

Adverse Reaction Tracking Setup Checklist

Existing Allergy/ADR data can be moved to the new system. Unmatched reactant data can be moved as free text, and then repointed to a standard entry using the GMRA Free Text Utility. NKA entries can be moved.

ACTIVITY	STATUS	RESPONSIBLE	COMMENTS
Please consult the Adverse Reaction User Manual documentation for examples and directions of how to set-up various files.			
1. Site Parameters: With Data Standardization there should not be a need for more than the HOSPITAL (first entry) in file 120.84. Using the option <i>Enter/Edit Site Parameters</i> [GMRA SITE FILE] set the following parameters:			
A. Top Ten Signs/Symptoms			
B. Autoverify Food/Drug/Other			
C. Autoverify Observed/Historical			
D. Require originator comments			
E. Documenting Patient Chart/ID Band as Marked (this isn't real relevant anymore with electronic charts)			
F. FDA Data Required – usually set to NO because sites are using ADERS to report FDA adverse reaction data.			
G. Enable Comments Field for Reactions that are Entered in Error – recommend this is set to YES			
H. SEND CHART MARK BULLETINS FOR NEW ADMISSIONS – suggested be set to NO. This is not multidivisional or by ward. Each new admission will send a bulletin.			
I. You may enter Reporter Information. This information will pre-populate on the VistA generated FDA Medwatch Form. If you are using VA ADERS to report reaction data, this information does not need to be populated.			
J. Decide if site will allow entries to be marked as “Entered			

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in Error” through CPRS. This is set by the OR ALLERGY EIE parameter under the ORCL Clinical Coordinator’s Menu – GUI Parameters. This may be set at the User, Class, Division or System level. (Suggested User Class listed under comments.)			
2. Implementation			
A. Security Keys: Assign the GMRA-ALLERGY VERIFY key to any clinic person (usually a Pharmacist) that will be responsible for verifying any newly entered ADR’s. Assign the GMRA SUPERVISOR key only to those who have the authority to override the system’s security to edit data.			
B. Mail Groups: There are a number of mail groups that need to be updated with new users once the mail groups and users have been entered into the system. Details on who should be added to these mail groups may be found in the ART User Manual in the Package Management section.			
1) GMRA MARK CHART			
2) GMRA P&T COMMITTEE FDA			
3) GMRA VERIFY DRUG ALLERGY			
4) GMRA VERIFY FOOD ALLERGY			
5) GMRA VERIFY OTHER ALLERGY			
6) GMRA REQUEST NEW REACTANT			
C. Assign Menus. Details on menus and recommended assignment can be found in the ART User Manual – Package Operation section.			
3. The critical files of 120.82 (GMR ALLERGIES) and 120.83 (SIGNS/SYMPTOMS) are now standardized and cannot be edited.			