selectable. The table below shows the Event Codes available, and the Mechanism and Type (Nature of Reaction) they are mapped to.

The Mechanism is the way the reaction is mediated. The options are Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent due to an immune-mediated response. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to a drug or drug ingredient due to a non-immune mediated response. Unknown is used for non-medication reactions or when the user is unsure of the mechanism. NOTE: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

The Type (Nature of Reaction) is what type of substance causes the reaction. The options are Food, Drug, Other, or combinations of the three types. These are set in the GMR ALLERGIES file or other files used to link to the causative agent. These are no longer editable by the user.

SNOMED Event	Type (Nature of Reaction)	Mechanism
Allergy to Substance	Other Drug, Food Drug, Other Food, Other	Unknown
Drug Allergy	Drug	Allergy
Drug Intolerance	Drug	Pharmacologic
Food Allergy	Food	Allergy
Food Intolerance	Food	Unknown
Propensity to Adverse Reactions	Other Drug, Food Drug, Other Food, Other	Unknown
Propensity to Adverse Reaction to Substance	Other	Unknown
Propensity to Adverse Reaction to Drug	Drug	Pharmacologic
Propensity to Adverse Reaction to Food	Food	Unknown

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 for reactions designated as observed. If the entry is being edited and any existing comments exist for this causative agent, the software will display those comments and their author (the originator of the entry, a verifier, or a person who marked the entry as entered in error). This is only true for OBSERVED type reactions. Comments entered for reactions designated as historical are optional. NOTE: sites are strongly encouraged to enter comments for reactions marked entered in error for auditing purposes.

FDA Data: When the type of 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 they hold 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 sites 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 GMRA-ALLERGY VERIFY key, 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.

Signing off on an Entry: Signing off (i.e. answering YES to “Is this 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.

Previous versions of the software allowed users to leave entries in a “not signed off” state. Although not complete, the allergy became part of the patient’s record, even though the user was told it would not be. Depending on how the entry was made, an alert might not be sent indicating that the entry needed to be signed off. Ultimately, an unfinished entry might never be finished, but still appear in the patient’s record.

A change has been made so that no new entry can be left in a “not signed off” state. Upon entering a new reaction, if the user enters an “^” at any point during the data gathering process, the entry will be deleted. Upon completing the new entry, the user will be asked if the entry is okay. If the answer is NO, the user will be given the opportunity to edit or delete the entry. The entry must then be deleted or accepted before exiting the process. As a result, no new entries will be allowed to be in an unsigned state.

NOTE: sites should run the "Patient Allergies Not Signed Off" option to identify all existing entries that have not yet been completed. Each entry should be reviewed and marked as entered in error or completed by entering the required information. Once these entries are cleaned up, then no unsigned entries should appear in the patient's record. The user is not required to update these entries as data may not be available, but the user should review them and take action if possible. The post-installation routine will also list any reactions that are observed, have been signed off, but are missing either an observed date or a sign/symptom. These entries should also be reviewed and updated if possible.

Example:

```
Select Adverse Reaction Tracking Verifier Menu Option: 1  Enter/Edit Patient Rea

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
 2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
 3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
 4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
 5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT SOURCE VER. MECH. OBS/
-----
BEN-GAY YES UNKNOWN HIST DRUG

Enter Causative Agent: IBUPROFEN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

IBUPROFEN OK? Yes// N (No)

Now checking the National Drug File - Generic Names (#50.6)

 1 IBUPROFEN
 2 IBUPROFEN/PSEUDOEPHEDRINE
CHOOSE 1-2: 1 IBUPROFEN
IBUPROFEN OK? Yes// (Yes)

SOURCE: ?
Only allow items designates as a source of information
Answer with BEH ALLERGY VALUES NAME
Do you want the entire BEH ALLERGY VALUES List? Y (Yes)
Choose from:
CHART REVIEW
EXTERNAL SOURCE
FAMILY
FRIEND
MEDICAL PROVIDER
OTHER SOURCE
PATIENT
SPOUSE

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

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

- | | |
|----------------------------|------------------------|
| 1. ANXIETY | 7. HIVES |
| 2. ITCHING | 8. DYSPEPSIA |
| 3. SWELLING (NON-SPECIFIC) | 9. ANAPHYLAXIS |
| 4. DROWSINESS | 10. RASH |
| 5. NAUSEA,VOMITING | 11. OTHER SIGN/SYMPTOM |
| 6. DIARRHEA | |

Enter from the list above : 11

Select SIGN/SYMPTOMS NAME: GI REACTION NATIONAL SIGN/SYMPTOM

Select SIGN/SYMPTOMS NAME:

Date(Time Optional) of appearance of Sign/Symptom(s): 4-4-1973 (APR 04, 1973)

Select source: ?

Answer with BEH ALLERGY VALUES NAME

Do you want the entire BEH ALLERGY VALUES List? Y (Yes)

Choose from:

- CHART REVIEW
- EXTERNAL SOURCE
- FAMILY
- FRIEND
- MEDICAL PROVIDER
- OTHER SOURCE
- PATIENT
- SPOUSE

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

Signs/Symptoms	Date Observed

1 GI REACTION	Apr 04, 1973

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

SNOMED EVENT: ??

Choose from:

- ALLERGY TO SUBSTANCE
- DRUG ALLERGY
- DRUG INTOLERANCE
- FOOD ALLERGY
- FOOD INTOLERANCE
- PROPENSITY TO ADVERSE REACTIONS
- PROPENSITY TO ADVERSE REACTIONS TO DRUG
- PROPENSITY TO ADVERSE REACTIONS TO FOOD
- PROPENSITY TO ADVERSE REACTIONS TO SUBSTANCE

COMMENTS:

No existing text

Currently you have verifier access.

Would you like to verify this Causative Agent now? Yes// N (No)

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE

BEN-GAY		YES	UNKNOWN	HIST	DRUG
IBUPROFEN	SPOUSE	NO	PHARM	HIST	DRUG

Reactions: GI REACTION(Source: SPOUSE)

Enter Causative Agent: PENICILLIN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

```

Now checking GMR ALLERGIES (#120.82) file for matches...

  PENICILLIN   OK? Yes//   (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: O  OBSERVED
Select date reaction was OBSERVED (Time Optional): 6-23-2001  (JUN 23, 2001)
JUN 23, 2001  (JUN 23, 2001)
  Are you adding 'JUN 23, 2001' as

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

The following are the top ten most common signs/symptoms:
  1. ANXIETY                7. HIVES
  2. ITCHING                8. DYSPEPSIA
  3. SWELLING (NON-SPECIFIC) 9. ANAPHYLAXIS
  4. DROWSINESS            10. RASH
  5. NAUSEA,VOMITING       11. OTHER SIGN/SYMP TOM
  6. DIARRHEA

Enter from the list above : 9
Date(Time Optional) of appearance of Sign/Symptom(s): Jun 23, 2001//  (JUN 23, 2
001)

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

      Signs/Symptoms                Date Observed
-----
  1  ANAPHYLAXIS                    Jun 23, 2001

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

COMMENTS:
  No existing text

Complete the observed reaction report? Yes//   (Yes)
DATE/TIME OF EVENT: JUN 23,2001//
OBSERVER: DEMO,DOCTOR
SEVERITY: ?

  MILD      - Requires minimal therapeutic intervention such as
              discontinuation of drug(s).
  MODERATE  - Requires active treatment of adverse reaction, or
              further testing or evaluation to assess
              extent of non-serious outcome (see SEVERE for
              definition of serious).
  SEVERE    - Includes any serious outcome, resulting in life or organ
              threatening situation or death, significant or permanent
              disability, requiring intervention to prevent permanent
              impairment or damage, or requiring/prolonging
              hospitalization.

  Choose from:
    1      MILD
    2      MODERATE
    3      SEVERE
SEVERITY: SEV SEVERE
DATE MD NOTIFIED: Jun 23,2001//  (JUN 23, 2001)
Complete the FDA data? Yes//   (Yes)
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//

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

Signs/Symptoms

1 ANAPHYLAXIS

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

Patient died?: N NO

Reaction treated with RX drug?: Y YES

Life Threatening illness?: Y YES

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?: YES

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

Select Action (A/D/E): ?

ENTER A TO ADD NEW LAB DATA, D TO DELETE LAB DATA OR

E TO EDIT LAB DATA ON FILE FOR THIS PATIENT

Select one of the following:

A	ADD
D	DELETE
E	EDIT

Select Action (A/D/E):

This patient has the following Drugs selected:

PENICILLIN

Select Action (A/D/E):

THIS PATIENT HAS NO CONCOMITANT DRUGS ON FILE

Select Action (A/D/E):

OTHER RELATED HISTORY:

No existing text

REPORTER NAME: PHARMACIST,PHARMACIST Replace

REPORTER ADDRESS1: DEMO INDIAN MEDICAL CENTER

REPORTER ADDRESS2: 100 S. MAIN//

REPORTER ADDRESS3:

REPORTER CITY: ANYTOWN//

REPORTER STATE: OKLAHOMA//

REPORTER ZIP: 74464//

REPORTER PHONE: 555-123-4567//

IS REPORTER A HEALTH CARE PROVIDER?: Y YES

Do you want the identity disclosed to the manufacturer?: N NO

OCCUPATION: PHARMACIST//

Currently you have verifier access.

Would you like to verify this Causative Agent now? Yes// N (No)

Causative Agent Data edited this Session:

ADVERSE REACTION

1) IBUPROFEN

Obs/Hist: HISTORICAL
Signs/Symptoms: GI REACTION (4/4/73)

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:38:44

User: NIESEN,MARY ANN

Title: PHARMACIST

SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
ALL NSAIDS

2) PENICILLIN

Obs/Hist: OBSERVED
Obs d/t: Jun 23, 2001
Signs/Symptoms: ANAPHYLAXIS (6/23/01)

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:40:11

User: NIESEN,MARY ANN

Title: PHARMACIST

REACTION WAS SEEN AND TREATED IN THE ER BUT NOT ADDED TO
ADVERSE REACTIONS

Are ALL these correct? NO// YES

This session you have CHOSEN:

IBUPROFEN

PENICILLIN

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

Select PATIENT NAME: demo

1	DEMO,ALLERGY CHARLES	<A>	M	11-02-1969	XXX-XX-5701	WW	104836
2	DEMO,ALLERGY CONNIE	<A>	F	10-24-1933	XXX-XX-4127	WW	110211
3	DEMO,ALLERGY LEA	<A>	F	12-04-1946	XXX-XX-9435	WW	150673
4	DEMO,AMILYA PEARL		F	06-30-2008	XXX-XX-0821	WW	106735
5	DEMO,AUSTIN WAYNE		M	** SENSITIVE **		WW	192640

ENTER '^' TO STOP, OR

CHOOSE 1-5: 1

REACTANT	SOURCE	VER.	MECH.	OBS/ HIST	TYPE
AMOXICILLIN	PATIENT	NO	ALLERGY	HIST	DRUG
WALNUTS		NO	UNKNOWN	HIST	FOOD
Reactions: GI REACTION(Source:)					
BEE STINGS		AUTO	UNKNOWN	HIST	OTHER

Enter Causative Agent: SPONGEBOB

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

Now checking the National Drug File - Generic Names (#50.6)

Now checking the National Drug File - Trade Names (#50.67)

```

Now checking the INGREDIENTS (#50.416) file for matches...

Now checking VA DRUG CLASS (50.605) file for matches...

Could not find SPONGEBOB in any files.

Before sending an email requesting the addition of a new reactant, please
try entering the first 3 or 4 letters of the reactant to search for
the desired entry.

Would you like to send an email requesting SPONGEBOB
be added as a causative agent?
Send email? NO// YES

You may now add any comments you may have to the message that
is going to be sent with the request to add this reactant.
You may want to add things like sign/symptoms, observed or historical, etc
that may be useful to the reviewer.

Enter RETURN to continue or '^' to exit:

==[ WRAP ]==[ INSERT ]===== < >===== [ <PF1>H=Help ]=====
THIS PATIENT REPORTS A VIOLENT REACTION TO WATCHING SPONGEBOB.

<=====T=====T=====T=====T=====T=====T=====T=====T=====T>=====

Message sent - NOTE: This reactant was NOT added for this patient.

Enter another Causative Agent? YES// NO

```

Mark a Reaction Entered in Error/Inactivate a reaction: A user may mark a reaction as entered in error. “Entered in Error” should *only* be used if the information is truly in error on the patient (i.e., entered on the wrong patient or using the wrong causative agent). Inactivation should be used for previous reactions that are no longer an issue for the patient (i.e., ibuprofen caused a GI upset reaction but the patient has found a variety of ibuprofen that is tolerable and now takes it routinely).

The user may select a patient, and a listing of the existing reaction entries will be shown. The user may select a reaction, and at the prompt "Is the reaction information correct?", select NO. The user will then see the prompt "Mark this reaction as 'Entered-in-Error'?" and may answer YES to make the reaction entered in error. Answering this question NO will bring the user to a second prompt "Inactivate this reaction?" Answer YES to make the reaction inactive. The user will be required to enter an inactivation reason. Options are NO LONGER ALLERGIC or REACTION IS TOLERABLE.

Example:

```
Select Adverse Reaction Tracking Verifier Menu Option: 1  Enter/Edit Patient Rea

Select PATIENT NAME: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE     M  ** SENSITIVE **        WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT                SOURCE          VER.   MECH.   OBS/
-----                -
BEN-GAY                 YES          UNKNOWN HIST   DRUG
IBUPROFEN              SPOUSE       NO     PHARM  HIST   DRUG
  Reactions: GI REACTION(Source: SPOUSE)
PENICILLIN             CHART REVIEW NO     ALLERGY OBS   DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)
WALNUTS                PATIENT      NO     UNKNOWN HIST   FOOD
  Reactions: HIVES(Source: PATIENT)

Enter Causative Agent: BEN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

                <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  BEN-GAY
  BEN-GAY  OK? Yes//  (Yes)

  PATIENT: DEMO,ALLERGY CONNIE CAUSATIVE AGENT: BEN-GAY
  INGREDIENTS:                VA DRUG CLASSES:

  ORIGINATOR: DAVIS,MARY J      ORIGINATED: Jul 15, 2004@09:00
  SIGN OFF: YES                 OBS/HIST: HISTORICAL

  ID BAND MARKED:              CHART MARKED: Jul 15, 2004@09:00:32

  MECHANISM: UNKNOWN

  VERIFIER: DAVIS,MARY J        VERIFIED: JUL 20, 2004@10:59:19
  Is the reaction information correct? Yes// N (No)
  Mark this reaction as 'Entered-in-Error'? YES

  COMMENTS:
```

```

No existing text
Edit? NO// YES

==[ WRAP ]==[ INSERT ]=====< COMMENTS >===== [ <PF1>H=Help ]=====
THIS REACTION IS NOT FOR THIS PATIENT, ACCIDENTALLY ENTERED ON
WRONG PATIENT.

<=====T=====T=====T=====T=====T=====T=====T=====T=====T>=====

REACTANT                SOURCE          VER.    MECH.    OBS/
-----                -
IBUPROFEN              SPOUSE          NO     PHARM    HIST    DRUG
  Reactions: GI REACTION(Source: SPOUSE)
PENICILLIN             CHART REVIEW   NO     ALLERGY  OBS     DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)
WALNUTS                PATIENT        NO     UNKNOWN  HIST    FOOD
  Reactions: HIVES(Source: PATIENT)

Enter Causative Agent: WALN

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

                <A>   F 10-24-1933 XXX-XX-4127   WW 110211
WALNUTS
WALNUTS   OK? Yes//   (Yes)

PATIENT: DEMO,ALLERGY CONNIE CAUSATIVE AGENT: WALNUTS

SOURCE OF INFORMATION: PATIENT
ORIGINATOR: NIESEN,MARY ANN          ORIGINATED: Apr 27, 2011@09:58
SIGN OFF: YES                        OBS/HIST: HISTORICAL
EVENT: FOOD INTOLERANCE              CODE: 235719002

ID BAND MARKED:                      CHART MARKED: Apr 27, 2011@09:59:49

SIGNS/SYMPTOMS: HIVES (Jan 29, 2010) SOURCE: PATIENT

MECHANISM: UNKNOWN
Is the reaction information correct? Yes// N (No)
Mark this reaction as 'Entered-in-Error'? NO
Inactivate this reaction? YES
Select reason: ??

```

```
Choose from:
NO LONGER ALLERGIC
REACTION IS TOLERABLE
```

```
Select reason: NO LONGER ALLERGIC
Enter another Causative Agent? YES// NO
```

3.5.2 Verify Patient Reaction Data

This option allows designated verifiers to verify the correctness of data entered by the clinical users, or to mark the reaction as entered in error or inactive. 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 both drug and non-drug reactions. The reaction data is displayed and the verifier may edit the type, ingredients (can be multiple), drug class (can be multiple), source, observed/historical response, signs/symptoms (can be multiple), and/or SNOMED Event type. 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 will remain in an unverified state.

Example:

```
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: DEMO
```

```
1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
```

```
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
```

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

PATIENT	ALLERGY	OBS/ HIST ADR TYPE
-----	-----	-----
1. DEMO,ALLERGY CONNIE (110211)	IBUPROFEN	HIST YES DRUG
2. DEMO,ALLERGY CONNIE (110211)	PENICILLIN	OBS NO DRUG

```

PATIENT: DEMO,ALLERGY CONNIE CAUSATIVE AGENT: IBUPROFEN
INGREDIENTS: IBUPROFEN VA DRUG CLASSES: NONSALICYLATE NSAIs,A

SOURCE OF INFORMATION: SPOUSE
ORIGINATOR: SMITH,MARY ORIGINATED: Apr 27, 2011@07:37
SIGN OFF: YES OBS/HIST: HISTORICAL
```

```

EVENT: DRUG INTOLERANCE          CODE: 59037007
                                OBS D/T: Apr 26, 2011

ORIGINATOR
COMMENTS:
    Date: Apr 27, 2011@07:38:44   User: SMITH,MARY
                                Title: PHARMACIST
    SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
    ALL NSAIDS

ID BAND MARKED:                  CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973)      SOURCE: SPOUSE

    MECHANISM: PHARMACOLOGIC

Is the reaction information correct? Yes// N (No)
Mark this reaction as 'Entered-in-Error'? NO

CAUSATIVE AGENT: IBUPROFEN
    TYPE: DRUG
    INGREDIENTS: IBUPROFEN
VA DRUG CLASSES: MS102 - NONSALICYLATE NSAIs,ANTIRHEUMATIC
    OBS/HIST: HISTORICAL

    SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973)    SOURCE: SPOUSE
    MECHANISM: PHARMACOLOGIC

Would you like to edit any of this data? Y (Yes)

CAUSATIVE AGENT: IBUPROFEN// (Uneditable)
  1  Drug
  2  Food
  3  Other
Select Classification(s) of Causative Agent: 1//
Select DRUG INGREDIENT: IBUPROFEN// ?
    Answer with DRUG INGREDIENTS:
    IBUPROFEN

        You may enter a new DRUG INGREDIENTS, if you wish
        Select primary drug ingredient.

    Answer with DRUG INGREDIENTS NAME
    Do you want the entire DRUG INGREDIENTS List? N (No)
Select DRUG INGREDIENT: IBUPROFEN//
Select VA DRUG CLASS: NONSALICYLATE NSAIs,ANTIRHEUMATIC// ?
    MS102          NONSALICYLATE NSAIs,ANTIRHEUMATIC

    Answer with VA DRUG CLASS CODE, or CLASSIFICATION
    Do you want the entire 578-Entry VA DRUG CLASS List? N (No)
Select VA DRUG CLASS: NONSALICYLATE NSAIs,ANTIRHEUMATIC//
SOURCE: SPOUSE//
(O)bserved or (H)istorical Allergy/Adverse Reaction: HISTORICAL

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

    Signs/Symptoms                      Date Observed
-----
  1  GI REACTION                          Apr 04, 1973

```

```

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

CAUSATIVE AGENT: IBUPROFEN
      TYPE: DRUG
      INGREDIENTS: IBUPROFEN
VA DRUG CLASSES: MS102 - NONSALICYLATE NSAIs,ANTIRHEUMATIC
      OBS/HIST: HISTORICAL

SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973)      SOURCE: SPOUSE
      MECHANISM: PHARMACOLOGIC

ORIGINATOR
COMMENTS:
      Date: Apr 27, 2011@07:38:44      User: SMITH,MARY
                                      Title: PHARMACIST
      SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
      ALL NSAIDS

COMMENTS:
      No existing text
      Edit? NO//
      PATIENT: DEMO,ALLERGY CONNIE CAUSATIVE AGENT: IBUPROFEN
INGREDIENTS: IBUPROFEN      VA DRUG CLASSES: NONSALICYLATE NSAIs,A

      SOURCE OF INFORMATION: SPOUSE
ORIGINATOR: SMITH,MARY      ORIGINATED: Apr 27, 2011@07:37
      SIGN OFF: YES      OBS/HIST: HISTORICAL
      EVENT: DRUG INTOLERANCE      CODE: 59037007
                                      OBS D/T: Apr 26, 2011

ORIGINATOR
COMMENTS:
      Date: Apr 27, 2011@07:38:44      User: SMITH,MARY
                                      Title: PHARMACIST

      SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
      ALL NSAIDS

ID BAND MARKED:      CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973)      SOURCE: SPOUSE

      MECHANISM: PHARMACOLOGIC

PATIENT      ALLERGY      OBS/
-----      -----      HIST ADR TYPE
-----      -----      -----

1. DEMO,ALLERGY CONNIE (110211) PENICILLIN      OBS NO DRUG

```

3.5.3 Reports Menu ...

This menu contains all the reports a verifier may need.

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 a 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

3.5.3.1 Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not inactive or entered in error) allergy/adverse reaction data for a particular patient. This report may be sent to 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, IHS chart number, 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, SNOMED event and code, 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 assessed for reactions, the body of the report will display a message stating that there is no reaction data on file.

Example:

```

Select Reports Menu Option: 1 Active Listing of Patient Reactions

Select PATIENT: DEMO
 1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
 2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
 3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
 4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
 5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211

DEVICE: HOME// VIRTUAL TERMINAL

ACTIVE ALLERGY/ADVERSE REACTION LISTING
Run Date/Time: 4/27/11 1:43:36 pm
DEMO,ALLERGY CO 110211 OCT 24,1933 (77)

ADVERSE REACTION VERIFIED OBS/
----- HIST

```

```

TYPE: DRUG
=====
IBUPROFEN                                NO          HIST
EVENT: DRUG INTOLERANCE
SNOMED CODE: 59037007
  Reactions: GI REACTION (Apr 04, 1973)
PENICILLIN                                NO          OBS
EVENT: DRUG ALLERGY
SNOMED CODE: 416098002
  Reactions: ANAPHYLAXIS (Jun 23, 2001)
Enter RETURN to continue or '^' to exit:

```

3.5.3.2 Print Patient Reaction Data

This option will allow the user to produce 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, IHS Chart number, date of birth, and age. The body of the report contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the source of the data, 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, the SNOMED Event and code, whether the patient ID band or chart is marked, a list of signs/symptoms, the mechanism, and additional comments made by the originator. For Inactive reactions it will also contain the inactive date, reason, and person who inactivated. A line of dots appears in the body of the report between the various reaction entries.

Example:

```

Select Reports Menu Option: 2  Print Patient Reaction Data

Select PATIENT: DEMO
 1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
 2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
 3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
 4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **        WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE    <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1-3

```

Select 1:ACTIVE, 2:ENTERED IN ERROR, 3:INACTIVE
Which would you like to see?: (1-3): 1-3

DEVICE: HOME// VIRTUAL TERMINAL

ALLERGY/ADVERSE REACTION REPORTS

Run Date/Time: 4/27/11 2:16:22 pm

DEMO,ALLERGY CO 110211 OCT 24,1933 (77)

STATUS: ACTIVE

TYPE: DRUG
=====

AGENT: IBUPROFEN
INGREDIENTS: IBUPROFEN VA DRUG CLASSES: NONSALICYLATE NSAIDs,A

SOURCE OF INFORMATION: SPOUSE
ORIGINATOR: NIESEN,MARY ANN ORIGINATED: Apr 27, 2011@07:37
SIGN OFF: YES OBS/HIST: HISTORICAL
EVENT: DRUG INTOLERANCE CODE: 59037007

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:38:44 User: NIESEN,MARY ANN
Title: PHARMACIST

SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
ALL NSAIDS

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973) SOURCE: SPOUSE

MECHANISM: PHARMACOLOGIC

.....
AGENT: PENICILLIN
INGREDIENTS: PENICILLIN VA DRUG CLASSES: (INACTIVE) PENICILLIN
PENICILLINS,AMINO DER

SOURCE OF INFORMATION: CHART REVIEW
ORIGINATOR: NIESEN,MARY ANN ORIGINATED: Apr 27, 2011@07:39
SIGN OFF: YES OBS/HIST: OBSERVED
EVENT: DRUG ALLERGY CODE: 416098002
SEVERITY: SEVERE OBS D/T: Jun 23, 2001

ORIGINATOR

COMMENTS:

Date: Apr 27, 2011@07:40:11 User: NIESEN,MARY ANN
Title: PHARMACIST

REACTION WAS SEEN AND TREATED IN THE ER BUT NOT ADDED TO
ADVERSE REACTIONS

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: ANAPHYLAXIS (Jun 23, 2001) SOURCE: CHART REVIEW

MECHANISM: ALLERGY

```

.....
STATUS: E/E
-----
TYPE: DRUG
=====

AGENT: BEN-GAY
INGREDIENTS: VA DRUG CLASSES:

ORIGINATOR: DAVIS, MARY J ORIGINATED: Jul 15, 2004@09:00
SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED: Jul 15, 2004@09:00:32

MECHANISM: UNKNOWN

VERIFIER: DAVIS, MARY J VERIFIED: JUL 20, 2004@10:59:19

USER ENTERING D/T ENTERED
IN ERROR: NIESEN, MARY ANN IN ERROR: APR 27, 2011@12:00:44

ENTERED IN ERROR
COMMENTS:
Date: Apr 27, 2011@12:00:44 User: NIESEN, MARY ANN
Title: PHARMACIST
THIS REACTION IS NOT FOR THIS PATIENT, ACCIDENTALLY
ENTERED ON WRONG PATIENT.

.....
STATUS: INACTIVE
-----
TYPE: FOOD
=====

AGENT: WALNUTS

SOURCE OF INFORMATION: PATIENT
ORIGINATOR: NIESEN, MARY ANN ORIGINATED: Apr 27, 2011@09:58
SIGN OFF: YES OBS/HIST: HISTORICAL
EVENT: FOOD INTOLERANCE CODE: 235719002

ID BAND MARKED: CHART MARKED: Apr 27, 2011@14:07:39

INACTIVE: APR 27, 2011@12:01:50
REASON: NO LONGER ALLERGIC BY: NIESEN, MARY ANN

SIGNS/SYMPTOMS: HIVES (Jan 29, 2010) SOURCE: PATIENT

MECHANISM: UNKNOWN

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

```

3.5.3.3 Print an FDA report for a Patient

This option allows 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 data into the system. The report should be queued to run on a printer with a 132-column width.

Example: *See section 3.4.3.3*

3.5.3.4 Print all FDA events within a 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 to the screen. 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.

Example: *for the unabbreviated report, see section 3.4.3.3 for an example*

```
Select Reports Menu Option: 4  Print All FDA Events within D/T Range
Select Start Date/Time: -3  (APR 26, 2011)
Select End Date/Time: (4/26/2011 - 4/29/2011): T//  (APR 29, 2011)
Do you want an Abbreviated report? Yes//  (Yes)

DEVICE: HOME//  VIRTUAL TERMINAL
Apr 29, 2011@06:42:43  Page: 1
FDA ABBREVIATED REPORT
PATIENT  SUSPECTED AGENT  D/T OF EVENT
-----
DEMO,ALLERGY CONNIE (110211) IBUPROFEN  Apr 26,2011
      (SENT TO FDA: Apr 26,2011)
DEMO,JAMES WILLIAM (192636)  IBUPROFEN  Apr 27,2011
Enter RETURN to continue or '^' to exit:
```

3.5.3.5 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 may select 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 it was run. The body contains the patient's name, IHS chart number, the causative agent, the origination date/time, and the name of the originator.

Example:

```
Select Reports Menu Option: 5  Print Patient FDA Exception Data

Select PATIENT NAME: PATIENT,CRSC
 1  PATIENT,CRSC  M 06-01-1972  WW 900003
 2  PATIENT,CRSCA  F 06-01-1944  WW 900081
 3  PATIENT,CRSCB  M 07-02-1956  WW 900082
```

```

 4 PATIENT,CRSCC          <A>  F 06-02-1954          WW 900083
 5 PATIENT,CRSCD          M 06-04-1955          WW 900084
ENTER '^' TO STOP, OR
CHOOSE 1-5: 4
  PATIENT,CRSCC          <A>  F 06-02-1954          WW 900083
Enter the Date to start search (Time optional): T-30// 1/1/07 (JAN 01, 2007)

DEVICE: HOME//    VIRTUAL TERMINAL
Apr 29,2011 06:57:46                               Page: 1
FDA EXCEPTION REPORT (1/1/07 to 4/29/11)
ORIGINATION D/T      CAUSATIVE AGENT              ORIGINATOR
-----

      Patient: PATIENT,CRSCC (HRN: 900083)
Nov 1,2007@10:37    PENICILLIN                    WADE,JUNE A
Enter RETURN to continue or '^' to exit:

```

3.5.3.6 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 the screen. The header of the report contains the name of the report, the date range selected, and the date/time that the report was run. The body of the report contains the patient's name and IHS chart number, the causative agent, the name of the person who originated the data entry, and the origination date/time of the data.

Example:

```

Select Reports Menu Option: 6 Print All FDA Exceptions within a D/T Range
Select Start Date: -180 (OCT 31, 2010)
Select End Date: (10/31/2010 - 4/29/2011): T// (APR 29, 2011)

DEVICE: HOME//    VIRTUAL TERMINAL
Apr 29,2011 07:00:39                               Page: 1
FDA EXCEPTION REPORT (10/31/10 to 4/29/11)
ORIGINATION D/T      CAUSATIVE AGENT              ORIGINATOR
-----

      Patient: DEMO,NORMAN DALE (HRN: 118159)
Mar 24,2011@13:15    CARTEOLOL                    ROZSINSKI,DAVID
      Patient: DEMO,CURTIS DALE (HRN: 198532)
Nov 4,2010@11:01     STREPTOMYCIN                 ROZSINSKI,DAVID
      Patient: DEMO,LYNELLE LEE (HRN: 198768)
Nov 2,2010@15:07     YEAST                        ROZSINSKI,DAVID
Enter RETURN to continue or '^' to exit:

```

3.5.3.7 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 of ID bands marked. 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). This applies to Inpatients only. When entering a reaction on an Outpatient, the option to indicate if the ID Band had been marked is not available or displayed.

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, IHS chart number, name of the causative agent, and whether the patient ID band, chart, or both were unmarked.

Example:

```
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):1
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, or TEAM
Do you want the entire HOSPITAL LOCATION List? y (Yes)
Choose from:
ICU
MEDICALSURGICAL
NEWBORN
OBSTETRICS

Select Location: ICU
Another Location: MEDICALSURGICAL
Another Location: NEWBORN
Another Location: OBSTETRICS
Another Location:

DEVICE: HOME// VIRTUAL TERMINAL

Apr 27,2011 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1
CURRENT INPATIENTS

PATIENT SSN ALLERGY UNMARKED
-----
          WARD: ICU
DEMO,TAMMY LYNN 18-73-35 PENICILLIN CHART
                   AMOXICILLIN CHART

Apr 27,2011 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 2
CURRENT INPATIENTS

PATIENT SSN ALLERGY UNMARKED
```

```

-----
                WARD: MEDICALSURGICAL
DEMO,LAVELDA WAPSKINEH   10-33-24   MORPHINE           CHART
DEMO,DOROTHY ROSE       99-99-99   COTTONSEED OIL    CHART
                        WINE           CHART
DEMO,TAMBRA ANNETTE    17-27-79   SULFA             CHART
                        ENALAPRIL    CHART
                        GATIFLOXACIN  CHART

Apr 27,2011      PATIENTS WITH UNMARKED ID BAND/CHART      PAGE 3
CURRENT INPATIENTS

PATIENT                SSN                ALLERGY                UNMARKED
-----
                WARD: NEWBORN
* No Patients for this Ward *

Apr 27,2011      PATIENTS WITH UNMARKED ID BAND/CHART      PAGE 4
CURRENT INPATIENTS

PATIENT                SSN                ALLERGY                UNMARKED
-----
                WARD: OBSTETRICS
DEMO,CRYSTAL ANN       19-73-28   DOXYCYCLINE       CHART

```

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

Example:

```

Select Adverse Reaction Tracking User Menu Option: 4 List by Location of Unmark
ed 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):1
Select Location: ALL
Do you mean ALL Locations? Yes// (Yes)
Another Location:

```

3.5.3.8 Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients who have not been signed off (completed) by the user entering the 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 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 IHS chart number, the causative agent, and the date/time the entry was made.

Example:

```
Select Reports Menu Option: 8 Patient Allergies Not Signed Off
DEVICE: HOME// VIRTUAL TERMINAL
ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 4/27/11 2:08:19 pm
```

ORIGINATOR	PATIENT	ALLERGY	ORINATION DATE/TIME
ADAIR,PETER	DEMO,BABY(99-99-95)	PENICILLIN	DEC 15, 2009@14:00
BARREL,SCOT A	DEMO,DANIEL(13-34-45)	IOD	JAN 14, 2004@09:53
BARREL,SCOT A	DEMO,JUDY LY(13-80-30)	PENICILLIN	MAR 24, 2004@10:15
BOWTIE,JEFF W	DEMO,SARA(11-05-92)	CLARITIN D	JUL 13, 2004@17:16
BOWTIE,JEFF W	DEMO,SARA(11-05-92)	UNKNOWN	JUL 13, 2004@17:17
BOWTIE,JEFF W	DEMO,MARTA (11-06-54)	SULFA	JUL 13, 2004@17:24
BOWTIE,JEFF W	DEMO,ANNA JA(11-06-90)	PENICILLIN	JUL 13, 2004@17:32
BOWTIE,JEFF W	DEMO,KELSIE(11-07-01)	CODEINE	JUL 13, 2004@17:38
BOWTIE,JEFF W	DEMO,CAITLI (11-10-56)	CECLOR	JUL 13, 2004@18:29
BOWTIE,JEFF W	DEMO,JORDAN (11-11-22)	CODEINE	JUL 13, 2004@18:39
BOWTIE,JEFF W	DEMO,CHRYST(11-19-16)	IBUPROFEN	JUL 13, 2004@19:54
BOWTIE,JEFF W	DEMO,ALBE(11-62-28)	CODEINE	JUL 13, 2004@20:07
BOWTIE,JEFF W	DEMO,ROBERT (11-67-78)	NONE	JUL 13, 2004@20:53
BOWTIE,JEFF W	DEMO,TIERRA(11-68-30)	ERTYTHROMYCIN	JUL 13, 2004@20:57
BOWTIE,JEFF W	DEMO,BYRON G(11-69-67)	VISTERIL	JUL 13, 2004@21:23

3.5.3.9 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 reactions. 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, IHS chart number, and provider. The room-bed will appear for current inpatients.

NOTE: This report will show patients as not having received an assessment if the assessment was entered after the end date of the range. For this reason, it is recommended to end the range with today. This can be done with an entry of "T" (for "Today") and the "Enter END Date (time optional): T/" prompt.

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

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

Example:

```
Select Adverse Reaction Tracking User 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.
```

```
Please note! This report will show patients as not having received an
assessment if the assessment was entered after the end date of
the range. For this reason, it is recommended to end the range
with today. This can be done with an entry of 'T' (for Today) at
the 'Enter END Date (time optional): T//' prompt.
```

```
Enter START Date (time optional): -90 (JAN 27, 2011)
Enter END Date (time optional): T// (APR 27, 2011)
Select Location: ALL
Do you mean ALL Locations? Yes// (Yes)
Another Location:
```

```
QUEUE TO PRINT ON
DEVICE: Home VIRTUAL TERMINAL [YOU CAN NOT SELECT A VIRTUAL TERMINAL]
```

```
Previously, you have selected queueing.
Do you STILL want your output QUEUED? Yes// N (No)
DEVICE: Home VIRTUAL TERMINAL
```

```
Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 1
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00
```

```
PATIENT SSN
-----
```

```
CLINIC: MED CLINIC
* No Patients for this Clinic *
```

```
Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 2
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00
```

```
PATIENT SSN PROVIDER
-----
```

```
WARD: ICU
DEMO,ALICIA LOUISE 160758 ASHLY,BARBARA A
Room/Bed: 3011-1
DEMO,LOIS JEANNETTE 180836 JOE,HOWARD
DEMO,ADRIAN 212735 SMITH,GRETA LOUISE
Room/Bed: 3012-1
ROADKILL,BUBBIT 253614 DEMO,DOCTOR
```

3.5.3.10 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 this report is run during the session, those values will be empty. If the report is run again in the same session, 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 the report contains the name of the report, the date it was run, and the date range entered. 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 4 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.

Example:

```
Select Reports Menu Option: 10 List Autoverified Reaction Data
* Previous selection: VERIFICATION DATE/TIME from Jan 1,1990 to Apr 29,2011@24:00
START WITH VERIFICATION DATE/TIME: Jan 1,1990// (JAN 01, 1990)
GO TO VERIFICATION DATE/TIME: Apr 29,2011// (APR 29, 2011)
* Previous selection: PATIENT:WARD LOCATION from ALL
START WITH WARD LOCATION: ALL//
GO TO WARD LOCATION: LAST//
* Previous selection: MECHANISM from A (ALLERGY)
START WITH MECHANISM: ALL// ERGY USES INTERNAL CODE: A
GO TO MECHANISM: LAST//
DEVICE: HOME VIRTUAL TERMINAL Right Margin: 80//
04/29/11 LIST OF AUTOVERIFIED ALLERGIES FROM 01/01/90 TO 04/29/11 Page: 1

PATIENT                ROOM-BED      REACTANT                VER. DATE
-----
WARD LOCATION: MEDICALSURGICAL
      MECHANISM: PHARMACOLOGIC
DEMO,TAMBRA ANN (9593                ZOCOR                JUN 21,2004
ORIGIN.: WRAY,FAY
SIGNS: WEAKNESS
COMMENTS:
DEMO,TAMBRA ANN (9593                GLUCOTROL            JUN 16,2004
ORIGIN.: BROWN,ROGER
SIGNS: SWEATING
COMMENTS: PT DENIES ALG
      MECHANISM: UNKNOWN
DEMO,TAMBRA ANN (9593                ASPIRIN              FEB  1,1998
ORIGIN.: ADAM,ADAM
SIGNS: HIVES
COMMENTS:
DEMO,TAMBRA ANN (9593                BACTRIM              FEB  2,1998
ORIGIN.: ADAM,ADAM
SIGNS: HIVES
```

COMMENTS:			
DEMO, TAMBRA ANN (9593		AMOXICILLIN	SEP 20, 2001
ORIGIN.: JOHN, PATRICK			
SIGNS: RASH			
COMMENTS:			
DEMO, TAMBRA ANN (9593		NAPROXEN	JUN 22, 2004
ORIGIN.: BROWN, ROGER			
SIGNS:			
COMMENTS:			
MECHANISM: ALLERGY			
DEMO, ALBERT TILLMA ()	3305-1	ASPIRIN	MAY 17, 2007
ORIGIN.: BRUNEI, CARLA			
SIGNS: HIVES			
ANAPHYLAXIS			
NAUSEA, VOMITING			
DIARRHEA			
SWELLING (NON-SPECIFIC)			
ANXIETY			
DROWSINESS			
RASH			
DYSPEPSIA			
COMMENTS:			
MECHANISM: UNKNOWN			
CLINTON, JANIE SUE (9120)	3311-1	IODINE	JUL 22, 2004
ORIGIN.: DAVIS, JANE			
SIGNS:			
COMMENTS:			

3.5.3.11 List by Location Not Verified Reactions

This option 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 the Application Coordinator or IT personnel 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 locations. The body contains the patient's name and IHS chart number, the causative agent, the name of the originator of the reaction, and the date/time the data originated. The Room-Bed is also displayed for each inpatient.

Example:

Select Reports Menu Option: 11	List by Location Not Verified Reactions
DEVICE: HOME//	VIRTUAL TERMINAL
Report Date: Apr 28, 2011	Page: 1
List of Unverified Reactions by Ward Location	
Ward Location: ICU	

Origination Date/Time	Originator	Reaction
3013-1 DEMO,JEREMY PAUL (20-23-08) Nov 13, 2008@14:38	JONES,CARLA	AMPICILLIN
Report Date: Apr 28, 2011		Page: 2
List of Unverified Reactions by Ward Location		
Ward Location: MEDICALSURGICAL		
Origination Date/Time	Originator	Reaction
3309-2 DEMO,DOROTHY ROSE (99-99-99) Apr 27, 2011@10:01	SMITH,MARY	WALNUTS
3319-1 DEMO,LAVELDA WAPSKINEH (10-33-24) Apr 17, 2008@10:35	JONES,CARLA	MORPHINE
Report Date: Apr 28, 2011		Page: 3
List of Unverified Reactions by Ward Location		
Ward Location: OUTPATIENT		
Origination Date/Time	Originator	Reaction
DEMO,BROOKE ANN EESHAHA (19-79-56) Aug 05, 2004@17:40	WILLIAMS,JOHN J	SULFA
DEMO,CAITLIN TIANA (11-10-56) Jul 13, 2004@18:29	BOWTIE,JEFF W	CECLOR
DEMO,WANDA CARROL (18-29-00) Aug 04, 2004@19:42	WILLIAMS,JOHN J	FOSINOPRIL
DEMO,JEREMY MICHAEL (17-59-45) Aug 04, 2004@19:55	FISHER,MARTHA A	SULFA
DEMO,MARIAH HOPE (19-75-66) Aug 05, 2004@18:32	WILLIAMS,JOHN J	PENICILLIN
Aug 05, 2004@18:32	WILLIAMS,JOHN J	AMPICILLIN
DEMO,AMOS LYNN (17-57-76) Aug 04, 2004@20:40	FISHER,MARTHA A	NAPROXEN
DEMO,SUE ELLEN (10-05-06) Jul 27, 2004@09:48	BOWTIE,JEFF W	SERTRALINE
DEMO,JORDAN LAY (12-99-01) Jul 21, 2004@17:46	BOWTIE,JEFF W	PENICILLIN

3.5.3.12 List by Location and Date all Signed Reactions

This option 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 terminal screen.

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

Example:

```
Select Reports Menu Option: 12 List by Location and Date All Signed Reactions
Enter Start Date: -30 (MAR 29, 2011)
Enter Ending Date: t (APR 28, 2011)
```

DEVICE: HOME// VIRTUAL TERMINAL

One moment please...

Apr 28, 2011

Page: 1

List all Signed Patient Reactions for Ward Location MEDICALSURGICAL
From Mar 29, 2011 to Apr 28, 2011@24:00

Date	Originator	Type	Causative Agent

Patient: DEMO,DOROTHY ROSE (99-99-99)			
Apr 27, 2011@10:01	SMITH,MARY	F	WALNUTS

Apr 28, 2011

Page: 2

List all Signed Patient Reactions for Out Patients
From Mar 29, 2011 to Apr 28, 2011@24:00

Date	Originator	Type	Causative Agent

Patient: DEMO,CRYSTAL LYNN (16-06-13)			
Mar 29, 2011@11:18	ROZINSKI,DAVID	D	TDAP
Patient: DEMO,ALLERGY CHARLES (10-48-36)			
Apr 20, 2011@09:01	SMITH,MARY	D	AMOXICILLIN
Apr 18, 2011@11:23	SMITH,MARY	F	WALNUTS
Patient: DEMO,ALLERGY CONNIE (11-02-11)			
Apr 27, 2011@07:37	SMITH,MARY	D	IBUPROFEN
Apr 27, 2011@07:39	SMITH,MARY	D	PENICILLIN
Apr 27, 2011@09:58	SMITH,MARY	F	WALNUTS
Patient: DEMO,JOHN (00-00-55)			
Apr 27, 2011@10:19	SMITH,MARY	D	PENICILLIN
Patient: DEMO,DUSTIN KEE (20-20-97)			
Apr 04, 2011@13:32	ROZINSKI,DAVID	D	INFLUENZA

Apr 28, 2011

Page: 3

List all Signed Patient Reactions for Out Patients
From Mar 29, 2011 to Apr 28, 2011@24:00

Date	Originator	Type	Causative Agent

Patient: DEMO,AMBER DAWN (10-15-65)			
Apr 26, 2011@10:03:28	HIMS,BARBARA	DF	PEANUTS
Patient: PATIENT,CRSFC (90-01-58)			
Mar 29, 2011@11:40	ROZINSKI,DAVID	D	TDAP
Patient: DEMO,GEOFFREY MICHAEL (20-07-13)			
Apr 04, 2011@11:23	ROZINSKI,DAVID	D	HEPATITIS A
Patient: TEST,CATHY (00-00-03)			
Apr 06, 2011@15:21	ROZINSKI,DAVID	D	CIPROFLOXACIN

Enter RETURN to continue or '^' to exit:

3.5.3.13 List FDA Data by Report Date

This option 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 screen.

The header of the report contains the title of the report, the date range selected, and the date the report was run. The body of the report contains the patient's name and IHS chart number, 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.

Example:

```

Select Reports Menu Option: 13 List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: -14 (APR 14, 2011)
Enter Ending Date: T (APR 28, 2011)

DEVICE: HOME// VIRTUAL TERMINAL
Report Date: Apr 28, 2011 Page: 1
Adverse Reaction Tracking Report
From: 4/14/11 To: 4/28/11
Patient Dates Related Reaction
-----
DEMO,ALLERGY CONNIE Obs DT: 4/23/11 PENICILLIN
(11-02-11) Trk DT: 4/27/11
Loc: OUT PATIENT
Obs: SMITH,MARY 5 Days Difference

DEMO,JOHN Obs DT: 4/26/11 PENICILLIN
(00-00-55) Trk DT: 4/27/11
Loc: OUT PATIENT
Obs: SMITH,MARY 1 Days Difference

Enter RETURN to continue or '^' to exit:

```

3.5.4 Edit Chart and ID Band

This option allows sites to update the ID Band marking status. All questions and displays regarding chart marking have been removed, since the entry of a reaction into ART is the marking of the chart.

The user may select a patient, and is then shown a list of reactions for that patient (active and inactive). The user may select one or more reactions. When done selecting reactions, the user must enter once more to get to the ID Band question. At the "Has the ID Band been marked or unmarked for this (these) CAUSATIVE AGENT(S)?" the user may select YES to indicate the band has been marked, or NO to indicate the band has not been marked.

Example:

```

Select Adverse Reaction Tracking Verifier Menu Option: 4  Edit Chart and ID Band
Select Patient: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL      F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE      M  ** SENSITIVE **          WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

CHOOSE FROM:
  IBUPROFEN
  PENICILLIN
  WALNUTS (Inactive)

Select CAUSATIVE AGENT: IBUPROF
  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  IBUPROFEN

Select another CAUSATIVE AGENT: PEN
  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  PENICILLIN

Select another CAUSATIVE AGENT: WALN
  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  WALNUTS

Select another CAUSATIVE AGENT:
This session you have CHOSEN:
  IBUPROFEN
  PENICILLIN
  WALNUTS

```

3.5.5 FDA Enter/Edit Menu ...

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 allow users to enter and edit the FDA data.

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

3.5.5.1 Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning and 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 refill 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 (e.g., Initial).

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

Example:

```

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

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

Select PATIENT NAME: DEMO
  1  DEMO,ALLERGY CHARLES  <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2  DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3  DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4  DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5  DEMO,AUSTIN WAYNE    M  ** SENSITIVE **        WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE    <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
  IBUPROFEN
  PENICILLIN

Select CAUSATIVE AGENT: PENICIL
                                <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  PENICILLIN

Select date reaction was OBSERVED (Time Optional): ??

Choose from:
JUN 23, 2001

```

Select date reaction was OBSERVED (Time Optional): 6/23/2001 (JUN 23, 2001)
...OK? Yes// (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): 1-5

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

Signs/Symptoms

1 ANAPHYLAXIS

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

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

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

Select Action (A/D/E):

This patient has the following Drugs selected:

PENICILLIN

Select Action (A/D/E):

THIS PATIENT HAS NO CONCOMITANT DRUGS ON FILE

Select Action (A/D/E):

OTHER RELATED HISTORY:

No existing text
Edit? NO//

MANUFACTURER NAME: LEDERLE

- 1 LEDERLE LABS
- 2 LEDERLE PARENTE
- 3 LEDERLE PIPCILL

CHOOSE 1-3: 1 LEDERLE LABS

MFR ADDRESS #1: PO Box 8299

MFR ADDRESS #2:

MFR ADDRESS #3:

MFR CITY: PHILADELPHIA

MFR STATE: PA PENNSYLVANIA

MFR ZIP: 19101

IND/NDA # FOR SUPPORT DRUG:

MFR CONTROL #: ??

This is the control number used by the manufacturer.

MFR CONTROL #: 234FD67

```

DATE RECEIVED BY MFR:
Select SOURCE: ?
    You may enter a new REPORT SOURCE, if you wish
    Choose from:
        f    FOREIGN
        h    HEALTH PROFESSIONAL
        s    STUDY
        l    LITERATURE
        c    CONSUMER

Select SOURCE: H (h    HEALTH PROFESSIONAL)
    Are you adding 'HEALTH PROFESSIONAL' as a new SOURCE (the 1ST for this ADVERSE
    REACTION REPORTING)? No// Y (Yes)
Select SOURCE:
15 DAY REPORT: ??
    This field is to determine if the 15 Day Report has been completed.

    Choose from:
        y    YES
        n    NO
15 DAY REPORT: N NO
REPORT TYPE: ??
    This is the type of report issued.

    Choose from:
        i    INITIAL
        f    FOLLOWUP

REPORTER NAME: PHARMACIST,PHARMACIST Replace
REPORTER ADDRESS1: DEMO INDIAN MEDICAL CENTER Replace
REPORTER ADDRESS2: 100 S. MAIN//
REPORTER ADDRESS3:
REPORTER CITY: ANYTOWN//
REPORTER STATE: OKLAHOMA//
REPORTER ZIP: 74464//
REPORTER PHONE: 555-123-4567//
IS REPORTER A HEALTH CARE PROVIDER?: YES//
Do you want the identity disclosed to the manufacturer?: NO
    //

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):

```

3.5.5.2 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.

Example:

```

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

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
 2 DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
 3 DEMO,ALLERGY LEANN <A>  F 12-04-1946 XXX-XX-9435  WW 150673
 4 DEMO,AMILYA PEARL      F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE      M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE      <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
  IBUPROFEN
  PENICILLIN

Select CAUSATIVE AGENT: PENI
                        <A>  F 10-24-1933 XXX-XX-4127  WW 110211
                        PENICILLIN
Select date reaction was OBSERVED (Time Optional): ??

  Choose from:
  JUN 23, 2001

Select date reaction was OBSERVED (Time Optional): 6/23/2001  (JUN 23, 2001)
  ...OK? Yes//  (Yes)

P&T Report Completion
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?: Y  YES
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: Y  YES
DATE REPORTED TO FDA: 4/26/2011  (APR 26, 2011)
P&T ACTION MFR REPORT: ??
  This field tells if the P&T committee determined whether to send the rep
  ort to
  the manufacturer.

  Choose from:
  y      YES
  n      NO
P&T ACTION MFR REPORT: Y  YES
DATE OF PATIENT CONSENT TO MFR: 4/26/2011  (APR 26, 2011)
DATE SENT TO MFR: 4/26/2011  (APR 26, 2011)

ADDENDUM:
  No existing text
  Edit? NO//

```

3.5.6 Online Reference Card

This option provides a very brief overview of entering patient reaction data. Users may navigate through the document using the up and down arrows on the keyboard:



Users may exit the online reference using the F1 key quickly followed by the E key:



3.5.7 Reactivate Reaction/Allergy

This option is used to reactivate a previously inactivated reaction. The user may select a patient with inactivated reactions. Selecting a patient without inactivated reactions results in the user being brought immediately back to the menu screen.

A list of the patient's inactivated reactions will be displayed, and the user may select one to reactivate. The software will check existing entries for duplication, and then verify that this reaction should be reactivated. Answering YES at the prompt will reactivate the reaction.

Example:

```
Select Adverse Reaction Tracking Verifier Menu Option: 7  Reactivate Reaction/Al
Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
 2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
 3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673
 4 DEMO,AMILYA PEARL F 06-30-2008 XXX-XX-0821 WW 106735
 5 DEMO,AUSTIN WAYNE M ** SENSITIVE ** WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT          SOURCE          VER.    MECH.    OBS/
-----          -
WALNUTS          PATIENT          NO     UNKNOWN  HIST  FOOD
```

```

Reactions: HIVES(Source: PATIENT)
Inactive: APR 27, 2011@12:01:50( NO LONGER ALLERGIC )

Enter Item to Reactivate: WALNUTS

Checking existing PATIENT ALLERGIES (#120.8) file for matches...
                <A>   F 10-24-1933 XXX-XX-4127  WW 110211
WALNUTS
WALNUTS  OK? Yes//   (Yes)

Reaction has been reactivated

```

3.5.8 Unable to assess allergies

This option allows the user to document the inability to assess the patient's reactions. This is intended to be used when circumstances are such that the user is unable to determine if the existing data in the database is correct and complete, or if no assessment has been done but circumstances prevent the gathering of this data.

The user may select a patient, and a current listing of active reaction will be shown. The user will be asked if the patient should be marked as being unable to assess for allergies. Answering YES will mark the patient, and the user will be required to enter a reason. The choices are ALTERED MENTAL STATUS, CAREGIVER DOES NOT KNOW, LANGUAGE BARRIER, OTHER, PATIENT DOES NOT KNOW, or UNCONSCIOUS. Selecting OTHER as the reason will allow the user to enter a brief explanation. NOTE: it is strongly recommended that this free text explanation be entered in mixed case, and to be limited to 30 characters or less to avoid display issues in the EHR.

Multiple instances of "unable to assess" may be entered during a stay/visit at the facility. The "unable to assess" will be removed when activity is performed on the patient's record: marking "no known" reactions, adding or editing a reaction, etc.

Example:

```

Select Adverse Reaction Tracking Verifier Menu Option: 8  Unable to assess aller

Select PATIENT NAME: DEMO
  1 DEMO,ALLERGY CHARLES  <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT                SOURCE          VER.    MECH.    OBS/
-----                -
IBUPROFEN                SPOUSE          NO     PHARM    HIST    DRUG
  Reactions: GI REACTION(Source: SPOUSE)
PENICILLIN                CHART REVIEW    NO     ALLERGY  OBS     DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)

```

```

WALNUTS                PATIENT      YES   UNKNOWN  HIST  FOOD
  Reactions: HIVES(Source: PATIENT)
  Inactive: APR 27, 2011@12:01:50( NO LONGER ALLERGIC )
  Reactivated: APR 28, 2011@16:33:19
Do you want to mark this patient as being unable to assess for allergies?? NO//Y
ES
Select reason: ??

  Choose from:
  ALTERED MENTAL STATUS
  CAREGIVER DOES NOT KNOW
  LANGUAGE BARRIER
  OTHER
  PATIENT DOES NOT KNOW
  UNCONSCIOUS

Select reason: UNCONSCIOUS
Patient has been marked unassessable

Select Adverse Reaction Tracking Clinician Menu Option: 1  Enter/Edit Patient Re

Select PATIENT NAME: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **        WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT                SOURCE      VER.    MECH.    OBS/
-----                -
IBUPROFEN              SPOUSE      NO     PHARM    HIST  DRUG
  Reactions: GI REACTION(Source: SPOUSE)
PENICILLIN             CHART REVIEW NO    ALLERGY  OBS    DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)
WALNUTS                PATIENT      YES   UNKNOWN  HIST  FOOD
  Reactions: HIVES(Source: PATIENT)
  Inactive: APR 27, 2011@12:01:50( NO LONGER ALLERGIC )
  Reactivated: APR 28, 2011@16:33:19
Patient has been marked as unassessable for allergies
Reason given is UNCONSCIOUS

Can this pt. now be assessed? YES//

Select PATIENT NAME: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **        WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2

REACTANT                SOURCE      VER.    MECH.    OBS/
-----                -
IBUPROFEN              SPOUSE      NO     PHARM    HIST  DRUG
  Reactions: GI REACTION(Source: SPOUSE)

```

```

PENICILLIN          CHART REVIEW  NO  ALLERGY  OBS  DRUG
  Reactions: ANAPHYLAXIS(Source: CHART REVIEW)
WALNUTS            PATIENT        YES  UNKNOWN  HIST  FOOD
  Reactions: HIVES(Source: PATIENT)
  Inactive: APR 27, 2011@12:01:50( NO LONGER ALLERGIC )
  Reactivated: APR 28, 2011@16:33:19

```

3.6 P&T Committee Menu (GMRA P&T 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 allow you 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 attending physician, as determined by the site.

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

3.6.1 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.

Example:

```

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

Select PATIENT NAME: DEMO
 1 DEMO,ALLERGY CHARLES  <A>  M 11-02-1969 XXX-XX-5701  WW 104836
 2 DEMO,ALLERGY CONNIE  <A>  F 10-24-1933 XXX-XX-4127  WW 110211
 3 DEMO,ALLERGY LEANN   <A>  F 12-04-1946 XXX-XX-9435  WW 150673
 4 DEMO,AMILYA PEARL    F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE    M  ** SENSITIVE **        WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE   <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
  IBUPROFEN
  PENICILLIN

Select CAUSATIVE AGENT: PENI
                                <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  PENICILLIN

Select date reaction was OBSERVED (Time Optional):  ??

  Choose from:
  JUN 23, 2001

```

```

Select date reaction was OBSERVED (Time Optional): 6/23/2001 (JUN 23, 2001)
...OK? Yes// (Yes)

P&T Report Completion
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?: Y YES
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: Y YES
DATE REPORTED TO FDA: 4/26/2011 (APR 26, 2011)
P&T ACTION MFR REPORT: ??
    This field tells if the P&T committee determined whether to send the rep
    ort to
    the manufacturer.

    Choose from:
        Y      YES
        n      NO

P&T ACTION MFR REPORT: Y YES
DATE OF PATIENT CONSENT TO MFR: 4/26/2011 (APR 26, 2011)
DATE SENT TO MFR: 4/26/2011 (APR 26, 2011)

ADDENDUM:
    No existing text
    Edit? NO//

```

3.6.2 Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning and 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 give, 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 refill 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 (e.g., Initial).

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

Example:

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

Select PATIENT NAME: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL      F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE      M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
  IBUPROFEN
  PENICILLIN

Select CAUSATIVE AGENT: PENICIL
                        <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  PENICILLIN
Select date reaction was OBSERVED (Time Optional): ??

  Choose from:
  JUN 23, 2001

Select date reaction was OBSERVED (Time Optional): 6/23/2001  (JUN 23, 2001)
  ...OK? Yes//  (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): 1-5

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

```
Signs/Symptoms
-----
1  ANAPHYLAXIS

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

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

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

This patient has the following Drugs selected:

        PENICILLIN
Select Action (A/D/E):

THIS PATIENT HAS NO CONCOMITANT DRUGS ON FILE
Select Action (A/D/E):

OTHER RELATED HISTORY:
  No existing text
  Edit? NO//

MANUFACTURER NAME: LEDERLE
  1  LEDERLE LABS
  2  LEDERLE PARENTE
  3  LEDERLE PIPCILL
CHOOSE 1-3: 1  LEDERLE LABS
MFR ADDRESS #1: PO Box 8299
MFR ADDRESS #2:
MFR ADDRESS #3:
MFR CITY: PHILADELPHIA
MFR STATE: PA  PENNSYLVANIA
MFR ZIP: 19101
IND/NDA # FOR SUPPORT DRUG:
MFR CONTROL #: ??
        This is the control number used by the manufacturer.

MFR CONTROL #: 234FD67
DATE RECEIVED BY MFR:
Select SOURCE: ?
        You may enter a new REPORT SOURCE, if you wish
        Choose from:
            f  FOREIGN
            h  HEALTH PROFESSIONAL
            s  STUDY
            l  LITERATURE
            c  CONSUMER

Select SOURCE: H (h  HEALTH PROFESSIONAL)
Are you adding 'HEALTH PROFESSIONAL' as a new SOURCE (the 1ST for this ADVERSE
REACTION REPORTING)? No// Y (Yes)
```

```

Select SOURCE:
15 DAY REPORT: ??
    This field is to determine if the 15 Day Report has been completed.

    Choose from:
        y      YES
        n      NO
15 DAY REPORT: N NO
REPORT TYPE: ??
    This is the type of report issued.

    Choose from:
        i      INITIAL
        f      FOLLOWUP

REPORTER NAME: PHARMACIST,PHARMACIST  Replace
REPORTER ADDRESS1: DEMO INDIAN MEDICAL CENTER  Replace
REPORTER ADDRESS2: 100 S. MAIN//
REPORTER ADDRESS3:
REPORTER CITY: ANYTOWN//
REPORTER STATE: OKLAHOMA//
REPORTER ZIP: 74464//
REPORTER PHONE: 555-123-4567//
IS REPORTER A HEALTH CARE PROVIDER?: YES//
Do you want the identity disclosed to the manufacturer?: NO
    //

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):

```

3.6.3 Reports Menu ...

This option is the menu of all reports that the Pharmacy and Therapeutics Committee can print.

1. Print an FDA report for a Patient
2. Print all FDA Events within a 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

3.6.3.1 Print an FDA Report for a Patient

This option allows 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 data into the system. The report should be queued to run on a printer with a 132-column width.

Example: *See section 3.4.3.3*

3.6.3.2 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 to the screen. 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.

Example: *for the unabbreviated report, see section 3.4.3.3 for an example*

```
Select Reports Menu Option: 2 Print All FDA Events within D/T Range
Select Start Date/Time: -3 (APR 26, 2011)
Select End Date/Time: (4/26/2011 - 4/29/2011): T// (APR 29, 2011)
Do you want an Abbreviated report? Yes// (Yes)

DEVICE: HOME// VIRTUAL TERMINAL
Apr 29, 2011@06:42:43 Page: 1
FDA ABBREVIATED REPORT
PATIENT SUSPECTED AGENT D/T OF EVENT
-----
DEMO,ALLERGY CONNIE (110211) IBUPROFEN Apr 26,2011
(SENT TO FDA: Apr 26,2011)
DEMO,JAMES WILLIAM (192636) IBUPROFEN Apr 27,2011
Enter RETURN to continue or '^' to exit:
```

3.6.3.3 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 may select 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 it was run. The body contains the patient's name, IHS chart number, the causative agent, the origination date/time, and the name of the originator.

Example:

```
Select Reports Menu Option: 3  Print Patient FDA Exception Data

Select PATIENT NAME: PATIENT,CRSC
 1 PATIENT,CRSC          M 06-01-1972          WW 900003
 2 PATIENT,CRSCA        F 06-01-1944          WW 900081
 3 PATIENT,CRSCB        M 07-02-1956          WW 900082
 4 PATIENT,CRSCC        <A> F 06-02-1954          WW 900083
 5 PATIENT,CRSCD        M 06-04-1955          WW 900084
ENTER '^' TO STOP, OR
CHOOSE 1-5: 4
  PATIENT,CRSCC          <A> F 06-02-1954          WW 900083
Enter the Date to start search (Time optional): T-30// 1/1/07 (JAN 01, 2007)

DEVICE: HOME//  VIRTUAL TERMINAL
Apr 29,2011 06:57:46                               Page: 1
FDA EXCEPTION REPORT (1/1/07 to 4/29/11)
ORIGINATION D/T      CAUSATIVE AGENT                ORIGINATOR
-----
Patient: PATIENT,CRSCC (HRN: 900083)
Nov 1,2007@10:37    PENICILLIN                      WADE,JUNE A
Enter RETURN to continue or '^' to exit:
```

3.6.3.4 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 the screen. The header of the report contains the name of the report, the date range selected, and the date/time that the report was run. The body of the report contains the patient's name and IHS chart number, the causative agent, the name of the person who originated the data entry, and the origination date/time of the data.

Example:

```
Select Reports Menu Option: 4  Print All FDA Exceptions within a D/T Range
Select Start Date: -180 (OCT 31, 2010)
Select End Date: (10/31/2010 - 4/29/2011): T// (APR 29, 2011)

DEVICE: HOME//  VIRTUAL TERMINAL
Apr 29,2011 07:00:39                               Page: 1
FDA EXCEPTION REPORT (10/31/10 to 4/29/11)
ORIGINATION D/T      CAUSATIVE AGENT                ORIGINATOR
-----
Patient: DEMO,NORMAN DALE (HRN: 118159)
Mar 24,2011@13:15    CARTEOLOL                      ROZSINSKI,DAVID
Patient: DEMO,CURTIS DALE (HRN: 198532)
Nov 4,2010@11:01    STREPTOMYCIN                   ROZSINSKI,DAVID
```

```

Patient: DEMO,LYNELLE LEE (HRN: 198768)
Nov 2,2010@15:07    YEAST                    ROZSINSKI,DAVID
Enter RETURN to continue or '^' to exit:

```

3.6.3.5 Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients who have not been signed off (completed) by the user entering the 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 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 IHS chart number, the causative agent, and the date/time the entry was made.

Example:

```

Select Reports Menu Option: 5 Patient Allergies Not Signed Off

DEVICE: HOME//    VIRTUAL TERMINAL

ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 4/27/11 2:08:19 pm

ORIGINATOR          PATIENT          ALLERGY          ORIGINATION DATE/TIME
-----
ADAIR,PETER DEMO,BABY(99-99-95)  PENICILLIN      DEC 15, 2009@14:00
BARREL,SCOT A DEMO,DANIEL(13-34-45)  IOD             JAN 14, 2004@09:53
BARREL,SCOT A DEMO,JUDY LY(13-80-30)  PENICILLIN     MAR 24, 2004@10:15
BOWTIE,JEFF W DEMO,SARA(11-05-92)  CLARITIN D    JUL 13, 2004@17:16
BOWTIE,JEFF W DEMO,SARA(11-05-92)  UNKNOWN        JUL 13, 2004@17:17
BOWTIE,JEFF W DEMO,MARTA (11-06-54)  SULFA          JUL 13, 2004@17:24
BOWTIE,JEFF W DEMO,ANNA JA(11-06-90)  PENICILLIN     JUL 13, 2004@17:32
BOWTIE,JEFF W DEMO,KELSIE(11-07-01)  CODEINE        JUL 13, 2004@17:38
BOWTIE,JEFF W DEMO,CAITLI (11-10-56)  CECLOR         JUL 13, 2004@18:29
BOWTIE,JEFF W DEMO,JORDAN (11-11-22)  CODEINE        JUL 13, 2004@18:39
BOWTIE,JEFF W DEMO,CHRYST(11-19-16)  IBUPROFEN     JUL 13, 2004@19:54
BOWTIE,JEFF W DEMO,ALBE(11-62-28)    CODEINE        JUL 13, 2004@20:07
BOWTIE,JEFF W DEMO,ROBERT (11-67-78)  NONE           JUL 13, 2004@20:53
BOWTIE,JEFF W DEMO,TIERRA(11-68-30)  ERTYTHROMYCIN JUL 13, 2004@20:57
BOWTIE,JEFF W DEMO,BYRON G(11-69-67)  VISTERIL      JUL 13, 2004@21:23

```

3.6.3.6 Print Patient Reaction Data

This option will allow the user to produce 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, IHS Chart number, date of birth, and age. The body of the report contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the source of the data, 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, the SNOMED Event and code, whether the patient ID band or chart is marked, a list of signs/symptoms, the mechanism, and additional comments made by the originator. For Inactive reactions it will also contain the inactive date, reason, and person who inactivated. A line of dots appears in the body of the report between the various reaction entries.

Example:

```
Select Reports Menu Option: 6  Print Patient Reaction Data

Select PATIENT: DEMO
  1 DEMO,ALLERGY CHARLES <A>  M 11-02-1969 XXX-XX-5701  WW 104836
  2 DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
  3 DEMO,ALLERGY LEANN <A>  F 12-04-1946 XXX-XX-9435  WW 150673
  4 DEMO,AMILYA PEARL      F 06-30-2008 XXX-XX-0821  WW 106735
  5 DEMO,AUSTIN WAYNE      M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE <A>  F 10-24-1933 XXX-XX-4127  WW 110211
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1-3
Select 1:ACTIVE, 2:ENTERED IN ERROR, 3:INACTIVE
Which would you like to see?: (1-3): 1-3

DEVICE: HOME//  VIRTUAL TERMINAL

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 4/27/11 2:16:22 pm
DEMO,ALLERGY CO      110211      OCT 24,1933 (77)
-----

STATUS: ACTIVE
-----
TYPE: DRUG
=====

AGENT: IBUPROFEN
INGREDIENTS: IBUPROFEN      VA DRUG CLASSES: NONSALICYLATE NSAIs,A

SOURCE OF INFORMATION: SPOUSE
ORIGINATOR: NIESEN,MARY ANN  ORIGINATED: Apr 27, 2011@07:37
SIGN OFF: YES              OBS/HIST: HISTORICAL
EVENT: DRUG INTOLERANCE    CODE: 59037007

ORIGINATOR
```

```

COMMENTS:
  Date: Apr 27, 2011@07:38:44   User: NIESEN,MARY ANN
                                Title: PHARMACIST

  SPOUSE STATES PATIENT HAS SEVERE STOMACH UPSET AND AVOIDS
  ALL NSAIDS

ID BAND MARKED:                CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: GI REACTION (Apr 04, 1973)   SOURCE: SPOUSE

  MECHANISM: PHARMACOLOGIC

.....
  AGENT: PENICILLIN
  INGREDIENTS: PENICILLIN   VA DRUG CLASSES: (INACTIVE) PENICILLIN
                                PENICILLINS,AMINO DER

  SOURCE OF INFORMATION: CHART REVIEW
  ORIGINATOR: NIESEN,MARY ANN   ORIGINATED: Apr 27, 2011@07:39
  SIGN OFF: YES                 OBS/HIST: OBSERVED
  EVENT: DRUG ALLERGY          CODE: 416098002
  SEVERITY: SEVERE             OBS D/T: Jun 23, 2001

ORIGINATOR
COMMENTS:
  Date: Apr 27, 2011@07:40:11   User: NIESEN,MARY ANN
                                Title: PHARMACIST

  REACTION WAS SEEN AND TREATED IN THE ER BUT NOT ADDED TO
  ADVERSE REACTIONS

ID BAND MARKED:                CHART MARKED: Apr 27, 2011@14:07:39

SIGNS/SYMPTOMS: ANAPHYLAXIS (Jun 23, 2001) SOURCE: CHART REVIEW

  MECHANISM: ALLERGY

.....
STATUS: E/E
-----
  TYPE: DRUG
  =====

  AGENT: BEN-GAY
  INGREDIENTS:                VA DRUG CLASSES:

  ORIGINATOR: DAVIS,MARY J     ORIGINATED: Jul 15, 2004@09:00
  SIGN OFF: YES                OBS/HIST: HISTORICAL

ID BAND MARKED:                CHART MARKED: Jul 15, 2004@09:00:32

  MECHANISM: UNKNOWN

  VERIFIER: DAVIS,MARY J       VERIFIED: JUL 20, 2004@10:59:19

  USER ENTERING                D/T ENTERED
  IN ERROR: NIESEN,MARY ANN     IN ERROR: APR 27, 2011@12:00:44

  ENTERED IN ERROR
  COMMENTS:
  Date: Apr 27, 2011@12:00:44   User: NIESEN,MARY ANN

```

```

                                Title: PHARMACIST
THIS REACTION IS NOT FOR THIS PATIENT, ACCIDENTALLY
ENTERED ON WRONG PATIENT.

.....
STATUS: INACTIVE
-----
TYPE: FOOD
=====

AGENT: WALNUTS

SOURCE OF INFORMATION: PATIENT
ORIGINATOR: NIESEN,MARY ANN      ORIGINATED: Apr 27, 2011@09:58
SIGN OFF: YES                    OBS/HIST: HISTORICAL
EVENT: FOOD INTOLERANCE         CODE: 235719002

ID BAND MARKED:                  CHART MARKED: Apr 27, 2011@14:07:39

INACTIVE: APR 27, 2011@12:01:50
REASON: NO LONGER ALLERGIC      BY: NIESEN,MARY ANN

SIGNS/SYMPTOMS: HIVES (Jan 29, 2010)      SOURCE: PATIENT

MECHANISM: UNKNOWN

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

```

3.6.3.7 Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not inactive or entered in error) allergy/adverse reaction data for a particular patient. This report may be sent to 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, IHS chart number, 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, SNOMED event and code, 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 assessed for reactions, the body of the report will display a message stating that there is no reaction data on file.

Example:

```

Select Reports Menu Option: 7 Active Listing of Patient Reactions

Select PATIENT: DEMO
 1 DEMO,ALLERGY CHARLES <A> M 11-02-1969 XXX-XX-5701 WW 104836
 2 DEMO,ALLERGY CONNIE <A> F 10-24-1933 XXX-XX-4127 WW 110211
 3 DEMO,ALLERGY LEANN <A> F 12-04-1946 XXX-XX-9435 WW 150673

```

```

 4 DEMO,AMILYA PEARL      F 06-30-2008 XXX-XX-0821  WW 106735
 5 DEMO,AUSTIN WAYNE     M  ** SENSITIVE **      WW 192640
ENTER '^' TO STOP, OR
CHOOSE 1-5: 2
  DEMO,ALLERGY CONNIE    <A> F 10-24-1933 XXX-XX-4127  WW 110211

DEVICE: HOME//  VIRTUAL TERMINAL

ACTIVE ALLERGY/ADVERSE REACTION LISTING
Run Date/Time: 4/27/11 1:43:36 pm
DEMO,ALLERGY CO          110211          OCT 24,1933 (77)

ADVERSE REACTION                                VERIFIED      OBS/
-----
                                         OBS/
                                         HIST

TYPE: DRUG
=====
IBUPROFEN                                         NO             HIST
EVENT: DRUG INTOLERANCE
SNOMED CODE: 59037007
  Reactions: GI REACTION (Apr 04, 1973)
PENICILLIN                                         NO             OBS
EVENT: DRUG ALLERGY
SNOMED CODE: 416098002
  Reactions: ANAPHYLAXIS (Jun 23, 2001)
Enter RETURN to continue or '^' to exit:

```

3.6.3.8 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 reactions. 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, IHS chart number, and provider. The room-bed will appear for current inpatients.

NOTE: This report will show patients as not having received an assessment if the assessment was entered after the end date of the range. For this reason, it is recommended to end the range with today. This can be done with an entry of "T" (for "Today") and the "Enter END Date (time optional): T/" prompt.

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

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

Example:

```
Select Reports Menu Option: 8 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.
```

```
Please note! This report will show patients as not having received an
assessment if the assessment was entered after the end date of
the range. For this reason, it is recommended to end the range
with today. This can be done with an entry of 'T' (for Today) at
the 'Enter END Date (time optional): T//' prompt.
```

```
Enter START Date (time optional): -90 (JAN 27, 2011)
```

```
Enter END Date (time optional): T// (APR 27, 2011)
```

```
Select Location: ALL
```

```
Do you mean ALL Locations? Yes// (Yes)
```

```
Another Location:
```

```
QUEUE TO PRINT ON
```

```
DEVICE: Home VIRTUAL TERMINAL [YOU CAN NOT SELECT A VIRTUAL TERMINAL]
```

```
Previously, you have selected queueing.
```

```
Do you STILL want your output QUEUED? Yes// N (No)
```

```
DEVICE: Home VIRTUAL TERMINAL
```

```
Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 1
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00
```

```
PATIENT SSN
-----
```

```
CLINIC: MED CLINIC
```

```
* No Patients for this Clinic *
```

```
Apr 27,2011 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 2
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 27,2011 TO Apr 27,2011@24:00
```

```
PATIENT SSN PROVIDER
-----
```

```
WARD: ICU
DEMO,ALICIA LOUISE 160758 ASHLY,BARBARA A
Room/Bed: 3011-1
DEMO,LOIS JEANNETTE 180836 JOE,HOWARD
DEMO,ADRIAN 212735 SMITH,GRETA LOUISE
Room/Bed: 3012-1
ROADKILL,BUBBIT 253614 DEMO,DOCTOR
```

3.6.3.9 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 this report is run during the session, those values will be empty. If the report is run again in the same session, 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 the report contains the name of the report, the date it was run, and the date range entered. 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 4 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.

Example:

```
Select Reports Menu Option: 9 List Autoverified Reaction Data
* Previous selection: VERIFICATION DATE/TIME from Jan 1,1990 to Apr 29,2011@24:00
START WITH VERIFICATION DATE/TIME: Jan 1,1990// (JAN 01, 1990)
GO TO VERIFICATION DATE/TIME: Apr 29,2011// (APR 29, 2011)
* Previous selection: PATIENT:WARD LOCATION from ALL
START WITH WARD LOCATION: ALL//
GO TO WARD LOCATION: LAST//
* Previous selection: MECHANISM from A (ALLERGY)
START WITH MECHANISM: ALL// ERGY USES INTERNAL CODE: A
GO TO MECHANISM: LAST//
DEVICE: HOME VIRTUAL TERMINAL Right Margin: 80//
04/29/11 LIST OF AUTOVERIFIED ALLERGIES FROM 01/01/90 TO 04/29/11 Page: 1

PATIENT                ROOM-BED      REACTANT                VER. DATE
-----
WARD LOCATION: MEDICALSURGICAL
      MECHANISM: PHARMACOLOGIC
DEMO,TAMBRA ANN (9593                ZOCOR                JUN 21,2004
ORIGIN.: WRAY,FAY
SIGNS: WEAKNESS
COMMENTS:
DEMO,TAMBRA ANN (9593                GLUCOTROL            JUN 16,2004
ORIGIN.: BROWN,ROGER
SIGNS: SWEATING
COMMENTS: PT DENIES ALG
      MECHANISM: UNKNOWN
DEMO,TAMBRA ANN (9593                ASPIRIN              FEB  1,1998
ORIGIN.: ADAM,ADAM
SIGNS: HIVES
COMMENTS:
DEMO,TAMBRA ANN (9593                BACTRIM              FEB  2,1998
ORIGIN.: ADAM,ADAM
SIGNS: HIVES
```

COMMENTS:			
DEMO, TAMBRA ANN (9593	AMOXICILLIN	SEP 20, 2001	
ORIGIN.: JOHN, PATRICK			
SIGNS: RASH			
COMMENTS:			
DEMO, TAMBRA ANN (9593	NAPROXEN	JUN 22, 2004	
ORIGIN.: BROWN, ROGER			
SIGNS:			
COMMENTS:			
MECHANISM: ALLERGY			
DEMO, ALBERT TILLMA () 3305-1	ASPIRIN	MAY 17, 2007	
ORIGIN.: BRUNEI, CARLA			
SIGNS: HIVES			
ANAPHYLAXIS			
NAUSEA, VOMITING			
DIARRHEA			
SWELLING (NON-SPECIFIC)			
ANXIETY			
DROWSINESS			
RASH			
DYSPEPSIA			
COMMENTS:			
MECHANISM: UNKNOWN			
CLINTON, JANIE SUE (9120) 3311-1	IODINE	JUL 22, 2004	
ORIGIN.: DAVIS, JANE			
SIGNS:			
COMMENTS:			

3.6.3.10 List by Location Not Verified Reactions

This option 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 the Application Coordinator or IT personnel 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 locations. The body contains the patient's name and IHS chart number, the causative agent, the name of the originator of the reaction, and the date/time the data originated. The Room-Bed is also displayed for each inpatient.

Example:

Select Reports Menu Option: 10	List by Location Not Verified Reactions
DEVICE: HOME//	VIRTUAL TERMINAL
Report Date: Apr 28, 2011	Page: 1
List of Unverified Reactions by Ward Location	
Ward Location: ICU	

Origination Date/Time	Originator	Reaction
3013-1 DEMO,JEREMY PAUL (20-23-08) Nov 13, 2008@14:38	JONES,CARLA	AMPICILLIN
Report Date: Apr 28, 2011		Page: 2
List of Unverified Reactions by Ward Location		
Ward Location: MEDICALSURGICAL		
Origination Date/Time	Originator	Reaction
3309-2 DEMO,DOROTHY ROSE (99-99-99) Apr 27, 2011@10:01	SMITH,MARY	WALNUTS
3319-1 DEMO,LAVELDA WAPSKINEH (10-33-24) Apr 17, 2008@10:35	JONES,CARLA	MORPHINE
Report Date: Apr 28, 2011		Page: 3
List of Unverified Reactions by Ward Location		
Ward Location: OUTPATIENT		
Origination Date/Time	Originator	Reaction
DEMO,BROOKE ANN EESHAHA (19-79-56) Aug 05, 2004@17:40	WILLIAMS,JOHN J	SULFA
DEMO,CAITLIN TIANA (11-10-56) Jul 13, 2004@18:29	BOWTIE,JEFF W	CECLOR
DEMO,WANDA CARROL (18-29-00) Aug 04, 2004@19:42	WILLIAMS,JOHN J	FOSINOPRIL
DEMO,JEREMY MICHAEL (17-59-45) Aug 04, 2004@19:55	FISHER,MARTHA A	SULFA
DEMO,MARIAH HOPE (19-75-66) Aug 05, 2004@18:32	WILLIAMS,JOHN J	PENICILLIN
Aug 05, 2004@18:32	WILLIAMS,JOHN J	AMPICILLIN
DEMO,AMOS LYNN (17-57-76) Aug 04, 2004@20:40	FISHER,MARTHA A	NAPROXEN
DEMO,SUE ELLEN (10-05-06) Jul 27, 2004@09:48	BOWTIE,JEFF W	SERTRALINE

3.6.3.11 List by Location and Date all Signed Reactions

This option 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 terminal screen.

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

Example:

```
Select Reports Menu Option: 11 List by Location and Date All Signed Reactions
Enter Start Date: -30 (MAR 29, 2011)
Enter Ending Date: t (APR 28, 2011)
```

```
DEVICE: HOME// VIRTUAL TERMINAL
```

```

One moment please...
Apr 28, 2011                                     Page: 1
      List all Signed Patient Reactions for Ward Location MEDICALSURGICAL
      From Mar 29, 2011 to Apr 28, 2011@24:00
Date          Originator          Type Causative Agent
-----
      Patient: DEMO,DOROTHY ROSE (99-99-99)
Apr 27, 2011@10:01 SMITH,MARY          F  WALNUTS

Apr 28, 2011                                     Page: 2
      List all Signed Patient Reactions for Out Patients
      From Mar 29, 2011 to Apr 28, 2011@24:00
Date          Originator          Type Causative Agent
-----
      Patient: DEMO,CRYSTAL LYNN (16-06-13)
Mar 29, 2011@11:18 ROZINSKI,DAVID          D  TDAP

      Patient: DEMO,ALLERGY CHARLES (10-48-36)
Apr 20, 2011@09:01 SMITH,MARY          D  AMOXICILLIN
Apr 18, 2011@11:23 SMITH,MARY          F  WALNUTS

      Patient: DEMO,ALLERGY CONNIE (11-02-11)
Apr 27, 2011@07:37 SMITH,MARY          D  IBUPROFEN
Apr 27, 2011@07:39 SMITH,MARY          D  PENICILLIN
Apr 27, 2011@09:58 SMITH,MARY          F  WALNUTS

      Patient: DEMO,JOHN (00-00-55)
Apr 27, 2011@10:19 SMITH,MARY          D  PENICILLIN

      Patient: DEMO,DUSTIN KEE (20-20-97)
Apr 04, 2011@13:32 ROZINSKI,DAVID          D  INFLUENZA
Apr 28, 2011                                     Page: 3
      List all Signed Patient Reactions for Out Patients
      From Mar 29, 2011 to Apr 28, 2011@24:00
Date          Originator          Type Causative Agent
-----
      Patient: DEMO,AMBER DAWN (10-15-65)
Apr 26, 2011@10:03:28HIMS,BARBARA          DF PEANUTS

      Patient: PATIENT,CRSFC (90-01-58)
Mar 29, 2011@11:40 ROZINSKI,DAVID          D  TDAP

      Patient: DEMO,GEOFFREY MICHAEL (20-07-13)
Apr 04, 2011@11:23 ROZINSKI,DAVID          D  HEPATITIS A

      Patient: TEST,CATHY (00-00-03)
Apr 06, 2011@15:21 ROZINSKI,DAVID          D  CIPROFLOXACIN

Enter RETURN to continue or '^' to exit:

```

3.6.3.12 List FDA Data by Report Date

This option 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 screen.

The header of the report contains the name of the report, the date range selected, and the date that the report was run. The body of the report contains the patient's name and IHS chart number, 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.

Example:

```

Select Reports Menu Option: 12  List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: -14  (APR 14, 2011)
Enter Ending Date: T  (APR 28, 2011)

DEVICE: HOME//  VIRTUAL TERMINAL
Report Date: Apr 28, 2011                               Page: 1
Adverse Reaction Tracking Report
From: 4/14/11 To: 4/28/11
Patient              Dates      Related Reaction
-----
DEMO,ALLERGY CONNIE      Obs DT: 4/23/11  PENICILLIN
(11-02-11)              Trk DT: 4/27/11
Loc: OUT PATIENT
Obs: SMITH,MARY          5 Days Difference

DEMO,JOHN              Obs DT: 4/26/11  PENICILLIN
(00-00-55)              Trk DT: 4/27/11
Loc: OUT PATIENT
Obs: SMITH,MARY          1 Days Difference

Enter RETURN to continue or '^' to exit:

```

3.6.3.13 List of Fatal Reaction Over a Date Range

This option lists all fatal adverse reactions over a selected date range.

The header of the report contains the name of the report, the date range selected, and the date that the report was printed. The body of the report contains the name of the patient, the IHS chart number, the date of the reaction, the name of the related reaction, and the date the patient died.

Example:

```

Select Reports Menu Option: 13  List of Fatal Reaction over a Date Range
Select an Observed date range for this report.
Enter Start Date: -4  (APR 25, 2011)
Enter Ending Date: T  (APR 29, 2011)

DEVICE: HOME//  VIRTUAL TERMINAL
Report Date: Apr 29, 2011                               Page: 1
List of Fatal Reaction over a date range
From: 4/25/11 To: 4/29/11
Patient              Dates      Related Reaction  Date Died
-----

```

```
-----
DEMO,ALLERGY LEANN (15-06-73) 4/27/11 IBUPROFEN 4/27/11
```

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

3.6.3.14 Print Summary of Outcomes

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

The header of the report contains the name of the report, the date range selected, 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 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).

Example:

```
Select Reports Menu Option: 14 Print Summary of Outcomes
Select an Observed date range for this report.
Enter Start Date: -30 (MAR 30, 2011)
Enter Ending Date: T (APR 29, 2011)

DEVICE: HOME// VIRTUAL TERMINAL
Report Date: Apr 29, 2011 Page: 1
Summary of Outcomes
From: 3/30/11 To: 4/29/11
```

	Yes	No	No Response

Patients that Died:	1	2	1
Reactions treated with RX drugs:	2	1	1
Life Threatening illness:	1	2	1
Required ER/MD visit:			4
Required hospitalization:	1	2	1
Prolonged Hospitalization:		3	1
Resulted in permanent disability:		3	1
Patient recovered:			4
Congenital Anomaly:		3	1
Required intervention:	2	1	1

Totals:	7	17	16

Total number of records processed 4

3.6.3.15 Frequency Distribution of Causative Agents

This option 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, 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.

Example:

```
Select Reports Menu Option: 15  Frequency Distribution of Causative Agents
Select an Observed date range for this report.
Enter Start Date: -30  (MAR 30, 2011)
Enter Ending Date: T  (APR 29, 2011)
```

```
DEVICE: HOME//  VIRTUAL TERMINAL
Report Date: Apr 29, 2011                               Page: 1
Frequency Distribution of Causative Agents
From: 3/30/11 To: 4/29/11
Causative Agents                                     Number
-----
                IBUPROFEN :      3
                CIPROFLOXACIN :    1

Total number of records processed 4
```

3.6.3.16 Frequency Distribution of Drug Classes

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

The header of the report contains the name of the report, the date range selected, and the date that 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.

Example:

```
Select Reports Menu Option: 16  Frequency Distribution of Drug Classes
Select an Observed date range for this report.
Enter Start Date: -60  (FEB 28, 2011)
Enter Ending Date: T  (APR 29, 2011)
```

```
DEVICE: HOME//  VIRTUAL TERMINAL
Report Date: Apr 29, 2011                               Page: 1
Frequency Distribution of Drug Classes
From: 2/28/11 To: 4/29/11
Drug Class                                           Number
-----
NONSALICYLATE NSAIs,ANTIRHEUMA (MS102) :      3
  ANTI-INFECTIVES,OTHER (AM900) :      1

Total number of records processed 4
```

3.6.3.17 Total Reported Reactions Over a Date Range

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

The header of the report contains the title of the report and the date/time that the report was run. The body of the report contains the total number of reactions reported for the date range selected.

Example:

```
Select Reports Menu Option: 17  Total Reported Reactions Over a Date Range
Select an Observed date range for this report.
Enter Start Date: -90  (JAN 29, 2011)
Enter Ending Date: T  (APR 29, 2011)

DEVICE: HOME//  VIRTUAL TERMINAL
Report Date: Apr 29, 2011
Reported Reactions
-----
Total Number of Reported Reactions: 4
From: 1/29/11  To: 4/29/11
Enter RETURN to continue or '^' to exit:
```

3.6.3.18 P&T Committee ADR Outcome Report

This option displays a list of reactions over a date range, and a summary of the listed outcomes for those reactions.

The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent and IHS chart number, 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 whether the patient died as a result of the reaction.

Example:

```
Select Reports Menu Option: 18  P&T Committee ADR Outcome Report
Select an Observed date range for this report.
Enter Start Date: -90  (JAN 29, 2011)
Enter Ending Date: T  (APR 29, 2011)

DEVICE: HOME//  VIRTUAL TERMINAL
Report Date: Apr 29, 2011
-----
P&T Committee ADR Outcome Report
From: 1/29/11  To: 4/29/11
-----
Obsv. | Causative agent-Pat. ID | Sign/Symptoms | Req. | Req. | Dis. | Death
Date  |                          |                 | Tx   | Hosp |      |
-----|-----|-----|-----|-----|-----|-----
4/1/11| CIPROFLOXACIN-000003 | DIARRHEA      |      |      |      |
      |                      | ITCHING       |      |      |      |
4/26/11| IBUPROFEN-110211   | GI REACTION   |      |      |      |
4/27/11| IBUPROFEN-150673   | ANAPHYLAXIS  | Y   | Y   |      | Y
```

```

4/27/11|IBUPROFEN-192636          |SWELLING-THROAT| Y |   |   |
Enter RETURN to continue or '^' to exit:

```

3.6.3.19 P&T Committee ADR Report

This option displays a list of reactions over a date range. The Sign/Symptoms, mechanism, Severity, and Comments are displayed for each reaction. 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, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent and IHS chart number, the signs and symptoms, the mechanism of the adverse reaction (i.e., A=Allergy, P=Pharmacologic, and U=Unknown), the severity of the reaction, and any comments entered. The comments are identified by category (i.e., Observer, Verifier, or Entered in Error).

Example:

```

Select Reports Menu Option: 19 P&T Committee ADR Report
Select an Observed date range for this report.
Enter Start Date: -90 (JAN 29, 2011)
Enter Ending Date: T (APR 29, 2011)

This report required a 132 column printer.
QUEUE TO PRINT ON
DEVICE: Home VIRTUAL TERMINAL [YOU CAN NOT SELECT A VIRTUAL TERMINAL]

Previously, you have selected queueing.
Do you STILL want your output QUEUED? Yes// N (No)
DEVICE: SL SLAVE SLAVE

Report Date: Apr 29, 2011 Page: 1
P&T Committee ADR Report
From: 1/29/11 To: 4/29/11
-----
Obsv. | Causative agent-Pat. ID | Sign/Symptoms | ADR | ADR | Comments
Date | | | Mech | Svr. |
-----
4/1/11 | CIPROFLOXACIN-00-00-03 | DIARRHEA | P | | OBSERVER COMMENTS:
| | | ITCHING | | | TESTING
4/26/11 | IBUPROFEN-11-02-11 | GI REACTION | P | | OBSERVER COMMENTS:
| | | | | | SPOUSE STATES
| | | | | | PATIENT HAS SEVERE
| | | | | | STOMACH UPSET AND
| | | | | | AVOIDS ALL NSAIDS
4/27/11 | IBUPROFEN-15-06-73 | ANAPHYLAXIS | A | SVR. |
4/27/11 | IBUPROFEN-19-26-36 | SWELLING-THROAT | A | MOD. |

```

--	--	--	--	--	--

Appendix A: Using ART in the Electronic Health Record (EHR)

Below is information on documenting adverse reactions in the Electronic Health Record. Please see the EHR user manual and the various patch notes for additional information.

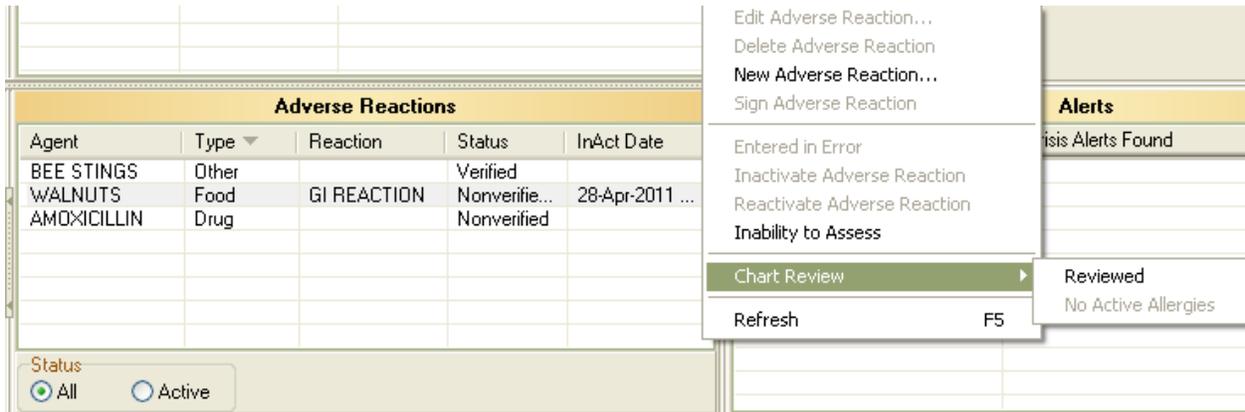
A.1 Overview of Adverse Reaction Data Entry

RPMS-EHR displays the patient's adverse reactions on the Adverse Reactions Component. This is usually located on the cover sheet tab. If patients have causative agents listed in this pane, RPMS-EHR also displays the letter **A** (for allergies) on the Patient Postings button. To view more information about allergies or adverse reactions associated with the causative agents listed in the Adverse Reactions pane, click the causative agent in which you are interested. RPMS-EHR then displays a comprehensive listing of the details associated with this causative agent.

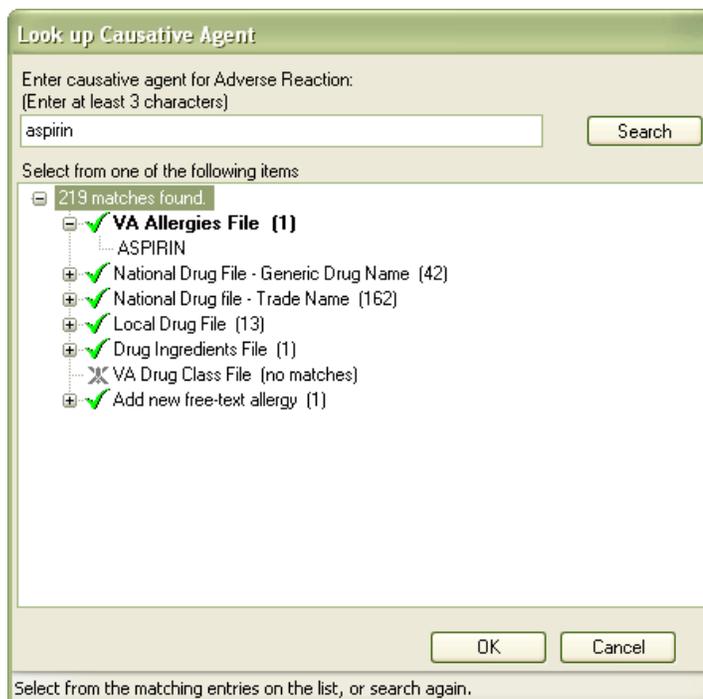
From the Adverse Reactions Component you can also:

- Enter new adverse reactions
- Edit existing adverse reactions
- Delete the logged on user's own *unsigned* adverse reactions which have been entered in error.
- Enter no-known-allergies (NKA) assessments
- Mark existing reactions as "entered-in-error"
- Inactivate or reactivate existing reactions
- Document the inability to assess adverse reactions
- Document review of existing reactions or no active allergies from chart review submenu (no active should be used ONLY after first documenting "No Known Allergies" as above)
- Verify existing reactions (if hold the correct key)

A.1.1 Enter a new adverse reaction

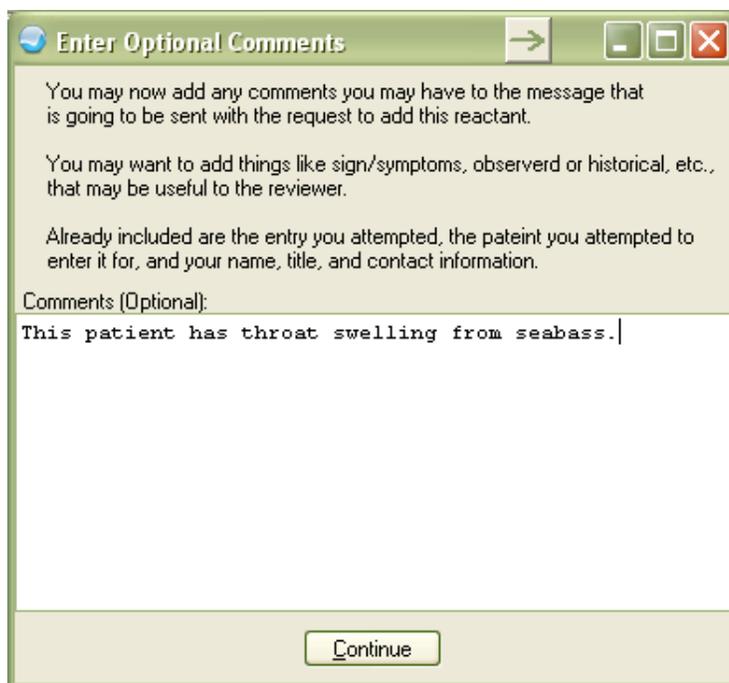


1. Move your mouse arrow to a location anywhere within the Adverse Reactions component
2. Right-click to display a pop-up menu.
3. From this menu, select New Adverse Reaction. RPMS-EHR displays the Causative Agent Lookup dialog.
4. Type the first three characters (minimum) of the causative agent's name and click Search.
5. RPMS-EHR displays a list of possible matches.



1. If the causative agent you typed matches an agent that is currently available, select the agent. (Click + to expand a heading.)
 - a. For medications, use an entry from the National Drug File for best order check results.
 - b. For other agents, use the best match from the first three files for best order check results.
2. If the causative agent you typed does not match, you may request a new causative agent to be added by selecting YES to send a bulletin. **NO REACTION WILL BE RECORDED.**





Enter Optional Comments

You may now add any comments you may have to the message that is going to be sent with the request to add this reactant.

You may want to add things like sign/symptoms, observed or historical, etc., that may be useful to the reviewer.

Already included are the entry you attempted, the patient you attempted to enter it for, and your name, title, and contact information.

Comments (Optional):

This patient has throat swelling from seabass.

Continue



Information

Bulletin has been sent.
NOTE: This reactant was NOT added for this patient.

OK

1. Once the causative agent has been chosen, fill in the rest of the information:

Create Adverse Reaction

Reaction

Causative agent: ASPIRIN

Nature of Reaction: Drug

Event Code: DRUG ALLERGY

Source of Information: FAMILY

Observed

Observer: Niesen, Mary Ann

Reaction Date/Time: 03-May-2011 09:00

Severity: Severe

Signs/Symptoms

Available

- ANAPHYLAXIS
- AGITATION
- AGRANULOCYTOSIS
- ALOPECIA
- ANAPHYLAXIS
- ANEMIA
- ANOREXIA
- ANXIETY
- APNEA
- APPETITE, INCREASED
- ARRHYTHMIA

Selected

ANAPHYLAXIS May 03, 2011 @ 09:00 EXTERNAL SOURCE

Date/Time: 03-May-2011 09:00

Source: EXTERNAL SOURCE

Comments

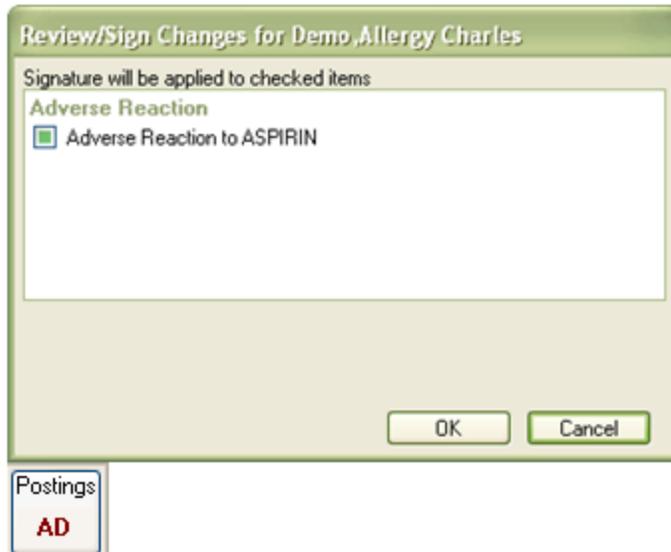
Checked with Keystone Hospital records for details of reaction. Patient was treated with epinephrine and released.

Current OK Cancel

Note: You can view a patient's current adverse reactions by clicking the Current button.

- Select the Observed button to indicate observed adverse reactions. If you are entering an observed allergy, use the Reaction Date/Time and Severity boxes to select a reaction date, time, and severity.
- Nature of Reaction is filled in based on the causative agent selected and cannot be edited.
- Select the Event Code (Allergy to Substance, Drug Allergy, Drug Intolerance, Food Allergy, Food Intolerance, Propensity to Adverse Reactions, Propensity to Adverse Reactions to Substance, Propensity to Adverse Reactions to Drug, Propensity to Adverse Reactions to Food).
- Select the source of the causative agent information (Patient, Spouse, Family, Friend, Other Source, Chart Review, Medical Provider, External Source).

- e. Using the Signs/Symptoms box, select one or more signs or symptoms. The signs and symptoms you select appear in the Selected Symptoms pane. If you mistakenly enter a sign or symptom but have not yet accepted it by selecting OK, select the symptom in the Selected Symptoms pane and click the left-pointing arrow button. Add a date/time for the reaction, and the source of the reaction information.
 - f. Type comments for the adverse reaction in the Comments box.
 - g. Click OK. RPMS-EHR displays the newly entered causative agent in the Adverse Reactions component. If you click on the causative agent, RPMS-EHR displays all of the information you just entered about the associated adverse reaction.
2. Select the integrated signature tool to sign the adverse reaction. RPMS-EHR also displays the letter A (for allergies) on the Postings button.



- a. If the signer has permission to verify, then signing the adverse reaction will automatically verify. If the signer does not hold the verifier key, the adverse reaction will be displayed throughout EHR as unverified.

Important:

The new adverse reaction must be signed to be available for display throughout RPMS-EHR. The providers can delete their own unsigned adverse reactions that have entered in error.

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other		Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS	Verified	

Status

All Active

A.1.2 Edit an existing reaction

This option allows you to edit an existing reaction. The causative agent cannot be edited.

Right click on the reaction to be edited. The Event Code, Source of Information, Signs/Symptoms data, and comments can all be edited.

Edit Adverse Reaction (Verified)

Reaction

Causative agent: BEE STINGS

Nature of Reaction: Other

Event Code: ALLERGY TO SUBSTANCE

Source of Information: CHART REVIEW

Observed

Observer:

Reaction Date/Time:

Severity:

Signs/Symptoms

Available:

- HIVES
- HYPERSENSITIVITY
- HYPERTENSION
- HYPOTENSION
- IMPAIRMENT OF ERECTION
- IMPOTENCE
- INAPPROPRIATE PENILE EREC
- INSOMNIA
- IRRITABILITY
- ITCHING

Selected:

HIVES Jul 19, 2004@13:24 CHART REVIEW

Date/Time: 19-Jul-2004 13:24

Source: CHART REVIEW

Comments

reaction detail added from chart review

Current OK Cancel

A.1.3 Delete the user's own UNSIGNED reaction

Providers can only delete their own *unsigned* adverse reactions which have been entered in error. Right-click on the allergy and select Delete Adverse Reaction.

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other	HIVES	Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS;AL...	Verified	
IBUPROFEN	Drug	RASH	*Unsigned	

- Edit Adverse Reaction...
- Delete Adverse Reaction
- New Adverse Reaction...
- Sign Adverse Reaction

- Entered in Error
- Inactivate Adverse Reaction
- Reactivate Adverse Reaction
- Inability to Assess

- Chart Review ▶

Refresh F5

Status

All Active

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other	HIVES	Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS;AL...	Verified	
IBUPROFEN	Drug	RASH	*Unsigned	

- Edit Adverse Reaction...
- Delete Adverse Reaction
- New Adverse Reaction...
- Sign Adverse Reaction

- Entered in Error
- Inactivate Adverse Reaction
- Reactivate Adverse Reaction
- Inability to Assess

- Chart Review ▶

Refresh F5

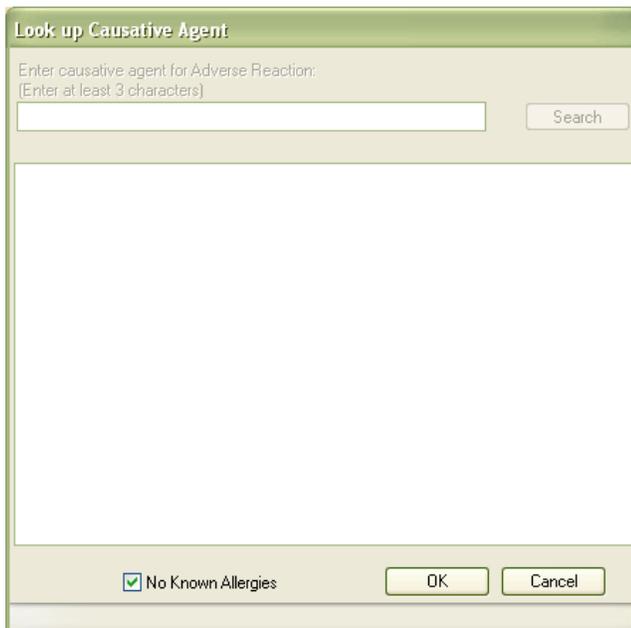
Status

All Active

A.1.4 Enter “No Known Allergies”

This option allows the user to mark a patient as having no known reactions. It can only be used if there are no existing reactions documented. Once a patient has been marked as having no known allergies, the chart review function may be used later to document that the status has not changed (see EHR version 1.1 patch 8 notes for more information on the chart review component).

Right click in the allergies component in a blank area, and select “New Adverse Reaction” as above. In the causative agent search dialogue box, click on the “No Known Allergies” check box, then click OK.



A.2 Mark an existing reaction as “entered in error”

This option allows a user to mark a reaction as “entered in error”. This is used for signed and/or verified entries where the entry is truly an error: on the wrong patient, using the wrong causative agent, etc.

Right click on the desired entry, and select “Entered in Error”.

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other	HIVES	Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS;AL...	Verified	
IBUPROFEN	Drug	RASH	Verified	

- Edit Adverse Reaction...
- Delete Adverse Reaction
- New Adverse Reaction...
- Sign Adverse Reaction
- Entered in Error
- Inactivate Adverse Reaction
- Reactivate Adverse Reaction
- Inability to Assess
- Chart Review
- Refresh F5

Status: All Active

Click "Yes" in the confirmation screen.

Confirm ✕

Are you sure you want to mark the IBUPROFEN adverse reaction as ENTERED IN ERROR?

The reaction will drop off the adverse reaction component; however, it will be searchable in the adverse reaction tracking package in RPMS for audit purposes.

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other	HIVES	Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS;AL...	Verified	

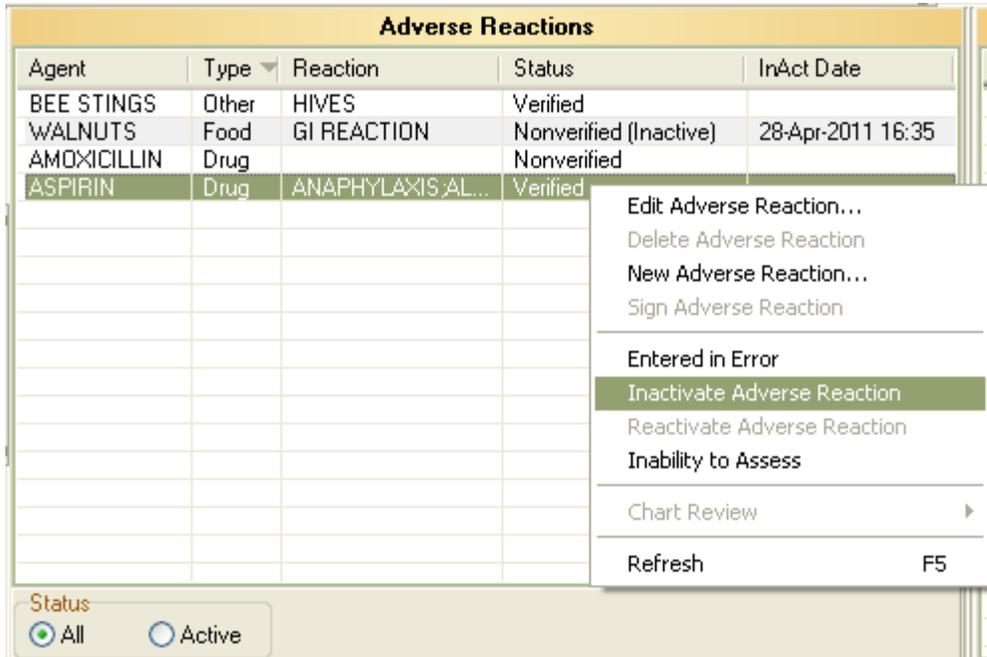
Status: All Active

A.3 Inactivate or reactivate an existing reaction

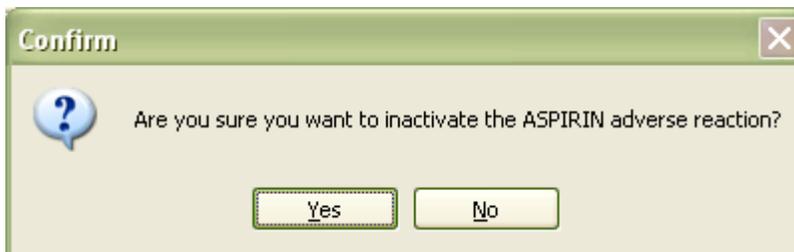
This option will allow you to inactivate an existing reaction, or reactivate a previously inactivated reaction. This is intended for reactions the patient reports but later is able to tolerate, or where de-sensitization has occurred, etc.

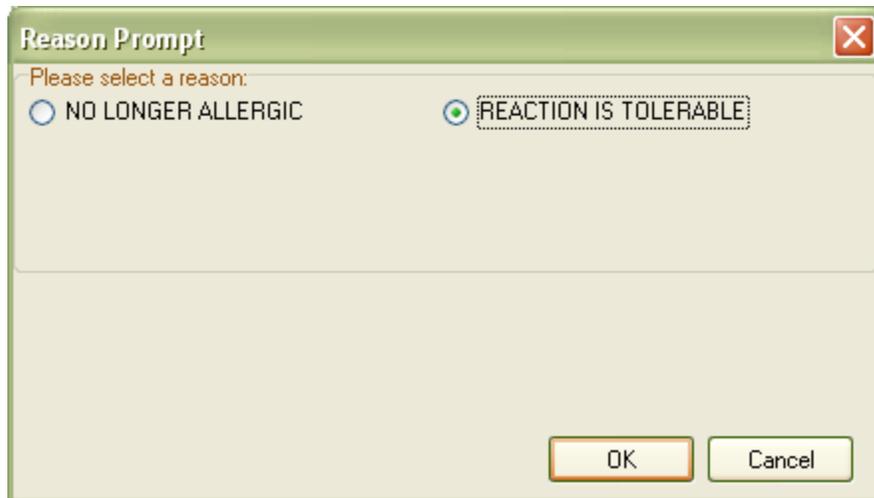
1. Inactivate:

- Right click on the entry to be inactivated and select “Inactivate Adverse Reaction”.



- Click “Yes” on the confirmation dialogue, select the reason, and click “OK”. The reaction will now only show if the “All” status radio button in the lower portion of the component is selected.





Reason Prompt

Please select a reason:

NO LONGER ALLERGIC REACTION IS TOLERABLE

OK Cancel

1. Reactivate:

- If needed, select the “All” status radio button to view the inactive reactions.
- Right click on the entry to reactivate.

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other	HIVES	Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS;ALD...	Verified (Inactive)	04-May-2011 18:51

Edit Adverse Reaction...

Delete Adverse Reaction

New Adverse Reaction...

Sign Adverse Reaction

Entered in Error

Inactivate Adverse Reaction

Reactivate Adverse Reaction

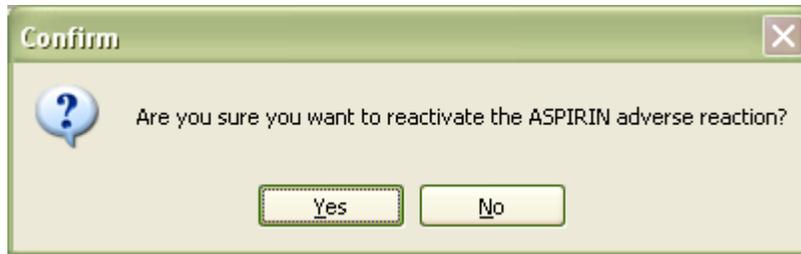
Inability to Assess

Chart Review ▶

Refresh F5

Status: All Active

- Select “Reactivate Adverse Reaction” and click “Yes” on the confirmation dialogue.



- The reaction will return to an unsigned, unverified state.

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other	HIVES	Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS,ALD...	*Unsigned	

Status: All Active

A.4 Mark a Patient as “Unassessible”

This option allows a user to mark the patient as being “unassessible” for adverse reactions. This information will be stored and displayed until an assessment is made, and a log will be kept for audit purposes.

Right click in the adverse reactions component in a blank area, and select “Inability to Assess”. Fill out the reason dialogue and click OK. *NOTE* if using “other” as a reason, you will be required to type in a reason with a 30 character limit.

A dialog box titled "Reason Prompt" with a close button (X) in the top right corner. It contains a section "Please select a reason:" with five radio button options: UNCONSCIOUS, LANGUAGE BARRIER, ALTERED MENTAL STATUS, CAREGIVER DOES NOT KNOW, PATIENT DOES NOT KNOW, and OTHER. The "OTHER" option is selected. Below this is a "Comment:" field with the text "pt unwilling to cooperate". At the bottom are "OK" and "Cancel" buttons.

If the patient was previously marked as having no known allergies, the “unassessible” will display in the header bar of the adverse reaction component. If there are existing reactions, it will display in with these other reactions.

Adverse Reactions				
Agent	Type	Reaction	Status	InAct Date
BEE STINGS	Other	HIVES	Verified	
WALNUTS	Food	GI REACTION	Nonverified (Inactive)	28-Apr-2011 16:35
AMOXICILLIN	Drug		Nonverified	
ASPIRIN	Drug	ANAPHYLAXIS;ALO...	*Unsigned	

Edit Adverse Reaction... Delete Adverse Reaction New Adverse Reaction... Sign Adverse Reaction <hr/> Entered in Error Inactivate Adverse Reaction Reactivate Adverse Reaction Inability to Assess <hr/> Chart Review ▶ Refresh F5				
				Reviewed No Active Allergies

Status

All
 Active

The documentation of “reviewed”, “updated”, or “no active” must be signed to be stored, by clicking on the integrated signature tool and applying the electronic signature. You may uncheck any action that was not actually performed.

Review/Sign Changes for Demo, Allergy Charles

Signature will be applied to checked items

Chart Review

Adverse Reactions - Reviewed

Electronic Signature Code:

A.6 Verifying Adverse Reactions

This option allows a designated verifier to verify the completeness of data entered by the clinical users into the Adverse Reaction Tracking System. The verifier is usually a pharmacist, as they have knowledge of the technical data required to allow order checks to function properly. It is recommended that, at minimum, all observed and medication adverse reactions are manually verified; it is strongly encouraged that **all** reactions are manually verified.

Only those with the appropriate security key can verify. If you have verification permissions and you enter an adverse reaction, signing it also verifies it. Otherwise, signing it just releases it for verification.

Users holding the appropriate key and membership in the appropriate mailman group will receive notifications in the EHR of reactions requiring verification. Double clicking on the notification will change patients and bring up the verification dialogue.

Verify Adverse Reaction

Reaction

Causative agent: AMOXICILLIN AM111

Nature of Reaction: Drug

Event Code: DRUG ALLERGY

Source of Information: PATIENT

Observed

Observer:

Reaction Date/Time:

Severity:

Signs/Symptoms

Available

- AGITATION
- AGRANULOCYTOSIS
- ALOPECIA
- ANAPHYLAXIS
- ANEMIA
- ANOREXIA
- ANXIETY
- APNEA
- APPETITE, INCREASED
- ARRHYTHMIA

Selected

RASH, PAPULAR May 04, 2011@19:20

Date/Time:

Source:

Comments

Current Verify OK Cancel

Clicking on the VA Class code button near the causative agent will bring up details on the VA Class codes and ingredients associated with the reaction.

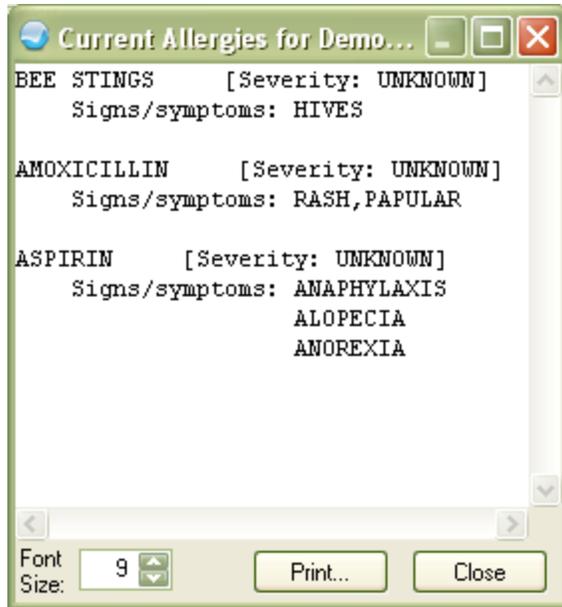
Drug Class and Ingredient Details

DRUG CLASSES: PENICILLINS, AMINO DERIVATIVES

INGREDIENTS: AMOXICILLIN

OK

Clicking on the “Current” button will bring up a list of the patient’s currently documented active reactions



If all information is present to allow order checks to function, you may click the “Verify” button and enter your electronic signature to change the status to “Verified”. **IMPORTANT:** Sites may have additional clinical verification requirements beyond this technical verification process. See the GMRA User Manual for details on documenting this type of information in RPMS Adverse Reaction Tracking.

Appendix B: Adverse Reaction Data Entry Set Up

Adapted from the EHR version 1.1 patch 1 notes. Most sites will have already made these changes, however this is presented here for completeness and due to the EHR version 1.1 patch 8 change of disabling the Adverse Reaction “ordering” dialogue.

B.1 Adverse Reaction Data Entry

This is a component that may be invoked from the adverse reaction cover sheet popup menu. It permits authorized users to enter, edit, and verify adverse reaction information into RPMS-EHR. The data is stored and managed through the RPMS Adverse Reaction Tracking application.

B.2 Implementing Adverse Reaction Data Entry

- Train providers on coversheet adverse reaction data entry
- Educate providers that allergy ordering and display will no longer be available on the Orders tab
- Train pharmacist (or whoever verifies your allergies currently) on adverse reaction verification
- Disable allergy ordering on Orders tab
- Disable allergy display on Orders tab
- Verify that staff who enter allergies have electronic signatures
- Configure permissions for adverse reaction data entry
- Review permissions for adverse reaction verification
- Review mail group membership

B.2.1 Disable Allergy Ordering and Display on the Orders Tab

Important:

The intent of the Adverse Reaction Tracking System is to eliminate the paradigm of “ordering” allergies.

Allergies that are entered via the Cover Sheet will not display on the orders list. Sites should take the allergy order off the Orders tab and disable the display of allergies on the Orders tab.

B.2.1.1 Disable Allergy Ordering on the Orders Tab

Allergy Ordering can be disabled by removing the GMAOR ALLERGY ENTER/EDIT from the Write Orders list. This needs to be done for all users. Complete instructions on configuring the Write Orders List are available in the CAC Setup Guide.

B.2.1.2 Disable Allergy Display on the Orders Tab

You can disable allergies from displaying on the orders tab by following the instructions below. Have your SITE MANAGER do this, because it needs to be done in Fileman. Be very careful

There is a file called DISPLAY GROUP. There is an entry in this file called ALL SERVICES (This works just like the ALL SERVICES in consults). Remove ALLERGIES from the MEMBER field of this file:

It should be number 12 on your system.

```
NAME: ALL SERVICES//
Select MEMBER: SUPPLIES/DEVICES// ?
Answer with MEMBER, or SEQUENCE
Do you want the entire 12-Entry MEMBER List? Y (Yes)
Choose from:
1          PHARMACY
2          LABORATORY
3          IMAGING
4          DIETETICS
5          CONSULTS
6          VITALS/MEASUREMENTS
7          NURSING
8          SURGERY
9          M.A.S.
10         OTHER HOSPITAL SERVICES
11         PROVEDURES
12         ALLERGIES ←This one
13         SUPPLIES/DEVICES
```

B.2.2 Configure Permissions for Adverse Reaction Data Entry

Adverse Reaction Data Entry is configured by going to the RPMS-EHR Configuration Menu | Adverse Reaction Tracking Configuration (ART) | Enable Adverse Reaction Data Entry (ENT).

```

DEMO HOSPITAL                RPMS-EHR Management
                             Enable Adverse Reaction Data Entry

Allow entry of adverse reaction data may be set for the following:

    100 User          USR    [choose from NEW PERSON]
    200 Class         CLS    [choose from USR CLASS]
    800 Division      DIV    [DEMO HOSPITAL]
    900 System        SYS    [DEMO.MEDSPHERE.COM]

Enter selection: █

```

Figure 3-1: Adverse Reaction Data Entry

B.2.2.1 Review Permissions for Adverse Reaction Verification

This option allows those with the GMRA ALLERGY-VERIFY key to verify the completeness of data entered by the clinical users into the Adverse Reaction Tracking System.

Verifiers can be clinical pharmacists, or other clinical personnel. **Usually the pharmacist or designated verifier will already have the existing security keys needed to allow verification.**

Important: Do not set this parameter for all users—adverse reactions should be verified by a pharmacist or other designated verifying staff.

Adverse Reaction Verification is configured by going to the RPMS-EHR Configuration Menu | Adverse Reaction Tracking Configuration (ART) | Allow Adverse Reaction Verification (VER).

```

DEMO HOSPITAL                RPMS-EHR Management                Version 1.1
                             Allow Adverse Reaction Verification

GMRA-ALLERGY VERIFY Key Management

Select a user for key assignment: user,n  USER,NURSE          NU          NURSE

This user does not currently have the GMRA-ALLERGY VERIFY key.
Do you wish to assign this key to the selected user? █

```

```

DEMO HOSPITAL                RPMS-EHR Management                Version 1.1
Allow Adverse Reaction Verification

GMRA-ALLERGY VERIFY Key Management

Select a user for key assignment: user,p  USER,POWER        DKM        IT SPECI
ALIST

This user already has the GMRA-ALLERGY VERIFY key.
Do you wish to remove the key assignment? N

```

B.2.2.2 Mail Bulletin Setup

Automated mail bulletins will be sent to the ART verifiers when an allergy/adverse reaction has been entered and signed (completed) by a user. Review the membership of the following mail groups to ensure that the verifiers are included:

GMRA VERIFY DRUG ALLERGY
 GMRA VERIFY FOOD ALLERGY
 GMRA VERIFY OTHER ALLERGY

Additional bulletins may be sent to the ART package coordinator(s) when new reactants are requested by the users. Review the membership of the GMRA REQUEST NEW REACTANT mail group to ensure all needed members are present. NOTE: the GMRA VERIFY DRUG ALLERGY group will be added to this group upon installation. This can be modified as the site requires.

Additional mail groups that can be set up:

GMRA MARK CHART
 GMRA P&T COMMITTEE FDA

Once the groups have been reviewed, ensure the appropriate groups are attached to the bulletins. At a minimum, the GMRA VERIFY ALLERGY bulletin should be set up. The bulletins for new reactants do not require set up. Sites may choose to set up additional bulletins as processes dictate:

GMRA ENTERED IN ERROR
 GMRA MARK CHART
 GMRA P&T COMMITTEE FDA
 GMRA SIGNS/SYMPTOMS UPDATE

Appendix C: Rules of Behavior

The Resource and Patient Management (RPMS) system is a United States Department of Health and Human Services (HHS), Indian Health Service (IHS) information system that is **FOR OFFICIAL USE ONLY**. The RPMS system is subject to monitoring; therefore, no expectation of privacy shall be assumed. Individuals found performing unauthorized activities are subject to disciplinary action including criminal prosecution.

All users (Contractors and IHS Employees) of RPMS will be provided a copy of the Rules of Behavior (RoB) and must acknowledge that they have received and read them prior to being granted access to a RPMS system, in accordance IHS policy.

- For a listing of general ROB for all users, see the most recent edition of *IHS General User Security Handbook* (SOP 06-11a).
- For a listing of system administrators/managers rules, see the most recent edition of the *IHS Technical and Managerial Handbook* (SOP 06-11b).

Both documents are available at this IHS Web site: <http://security.ihs.gov/>.

The ROB listed in the following sections are specific to RPMS.

C.1 All RPMS Users

In addition to these rules, each application may include additional RoBs that may be defined within the documentation of that application (e.g., Dental, Pharmacy).

C.1.1 Access

RPMS users shall

- Only use data for which you have been granted authorization.
- Only give information to personnel who have access authority and have a need to know.
- Always verify a caller's identification and job purpose with your supervisor or the entity provided as employer before providing any type of information system access, sensitive information, or nonpublic agency information.
- Be aware that personal use of information resources is authorized on a limited basis within the provisions *Indian Health Manual* Part 8, "Information Resources Management," Chapter 6, "Limited Personal Use of Information Technology Resources."

RPMS users shall not

- Retrieve information for someone who does not have authority to access the information.

- Access, research, or change any user account, file, directory, table, or record not required to perform their *official* duties.
- Store sensitive files on a PC hard drive, or portable devices or media, if access to the PC or files cannot be physically or technically limited.
- Exceed their authorized access limits in RPMS by changing information or searching databases beyond the responsibilities of their jobs or by divulging information to anyone not authorized to know that information.

C.1.2 Information Accessibility

RPMS shall restrict access to information based on the type and identity of the user. However, regardless of the type of user, access shall be restricted to the minimum level necessary to perform the job.

RPMS users shall

- Access only those documents they created and those other documents to which they have a valid need-to-know and to which they have specifically granted access through an RPMS application based on their menus (job roles), keys, and FileMan access codes. Some users may be afforded additional privileges based on the functions they perform, such as system administrator or application administrator.
- Acquire a written preauthorization in accordance with IHS policies and procedures prior to interconnection to or transferring data from RPMS.

C.1.3 Accountability

RPMS users shall

- Behave in an ethical, technically proficient, informed, and trustworthy manner.
- Log out of the system whenever they leave the vicinity of their personal computers (PCs).
- Be alert to threats and vulnerabilities in the security of the system.
- Report all security incidents to their local Information System Security Officer (ISSO)
- Differentiate tasks and functions to ensure that no one person has sole access to or control over important resources.
- Protect all sensitive data entrusted to them as part of their government employment.
- Abide by all Department and Agency policies and procedures and guidelines related to ethics, conduct, behavior, and information technology (IT) information processes.

C.1.4 Confidentiality

RPMS users shall

- Be aware of the sensitivity of electronic and hard copy information, and protect it accordingly.
- Store hard copy reports/storage media containing confidential information in a locked room or cabinet.
- Erase sensitive data on storage media prior to reusing or disposing of the media.
- Protect all RPMS terminals from public viewing at all times.
- Abide by all Health Insurance Portability and Accountability Act (HIPAA) regulations to ensure patient confidentiality.

RPMS users shall not

- Allow confidential information to remain on the PC screen when someone who is not authorized to that data is in the vicinity.
- Store sensitive files on a portable device or media without encrypting.

C.1.5 Integrity

RPMS users shall

- Protect their systems against viruses and similar malicious programs.
- Observe all software license agreements.
- Follow industry standard procedures for maintaining and managing RPMS hardware, operating system software, application software, and/or database software and database tables.
- Comply with all copyright regulations and license agreements associated with RPMS software.

RPMS users shall not

- Violate federal copyright laws.
- Install or use unauthorized software within the system libraries or folders.
- Use freeware, shareware, or public domain software on/with the system without their manager's written permission and without scanning it for viruses first.

C.1.6 System Logon

RPMS users shall

- Have a unique User Identification/Account name and password.

- Be granted access based on authenticating the account name and password entered.
- Be locked out of an account after five successive failed login attempts within a specified time period (e.g., one hour).

C.1.7 Passwords

RPMS users shall

- Change passwords a minimum of every 90 days.
- Create passwords with a minimum of eight characters.
- If the system allows, use a combination of alpha-numeric characters for passwords, with at least one uppercase letter, one lower case letter, and one number. It is recommended, if possible, that a special character also be used in the password.
- Change vendor-supplied passwords immediately.
- Protect passwords by committing them to memory or store them in a safe place (do not store passwords in login scripts or batch files).
- Change passwords immediately if password has been seen, guessed, or otherwise compromised, and report the compromise or suspected compromise to their ISSO.
- Keep user identifications (IDs) and passwords confidential.

RPMS users shall not

- Use common words found in any dictionary as a password.
- Use obvious readable passwords or passwords that incorporate personal data elements (e.g., user's name, date of birth, address, telephone number, or social security number; names of children or spouses; favorite band, sports team, or automobile; or other personal attributes).
- Share passwords/IDs with anyone or accept the use of another's password/ID, even if offered.
- Reuse passwords. A new password must contain no more than five characters per eight characters from the previous password.
- Post passwords.
- Keep a password list in an obvious place, such as under keyboards, in desk drawers, or in any other location where it might be disclosed.
- Give a password out over the phone.

C.1.8 Backups

RPMS users shall

- Plan for contingencies such as physical disasters, loss of processing, and disclosure of information by preparing alternate work strategies and system recovery mechanisms.
- Make backups of systems and files on a regular, defined basis.
- If possible, store backups away from the system in a secure environment.

C.1.9 Reporting

RPMS users shall

- Contact and inform their ISSO that they have identified an IT security incident and begin the reporting process by providing an IT Incident Reporting Form regarding this incident.
- Report security incidents as detailed in the *IHS Incident Handling Guide* (SOP 05-03).

RPMS users shall not

- Assume that someone else has already reported an incident. The risk of an incident going unreported far outweighs the possibility that an incident gets reported more than once.

C.1.10 Session Timeouts

RPMS system implements system-based timeouts that back users out of a prompt after no more than 5 minutes of inactivity.

RPMS users shall

- Utilize a screen saver with password protection set to suspend operations at no greater than 10 minutes of inactivity. This will prevent inappropriate access and viewing of any material displayed on the screen after some period of inactivity.

C.1.11 Hardware

RPMS users shall

- Avoid placing system equipment near obvious environmental hazards (e.g., water pipes).
- Keep an inventory of all system equipment.
- Keep records of maintenance/repairs performed on system equipment.

RPMS users shall not

- Eat or drink near system equipment.

C.1.12 Awareness

RPMS users shall

- Participate in organization-wide security training as required.
- Read and adhere to security information pertaining to system hardware and software.
- Take the annual information security awareness.
- Read all applicable RPMS manuals for the applications used in their jobs.

C.1.13 Remote Access

Each subscriber organization establishes its own policies for determining which employees may work at home or in other remote workplace locations. Any remote work arrangement should include policies that

- Are in writing.
- Provide authentication of the remote user through the use of ID and password or other acceptable technical means.
- Outline the work requirements and the security safeguards and procedures the employee is expected to follow.
- Ensure adequate storage of files, removal, and nonrecovery of temporary files created in processing sensitive data, virus protection, and intrusion detection, and provide physical security for government equipment and sensitive data.
- Establish mechanisms to back up data created and/or stored at alternate work locations.

Remote RPMS users shall

- Remotely access RPMS through a virtual private network (VPN) whenever possible. Use of direct dial in access must be justified and approved in writing and its use secured in accordance with industry best practices or government procedures.

Remote RPMS users shall not

- Disable any encryption established for network, internet, and Web browser communications.

C.2 RPMS Developers

RPMS developers shall

- Always be mindful of protecting the confidentiality, availability, and integrity of RPMS when writing or revising code.
- Always follow the IHS RPMS Programming Standards and Conventions (SAC) when developing for RPMS.
- Only access information or code within the namespaces for which they have been assigned as part of their duties.
- Remember that all RPMS code is the property of the U.S. Government, not the developer.
- Not access live production systems without obtaining appropriate written access, and shall only retain that access for the shortest period possible to accomplish the task that requires the access.
- Observe separation of duties policies and procedures to the fullest extent possible.
- Document or comment all changes to any RPMS software at the time the change or update is made. Documentation shall include the programmer's initials, date of change, and reason for the change.
- Use checksums or other integrity mechanism when releasing their certified applications to assure the integrity of the routines within their RPMS applications.
- Follow industry best standards for systems they are assigned to develop or maintain, and abide by all Department and Agency policies and procedures.
- Document and implement security processes whenever available.

RPMS developers shall not

- Write any code that adversely impacts RPMS, such as backdoor access, "Easter eggs," time bombs, or any other malicious code or make inappropriate comments within the code, manuals, or help frames.
- Grant any user or system administrator access to RPMS unless proper documentation is provided.
- Release any sensitive agency or patient information.

C.3 Privileged Users

Personnel who have significant access to processes and data in RPMS, such as, system security administrators, systems administrators, and database administrators, have added responsibilities to ensure the secure operation of RPMS.

Privileged RPMS users shall

- Verify that any user requesting access to any RPMS system has completed the appropriate access request forms.
- Ensure that government personnel and contractor personnel understand and comply with license requirements. End users, supervisors, and functional managers are ultimately responsible for this compliance.
- Advise the system owner on matters concerning information technology security.
- Assist the system owner in developing security plans, risk assessments, and supporting documentation for the certification and accreditation process.
- Ensure that any changes to RPMS that affect contingency and disaster recovery plans are conveyed to the person responsible for maintaining continuity of operations plans.
- Ensure that adequate physical and administrative safeguards are operational within their areas of responsibility and that access to information and data is restricted to authorized personnel on a need-to-know basis.
- Verify that users have received appropriate security training before allowing access to RPMS.
- Implement applicable security access procedures and mechanisms, incorporate appropriate levels of system auditing, and review audit logs.
- Document and investigate known or suspected security incidents or violations and report them to the ISSO, Chief Information Security Officer (CISO), and systems owner.
- Protect the supervisor, superuser, or system administrator passwords.
- Avoid instances where the same individual has responsibility for several functions (i.e., transaction entry and transaction approval).
- Watch for unscheduled, unusual, and unauthorized programs.
- Help train system users on the appropriate use and security of the system.
- Establish protective controls to ensure the accountability, integrity, confidentiality, and availability of the system.
- Replace passwords when a compromise is suspected. Delete user accounts as quickly as possible from the time that the user is no longer authorized system. Passwords forgotten by their owner should be replaced, not reissued.

- Terminate user accounts when a user transfers or has been terminated. If the user has authority to grant authorizations to others, review these other authorizations. Retrieve any devices used to gain access to the system or equipment. Cancel logon IDs and passwords, and delete or reassign related active and backup files.
- Use a suspend program to prevent an unauthorized user from logging on with the current user's ID if the system is left on and unattended.
- Verify the identity of the user when resetting passwords. This can be done either in person or having the user answer a question that can be compared to one in the administrator's database.
- Shall follow industry best standards for systems they are assigned to, and abide by all Department and Agency policies and procedures.

Privileged RPMS users shall not

- Access any files, records, systems, etc., that are not explicitly needed to perform their duties
- Grant any user or system administrator access to RPMS unless proper documentation is provided.
- Release any sensitive agency or patient information.

Glossary

Adverse Reaction

Any condition precipitated by a drug, food, or other substance that 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 RPMS applications are the Immunization package and the Laboratory package.

Application Coordinator

The person responsible for implementing a set of computer programs (application package) developed to support a specific functional area such as Immunizations, laboratory, Pharmacy, etc.

ART

See Adverse Reaction Tracking

Causative Agent

The name of the item that 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's ID Band or bracelet has been marked to indicate this allergy or adverse reaction.

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 an 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 had 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. ****NOTE**** the verification process within the ART package is currently more for technical verification that all data for order checking is present, rather than a clinical verification of the reaction.

Historical

An adverse reaction that had been stated by some source versus one that has actually been witnessed by some personnel at this facility

Ingredient file

A file (#50.416) that contains substances that 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 facility. 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.

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 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 of 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) that 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.

Verification

The process of reviewing for completeness 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.

VUID

VHA User Identification

Acronym List

ADR	Adverse Drug Reaction
ART	Adverse Reaction Tracking
EHR	Electronic Health Record
IHS	Indian Health Service
RPMS	Resource and Patient Management System
IT	Information Technology

Contact Information

If you have any questions or comments regarding this distribution, please contact the OIT Help Desk (IHS).

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