Pharmacy Information System (PhIS)
and
Clinic Pharmacy System (CPS)

System Design Document
(SDD)

Adverse Drug Reaction

Version	**: 1.3**
Document ID	**: PhIS_CPS/SDD/ADR**

REVISION HISTORY

Version No	Date of Release	Prepared by	Reviewed by	List of changes from Previous Version
0.1	5/3/2012	Norlaileza Sidek	G. Shenoy (SME)	Initial 1st draft
0.2	7/3/2012	Norlaileza Sidek	G. Shenoy (SME)	Comment added
0.3	12/3/2012	Norlaileza Sidek	G. Shenoy (SME)	Comment added
1.0	12/3/2012	Norlaileza Sidek	Maxine Wong (QA)	Comment added
1.1	10/4/2018	Norlaileza Sidek	MOH	Changes based on version 1.7 release
1.2	18/5/2018	Norlaileza Sidek	MOH	Comment added
1.3	1/3/2019	Norlaileza Sidek	MOH	Updated based on module owner comments

Reviewed By:

Pharmaniaga Logistics Sdn Bhd		Ministry Of Health	
Signature :		Signature :	
Name :		Name :	
Title :		Title :	
Date :		Date :	

Table of Content

1. Introduction

Pharmaniaga Logistics Sdn. Bhd. executes software development, enhancement and maintenance projects for its clients. The term “project” is used to describe the full set of activities from the time the proposal is accepted and project initiation note or contract is signed to the time all the software and services are delivered according to the acceptance of the proposal/contract.

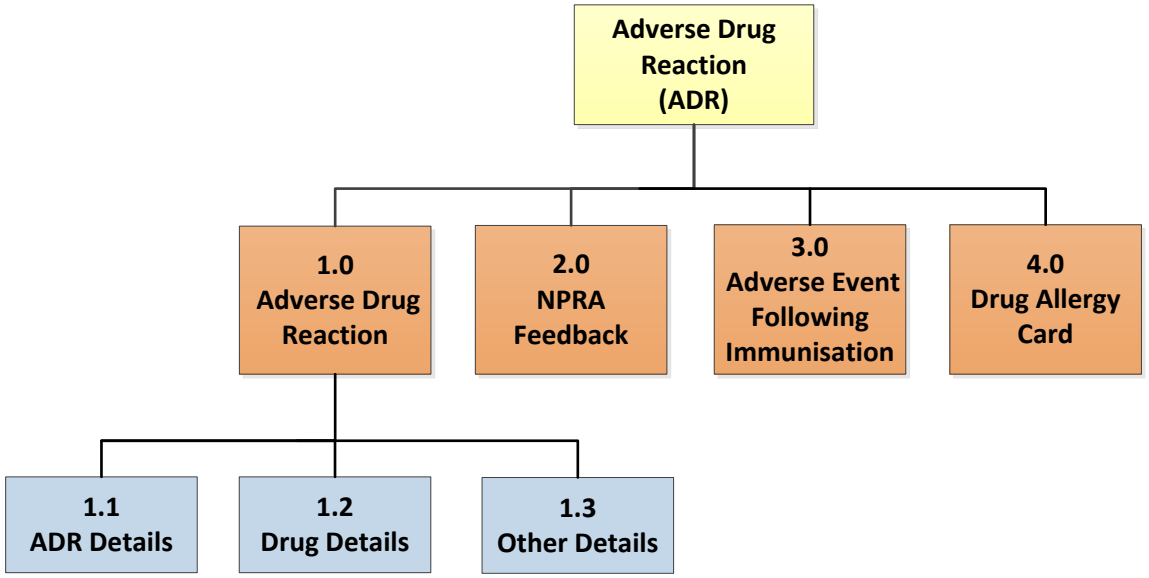
This process is to ensure both user requirements and software requirements of the projects developments are gathered appropriately from stakeholders and are documented in User Requirements Specification (URS) and System Design Documentation (SDD) specifically.

2. Purpose

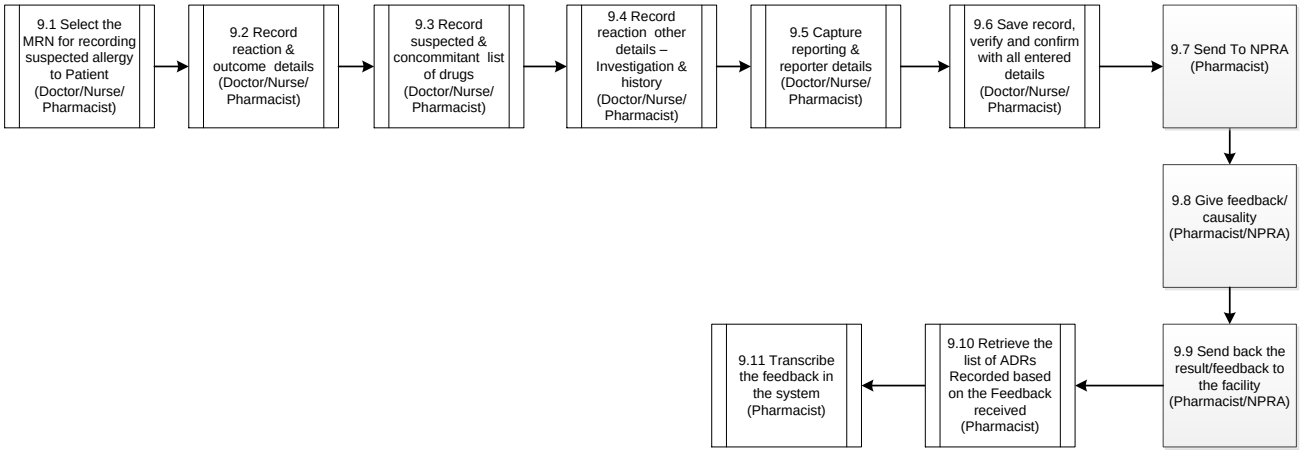
The purpose of the document is to describe the purpose and functionality of the software product requested by client. This document outlines the project's details, requirements, interface, design issues, and components to ensure that each requirement has been met.

3. Detailed System Design

3.1 Adverse Drug Reaction Overview



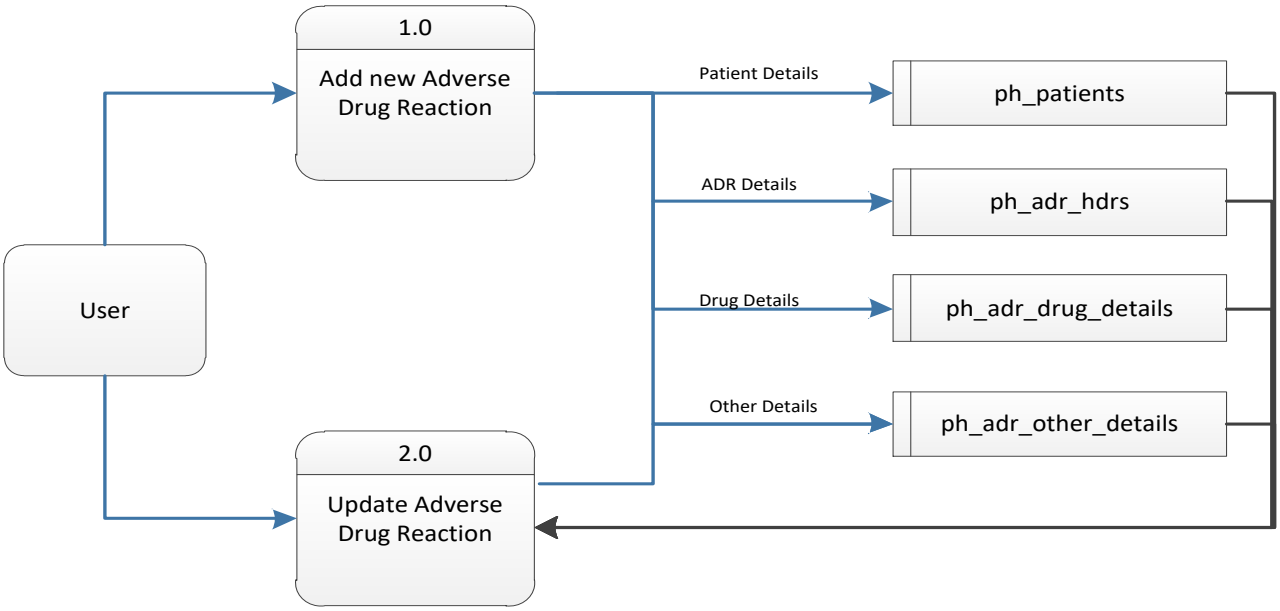
3.1.1 Block Diagram



3.1.2 Purpose

This module shall be used to record patient adverse drug reaction (ADR) in the system

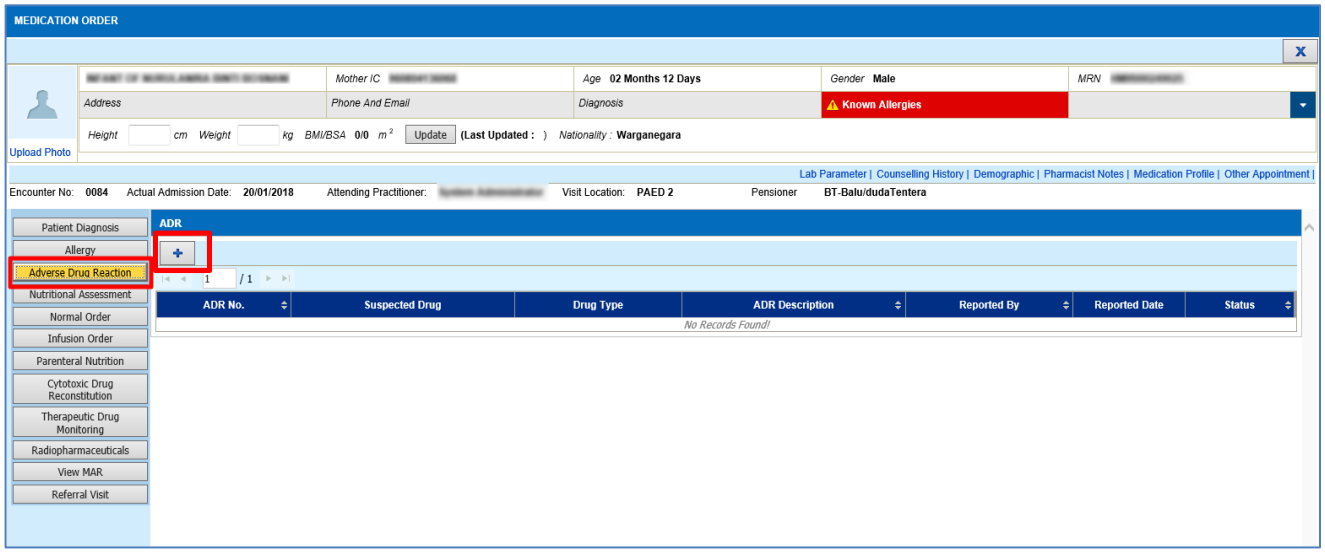
3.1.3 Screen Navigation Diagram



3.1.4 Detail Functionality and Screen

3.1.4.1 Adverse Drug Reaction (Medication Order Screen)

3.1.4.1.1 Screen Design

ID	MO.ADR.SD1
Description	Medication Order - Adverse Drug Reaction
Diagram	 *MO.ADR.SD1*
Notes	• Based on the access right, prescriber will access the ADR reporting screen from the Medication Order screen. • Click on 'Adverse Drug Reaction' menu, system will display ADR listing screen. • Click on the 'Add' button to record new ADR, ADR Reporting screen will appear. • Recorded ADR reporting will be shown in the listing. • Double click on the record to show details of report.
Cross References	None

3.1.4.1.2 Application Business Rules

No	Name	Description
1.	Add New Button	Medication Order Screen provides "Adverse Drug Reaction" menu. On click of the button will display Adverse Drug Reaction screen.
2.	Patient record	Patient Registration and Visit must already be created upon creating a new medication order record.
3.	Record New ADR	During recording of new ADR reported: i. User need to select patient from the 'Select Registered Patient' function. ii. One patient can have multiple record of ADR depending on the adverse reaction reported. iii. One record of ADR can have multiple suspected drug and multiple

		concomitant drugs. iv. Verify and confirm record will be assign based on access right. v. Reporter details is capturing record based on the user login id
4.	Update ADR record	User can edit the record as long as no verification from pharmacist.

3.1.4.1.3 Input Validation Rules

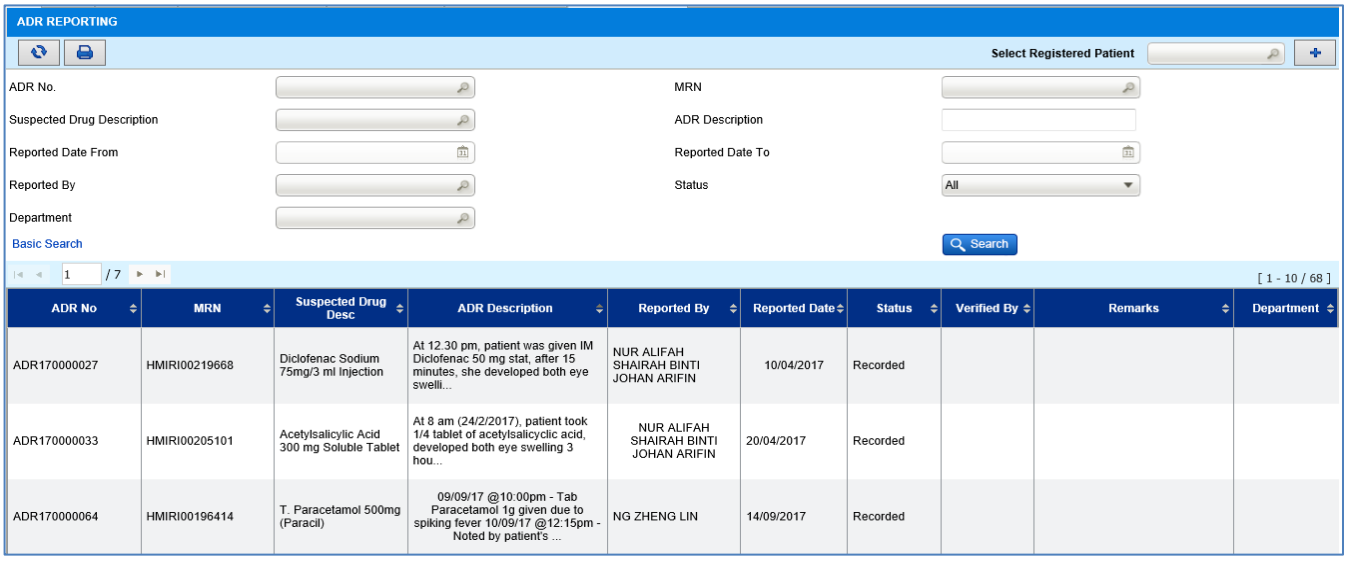
None.

3.1.4.2 Adverse Drug Reaction Listing

3.1.4.2.1 Screen Design

ID	ADR.SD1
Description	Adverse Drug Reaction Listing

Diagram



Notes	• Click on search button at 'Select Registered Patient' to search for the patient. • Click on Add button to add the patient for ADR Reporting record and system will display ADR Reporting Screen.
Cross References	None

3.1.4.2.2 Application Business Rules

No	Name	Description
1.	Select Registered Patient	ADR reporting listing screen is displayed for pharmacist to view recorded ADR and create new ADR record by select patient from the 'Select Registered Patient' field.
2.	Search filter	ADR reporting listing screen allow user to display record according to the filtering data selected. This screen will allow user to search by the following criteria: i. ADR No – ADR Reporting listing shall be retrieved from the database based on matching ADR No.

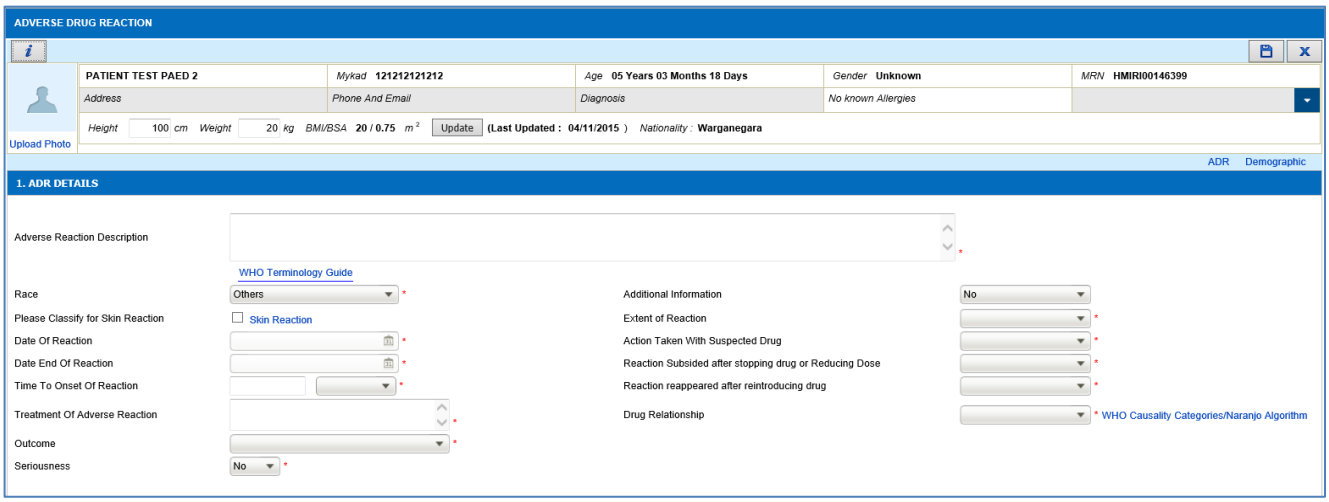
		ii. MRN – ADR Reporting listing shall be retrieved from the database based on matching MRN. iii. Suspected Drug Description – ADR Reporting listing shall be retrieved from the database based on matching Suspected Drug Description. iv. ADR Description – ADR Reporting listing shall be retrieved from the database based on matching ADR Description. v. Reported Date From – ADR Reporting listing shall be retrieved from the database based on matching Reported Date From. vi. Reported Date To – ADR Reporting listing shall be retrieved from the database based on matching Reported Date To. vii. Reported By – ADR Reporting listing shall be retrieved from the database based on matching Reported By. viii. Status – ADR Reporting listing shall be retrieved from the database based on matching Status. By default status will be as 'All' and user is allows to change. ix. Department – To retrieve from department listing
3.	ADR List	Results of the search will listed below the search criteria section. The ADR listing record will contain the following information: i. ADR No ii. MRN iii. Suspected Drug Description iv. ADR Description v. Reported By vi. Reported Date vii. Status viii. Verified By ix. Remarks x. Department
4.	Advanced Search	Click on 'Advanced Search' for more choices of filtering data and basic search to minimize the selection.
5.	Refresh Order Listing	Click on the Refresh button to reset all searched records and searching criteria's to default value.

3.1.4.2.3 Input Validation Rules

None.

3.1.4.3 *Adverse Drug Reaction Reporting Screen*

3.1.4.3.1 Screen Design

ID	ADR.SD2
Description	Add new record for ADR reporting
Diagram	
Notes	• ADR Reporting Screen has three sections, click header to expand the screen. Sections as below: - ADR Details - Drug Details - Other Details • Drug Details section shows list of drug prescribed to the patient (Medication Profile) • Click on the add button to add drug from the Drug Master list or traditional drug (free text). • Record verified and Click to confirm the record check box will be assign based on the access right. • Click on 'Save' button to save the record.
Cross References	None

3.1.4.3.2 Application Business Rules

No.	Name	Description
1.	Patient Banner	Patient banner is located at the upper screen and showing details of patient information. The information contains as below: i. Patient Image ii. Full Name iii. Mykad iv. Age v. Gender vi. MRN vii. Full Address viii. Phone and Email

No.	Name	Description
		ix. Diagnosis x. Allergies record xi. Height and Weight xii. BMI
2.	Hyperlink	Below the patient banner, there will be hyperlinks to access details of patient. User is able to click on the hyperlink and a pop up screen will be opened. The hyperlinks are as below: i. ADR If there is any adverse drug reaction recorded for the patient user can view it from this screen. This ADR hyperlink will be highlighted in different colour (red) as an alert for Doctor to view the previous ADR recorded. ii. Demographic Patient's demographic details will be shown in this screen.

3.1.4.3.3 Input Validation Rules

No.	Name	Description	Mandatory	Format
ADR Details				
1.	Adverse Reaction Description	Adverse Reaction Description is free text with a capacity of 500 characters. This field is mandatory	Yes	Text field
2.	WHO Terminology Guide	WHO Terminology Guide hyperlink will redirect screen to the WHO – Adverse Drug Reaction Terminology – WHO ART 2012 in pdf format. This file is a guideline for user.	No	Hyperlink
3.	Additional Information	Additional Information is to be selected from the drop down list. Dropdown will be populated from lookup table where domain = 'No'. If 'Yes' selected system will display another drop down menu to be select.	No	Drop Down field
4.	YES - Additional Information	Selection of drop down menu, value as below. - Brand Switching - Drug Interaction - Medication Error - Medication Ineffective - Others This field is mandatory	Yes	Drop Down field
5.	Race	This field will auto display record from the field 'Race' from Patient registration profile screen and allow to be edited	Yes	Drop Down field
6.	Extent of reaction	Drop down field to be selected, value as below:	Yes	Drop Down field

No.	Name	Description	Mandatory	Format
		- 1 = Mild - 2 = Moderate - 3 = Severe - 4 = unknown		
7.	Reaction Subsided after stopping drug or Reducing Dose	Drop down field to be selected, value as below: - 1 = Yes - 2 = No - 3 = Unknown	Yes	Drop Down field
8.	Action Taken With Suspected Drug	Drop down field to be selected, value as below: - 1 = Drug Withdrawn - 2 = Dose Reduced - 3 = Dose Increased - 4 = Dose Not Changed - 5 = Unknown - 6 = Not Applicable	Yes	Drop Down field
9.	Reaction reappeared after reintroducing drug	Drop down field to be selected, value as below: - 1 = Yes - 2 = No - 3 = Unknown	Yes	Drop Down field
10.	Please Classify for Skin Reaction	Skin Reaction hyperlink will be enabled as when click on the check box. Click on the hyperlink *(Refer to section 3.1.3.4 Clinical Manifestation of Adverse Drug Reaction)* and there will be a list type of cutaneous adverse drug reaction and the details. The checked values will be captured and sent to NPRA. User can select multiple reactions.	No	Check box
11.	Part of body affected	This should be a free text field with a maximum of 500 characters capacity.	No	Text field
12.	Date of reaction	Date field with Calendar popup. Date to be entered in dd/mm/yyyy format. Date should be less than system date.	Yes	Calendar
13.	Date End of reaction	Date field with Calendar popup. Date to be entered in dd/mm/yyyy format. Date should be less than system date.	Yes	Calendar
14.	Time to Onset of Reaction (1)	Text field maximum five (5) characters to be entered.	Yes	Text field
15.	Time to Onset of Reaction (2)	A drop down combo box is provided to select the time to onset of reaction. The values are populated from System parameter, category-Onset Time contains values as following:	Yes	Drop down

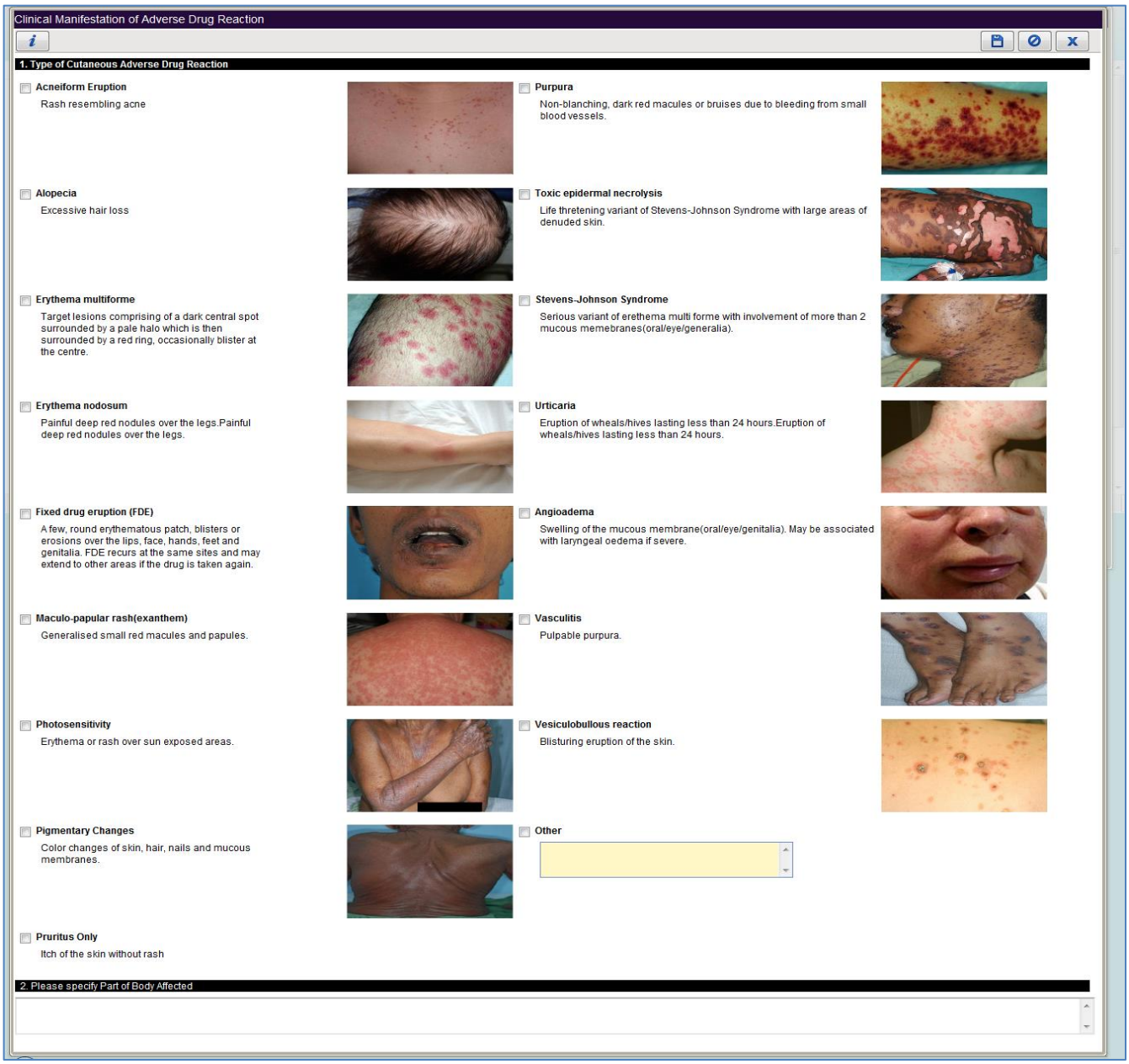
No.	Name	Description	Mandatory	Format
		- Immediately - Minutes - Hours - Days - Weeks - Months		
16.	Treatment of Adverse Reaction	This should be a free text field with a maximum of 500 characters capacity.	Yes	Text field
17.	Outcome	A drop down combo box is provided to select the outcome. The values are populated from System parameter, category-Outcome. The list contains values as following: - 1 = Recovered/Resolved - 2 = Recovering/Resolving - 3 = Recovered/Resolved With Sequelae - 4 = Not Recovered/Not Resolved - 5 = Unknown	Yes	Drop down
18.	Seriousness	Seriousness is to be selected from the drop down list. Dropdown will be populated from lookup table where domain = 'No'. If 'Yes' selected system will display another drop down menu to be select.	Yes	Drop down
19.	YES – Seriousness	A drop down combo box is provided to select the outcome. The values are populated from System parameter. The list contains values as following: - 1 = Results In Death - 2 = Life Threatening - 3 = Hospitalization/Prolong Hospitalization - 4 = Disability/Incapacity - 5 = Birth Defect If '1 = Results In Death' selected another field will appear as below: - Date of Death - Was Autopsy Done - Autopsy Determined Cause Of Death - Cause Of Death	Yes	Drop down
20.	Date of Death	Date field with Calendar popup. Date to be entered in dd/mm/yyyy format.	Yes	Calendar
21.	Was Autopsy Done	Drop down field to be selected, value as below: - 1 = Yes	Yes	Drop Down field

No.	Name	Description	Mandatory	Format
		- 2 = No - 3 = Unknown		
22.	Autopsy Determined Cause Of Death	Text field maximum 200 characters to be entered.	Yes	Text field
23.	Cause Of Death	Text field maximum 250 characters to be entered.	Yes	Text field
24.	Drug Relationship	A drop down combo box is provided to select a value. The values are populated from System parameter, category-reaction relationship. The list contains values as following: - 1 = Certain - 2 = Probable - 3 = Possible - 4 = Unlikely - 5 = Unclassifiable The value is selected based on the Causality Grading guide.	Yes	Drop down

3.1.4.4 *Clinical Manifestation of Adverse Drug Reaction*

3.1.4.4.1 *Screen Design*

ID	ADR.SD3
Description	Type of Cutaneous Adverse Drug Reaction
Diagram	



Notes	• Click on the ‘Cancel’ button to cancel the task. • Click on the ‘Save’ button to save the record and system will go back to the main ADR reporting screen.
Cross References	None

3.1.4.4.2 Application Business Rules

No.	Name	Description
1.	Type of Cutaneous Adverse Drug Reaction	This screen appears upon click on 'Skin Reaction' hyperlink at ADR Details Screen. User is allows to select multiple type of cutaneous adverse drug reaction in one reporting.

3.1.4.4.3 Input Validation Rules

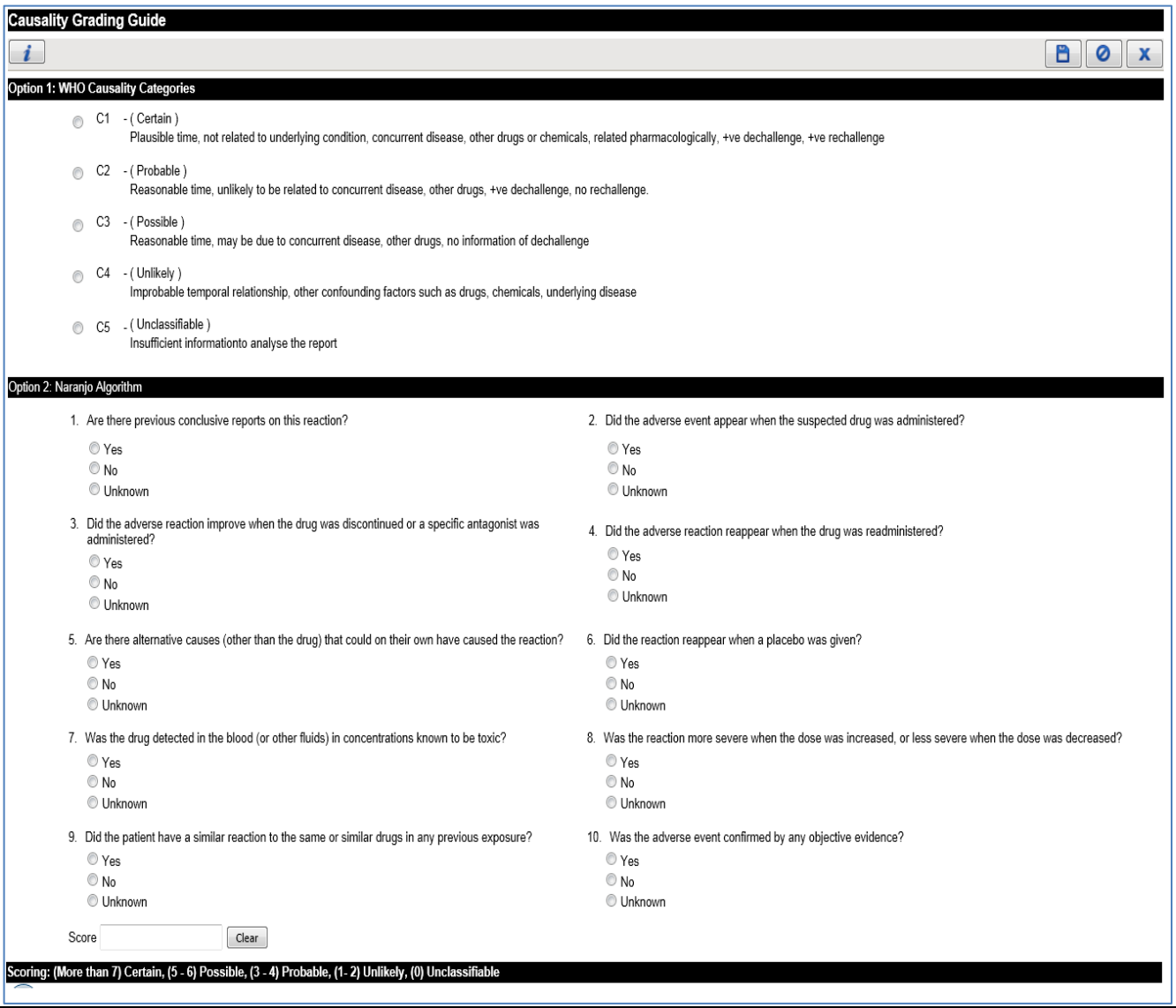
No.	Name	Description	Mandatory	Format
Clinical Manifestation of Adverse Drug Reaction				
1.	Acneiform	Check box provided	No	Check box
2.	Alopecia	Check box provided	No	Check box
3.	Erythema multiforme	Check box provided	No	Check box
4.	Erythema nodosum	Check box provided	No	Check box
5.	Fixed drug eruption	Check box provided	No	Check box
6.	Maculo popular rash	Check box provided	No	Check box
7.	Photo sensitivity	Check box provided	No	Check box
8.	Pigmentary changes	Check box provided	No	Check box
9.	Pruritus only	Check box provided	No	Check box
10.	Purpura	Check box provided	No	Check box
11.	Toxic epidermal necrolysis	Check box provided	No	Check box
12.	Stevens Johnson syndrome	Check box provided	No	Check box
13.	Urticaria	Check box provided	No	Check box
14.	Angioadema	Check box provided	No	Check box
15.	Vasculitis	Check box provided	No	Check box
16.	Vesiculobullous reaction	Check box provided	No	Check box
17.	Other 1	Check box provided	No	Check box
18.	Other 2	This should be a free text field with a maximum of 100 characters capacity.	No	Check box
19.	Please specify Part of Body Affected	This should be a free text field with a maximum of 1000 characters capacity.	No	Check box

3.1.4.5 Causality Grading

3.1.4.5.1 Screen Design

ID	ADR.SD4
Description	WHO Causality Categories/Naranjo Algorithm

Diagram



Notes	• Click on the 'Cancel' button to cancel the process. • There is two panels: - Option 1 - WHO Causality categories' - Option 2 – Naranjo Algorithm • Click on the 'Save' button to save the selected data from the 'WHO Causality categories' and will display at the 'Drug Relationship' field. • The 'Drug Relationship' field is editable based on the drop down menu.
Cross References	None

3.1.4.5.2 Application Business Rules

No.	Name	Description
1.	Option 1 – WHO Causality Grading	• This section allows user to select the Causality grading provided as below: i. C1 - (Certain) Plausible time, not related to underlying condition, concurrent disease, other drugs or chemicals, related pharmacologically, +ve dechallenge, +ve rechallenge ii. C2 - (Probable) Reasonable time, unlikely to be related to concurrent disease, other drugs, +ve dechallenge, no rechallenge. iii. C3 - (Possible) Reasonable time, may be due to concurrent disease, other drugs, no information of dechallenge iv. C4 - (Unlikely) Improbable temporal relationship, other confounding factors such as drugs, chemicals, underlying disease v. C5 - (Unclassifiable) Insufficient information to analyse the report • User can select to use option 1 or option 2. But only Answer from 'Option one – WHO Causality Categories' will be appear in the "Drug Relationship" field. If user change the answer from Drug Relationship field, should revert back the answer to Option 1 – WHO causality categories.
2.	Option 2 – Naranjo Algorithm	• Option 2 – Naranjo Algorithm is only for guideline. If user chooses to use this method, user needs to answer the entire question to get the score. Score will be display at the bottom questionnaire. • The Score will not effect to the 'Drug Relationship' and score in 'Option 1 – WHO Causality Categories'. • The score also will not be save into the database.

3.1.4.5.3 Input Validation Rules

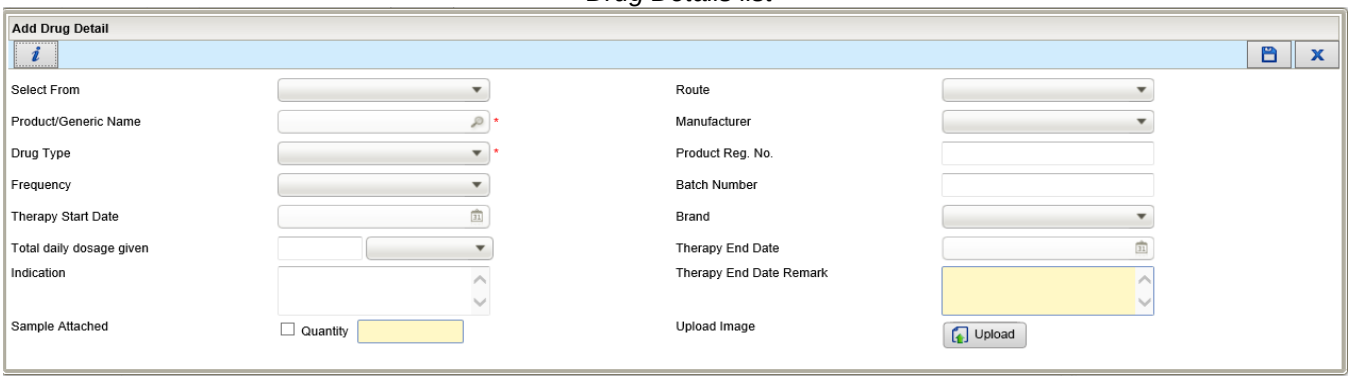
No.	Name	Description	Mandatory	Format
Option 1 – WHO Causality Grading				
1.	C1 - (Certain)	Radio button provided Plausible time, not related to underlying condition, concurrent disease, other drugs or chemicals, related pharmacologically, +ve dechallenge, +ve rechallenge	No	Radio button
2.	C2 - (Probable)	Radio button provided Reasonable time, unlikely to be related to concurrent disease, other drugs, +ve dechallenge, no rechallenge	No	Radio button
3.	C3 - (Possible)	Radio button provided Reasonable time, may be due to concurrent disease, other drugs, no information of dechallenge	No	Radio button
4.	C4 - (Unlikely)	Radio button provided Improbable temporal relationship, other confounding factors such as drugs, chemicals, underlying disease	No	Radio button
5.	C5 - (Unclassifiable)	Radio button provided Insufficient information to analyse the report	No	Radio button
Option 2 – Naranjo Algorithm				
1.	Are there previous conclusive reports on this reaction?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = +1 - If user select 'No' = 0 iv. If user select 'Unknown' = 0	No	Radio button
2.	Did the adverse event appear when the suspected drug was administered?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = +2 - If user select 'No' = -1 - If user select 'Unknown' = 0	No	Radio button

No.	Name	Description	Mandatory	Format
3.	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = +1 - If user select 'No' = 0 - If user select 'Unknown' = 0	No	Radio button
4.	Did the adverse reaction reappear when the drug was readministered?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = +2 - If user select 'No' = -1 - If user select 'Unknown' = 0	No	Radio button
5.	Are there alternative causes (other than the drug) that could on their own have caused the reaction?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = -1 - If user select 'No' = +2 If user select 'Unknown' = 0	No	Radio button
6.	Did the reaction reappear when a placebo was given?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = -1 - If user select 'No' = +1 - If user select 'Unknown' = 0	No	Radio button
7.	Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation:	No	Radio button

No.	Name	Description	Mandatory	Format
		- If user select 'Yes' = +1 - If user select 'No' = 0 - If user select 'Unknown' = 0		
8.	Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = +1 - If user select 'No' = 0 - If user select 'Unknown' = 0	No	Radio button
9.	Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = +1 - If user select 'No' = 0 - If user select 'Unknown' = 0	No	Radio button
10.	Was the adverse event confirmed by any objective evidence?	• Radio button provided. Selection as below: i. Yes ii. No iii. Unknown • Score calculation: - If user select 'Yes' = +1 - If user select 'No' = 0 - If user select 'Unknown' = 0	No	Radio button
11.	Score	The total score calculated in this field defines the categories of adverse reaction belongs to. The categories are define as below: i. Definite(Certain) – (total score >8) ii. Probable – (total score 5-8) iii. Possible – (total score 1-4) iv. Doubtful(Unlikely) – (total score <1)	No	Radio button

3.1.4.6 *Drug Details*

3.1.4.6.1 *Screen Design*

ID	ADR.SD5
Description	Drug Details
Diagram	 *Drug Details list*  *Add Drug Detail*
Notes	• Click on the header pane to expand the screen. • Click on Add button to add new drug. Screen for Add new drug will appear. • Click on close button to close the Add Drug Detail pop screen. • Click on Save button to save the record and record will be added and display at Drug Details list.
Cross References	None

3.1.4.6.2 *Application Business Rules*

No	Name	Description
1.	Drug Details	• System will display all drug detail prescribed from patient medication profile. • Record will be display in the listing as below: i. MDC ii. Product/Generic Name iii. Drug Type iv. Total daily dosage given v. Frequency vi. Route vii. Manufacturer viii. Product Reg No. ix. Brand x. Therapy Start Date

		xi. Therapy End Date xii. Therapy End Date Remarks xiii. Indication xiv. Sample Quantity xv. Preview • Double click on the record to view details and user shall select the 'Drug Type' • Drug Type is compulsory to be filled and must select at least one 'Suspected'
2.	Add New Drug Details	• User is allowed to add new drug which is not prescribed from the reported facility. User can add the drug details by click on the 'Add' button. • Upon click on the 'Add' button system will display 'Add Drug Details' screen.

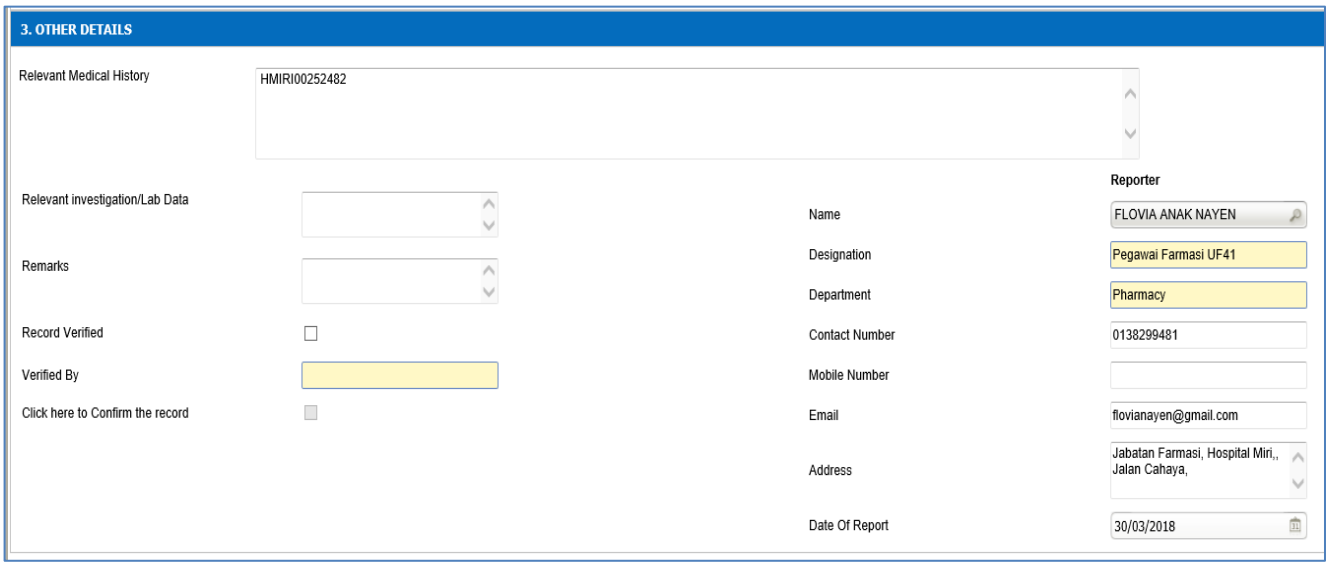
3.1.4.6.3 Input Validation Rules

No.	Name	Description	Mandatory	Format
1.	Select From	A drop down combo box is provided to select. The values are populated from System parameter, category-adr-select from. The list contains values as following: - Drug master - Others	Yes	Drop Down
2.	Route	Defaulted from drug master for either patient drug profile or drug master option selected, only for free text it will be a drop down combo box with the values populated from admin route master.	No	Drop Down
3.	Product/Generic Name	The drug to be selected from drug search. The data to be populated from database-Drug Master.	Yes	Searching Field
4.	Manufacturer	Drop down field with data to be populated from database-Manufacturer Master and based on the associated drug/item master only.	No	Drop Down
5.	Drug Type	A drop down combo box is provided to select. The values are populated from System parameter, category-adr drug type. The list contains values as following: - Suspected - Concomitant - Interaction	Yes	Drop Down
6.	Product Reg.No.	Defaulted from drug master for either patient drug profile or drug master option selected, only for free text it will be an entered field.	No	Text field
7.	Frequency	Defaulted from drug master for either patient drug profile or drug master option selected, only for free text it will be an entered field with maximum 30 Characters.	No	Drop Down

No.	Name	Description	Mandatory	Format
8.	Brand	This shall be a free text field with a maximum of 100 characters capacity.	No	Drop Down
9.	Therapy Start Date	Date entry field with calendar popup. Date to be entered in dd/mm/yyyy format.	No	Calendar
10.	Therapy End Date	Date entry field with calendar popup. Date to be entered in dd/mm/yyyy format.	No	Calendar
11.	Therapy End Date Remarks	This shall be a free text field with a maximum of 100 characters capacity.	No	Text field
12.	Indication	This shall be a free text field with a maximum of 100 characters capacity.	No	Text field
13.	Sample Attached	The checkbox to be checked if sample drugs to be attached. On check a text box will be displayed to enter the no. of samples attached.	No	Check box
14.	Quantity	This shall be a free text field with a maximum of 3 characters capacity.	No	Text field
15.	Total daily dosage given	Defaulted from drug master for either patient drug profile or drug master option selected, only for free text it will be an entered field with maximum five (5) Characters.	Yes	Text field
16.	Upload Image	Upload button provided to browse and select the file for upload.The picture shall be in .jpg format and the size must be limited to say about 10-20 kb.	No	Others

3.1.4.7 Other Details

3.1.4.7.1 Screen Design

ID	ADR.SD6
Description	Other Details
Diagram	
Notes	• Click on the 'Save' button to save the record. Status will be 'Recorded'. • Click on Verified check box to verify the record. This function is available for Pharmacist only. • Click on 'Click here to confirm the record' check box to confirm the record. This function also available for Pharmacist only. • After 'Save' the record 'Print' button will be available.
Cross References	None

3.1.4.7.2 Application Business Rules

No.	Name	Description
1.	Other Details	• Reporter section on the right pane is auto captured from the user id profile. • Record Verified & Click here to confirm the record will be based on access right. Only Pharmacist granted for this function. • After click on Verify record no longer can be edit.

3.1.4.7.3 Input Validation Rules

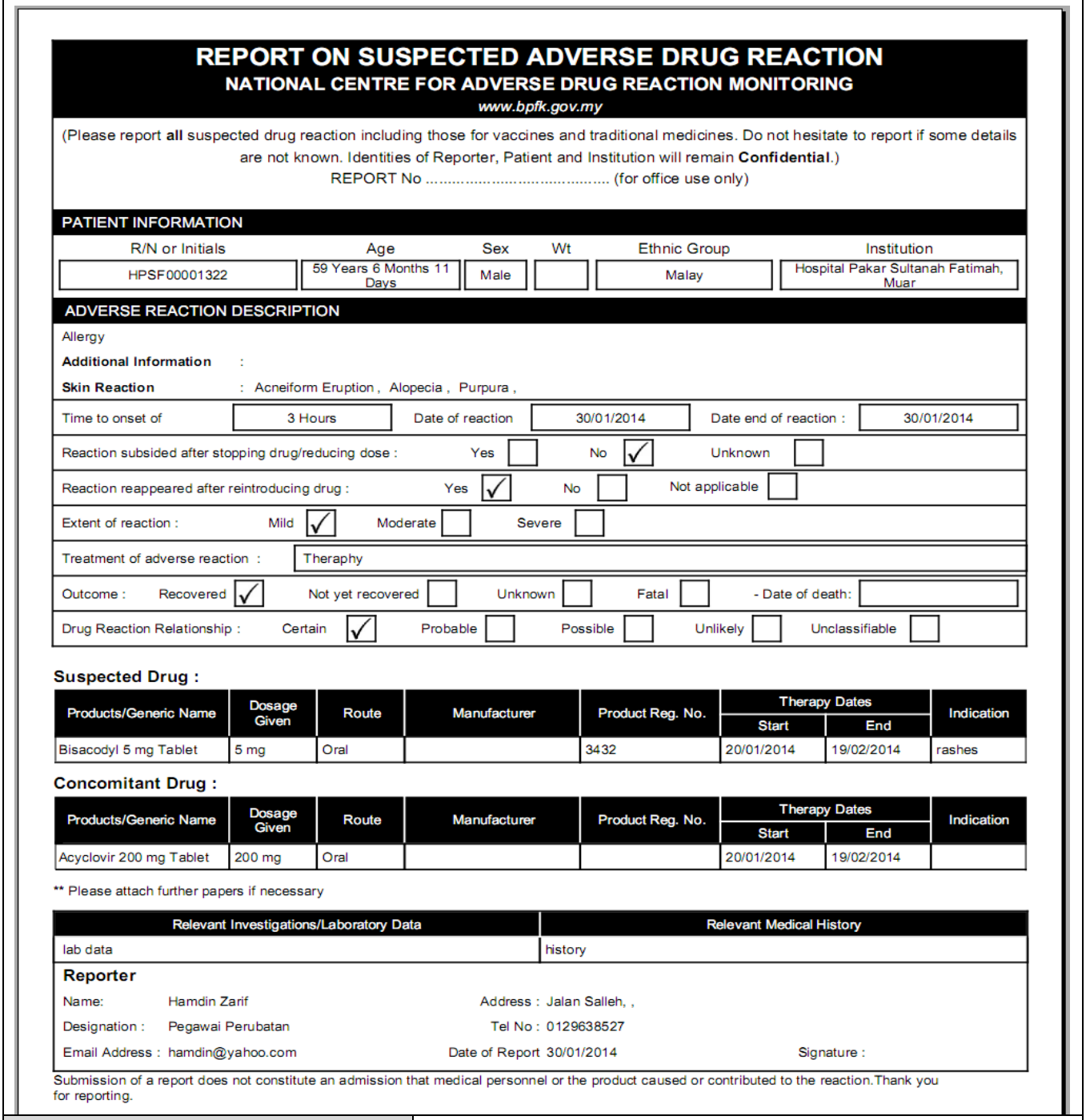
No	Name	Description	Mandatory	Format
Other Details				
1.	Relevant Investigation/Lab Data	This shall be a free text field with a maximum of 500 characters capacity.	No	Text Field
2.	Relevant Medical History	This shall be a free text field with a maximum of 500 characters capacity.	No	Text Field
3.	Remarks	This shall be a free text field with a maximum of 500 characters capacity.	No	Text Field
4.	Name	Name is captured from user name setup in PhIS user profile	Yes	Searching field
5.	Designation	Designation is captured from user designation setup in PhIS user profile	Yes	Text Field
6.	Discipline	Discipline is captured from user discipline setup in PhIS user profile	Yes	Text Field
7.	Contact Number	Contact Number is captured from user contact name setup in PhIS user profile	No	Text Field
8.	Mobile Number	Mobile Number is captured from user mobile number setup in PhIS user profile	No	Text Field
9.	Email	Email is captured from user email setup in PhIS user profile	No	Text Field
10.	Address	Address is captured from user address setup in PhIS user profile	No	Text Field
11.	Date of report	Date of report is default to current date and allows user to edit	No	Text Field
12.	Record Verified	The checkbox to be checked to verify the ADR record. Status will be Verified	No	Check box
13.	Verified By	Verified By name will capture name based on user login id.	Yes	Text Field
14.	Click here to confirm the record	The checkbox to be checked to confirm the ADR record. Status will be Confirmed	No	Check box

3.1.4.8 *ADR Report Printing*

3.1.4.8.1 Screen Design

ID	ADR.SD7
Description	ADR Report Printing

Diagram



REPORT ON SUSPECTED ADVERSE DRUG REACTION

NATIONAL CENTRE FOR ADVERSE DRUG REACTION MONITORING

www.bpfk.gov.my

(Please report **all** suspected drug reaction including those for vaccines and traditional medicines. Do not hesitate to report if some details are not known. Identities of Reporter, Patient and Institution will remain **Confidential**.)

REPORT No ..... (for office use only)

PATIENT INFORMATION

R/N or Initials	Age	Sex	Wt	Ethnic Group	Institution
HPSF00001322	59 Years 6 Months 11 Days	Male		Malay	Hospital Pakar Sultanah Fatimah, Muar

ADVERSE REACTION DESCRIPTION

Allergy

Additional Information :

Skin Reaction : Acneiform Eruption , Alopecia , Purpura ,

Time to onset of: 3 Hours | Date of reaction: 30/01/2014 | Date end of reaction : 30/01/2014

Reaction subsided after stopping drug/reducing dose : Yes ☐ No ☑ Unknown ☐

Reaction reappeared after reintroducing drug : Yes ☑ No ☐ Not applicable ☐

Extent of reaction : Mild ☑ Moderate ☐ Severe ☐

Treatment of adverse reaction : Theraphy

Outcome : Recovered ☑ Not yet recovered ☐ Unknown ☐ Fatal ☐ - Date of death:

Drug Reaction Relationship : Certain ☑ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable ☐

Suspected Drug :

Products/Generic Name	Dosage Given	Route	Manufacturer	Product Reg. No.	Therapy Dates		Indication
					Start	End	
Bisacodyl 5 mg Tablet	5 mg	Oral		3432	20/01/2014	19/02/2014	rashes

Concomitant Drug :

Products/Generic Name	Dosage Given	Route	Manufacturer	Product Reg. No.	Therapy Dates		Indication
					Start	End	
Acyclovir 200 mg Tablet	200 mg	Oral			20/01/2014	19/02/2014	

** Please attach further papers if necessary

Relevant Investigations/Laboratory Data	Relevant Medical History
lab data	history

Reporter

Name: Hamdin Zarif Address : Jalan Salleh, ,

Designation : Pegawai Perubatan Tel No : 0129638527

Email Address : hamdin@yahoo.com Date of Report 30/01/2014 Signature :

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the reaction.Thank you for reporting.

Notes	• Click on print button to print the report • Click on Export to excel button to export the report into excel file format.
Cross References	None

3.1.4.8.2 Application Business Rules

No	Name	Description
1.	Patient Information	To display patient information details. Information as below: i. MRN ii. Age iii. Sex iv. Weight v. Ethnic Group vi. Institution – Facility name
2.	Adverse Reaction Description	To display Adverse Reaction Description, information to be display as below: i. Reaction Description ii. Additional Information iii. Skin Reaction Details iv. Time to Onset of Reaction v. Date of Reaction vi. Date End of Reaction vii. Reaction Subsided after stopping drug/reducing dose viii. Reaction reappeared after reintroducing drug ix. Extent of reaction x. Treatment of adverse reaction xi. Outcome xii. Drug reaction relationship
3.	Suspected Drug	To display suspected drug recorded
4.	Concomitant Drug	To display concomitant drug recorded
5.	Relevant Investigation/ Laboratory data	To display Relevant Investigation/ Laboratory data recorded
6.	Relevant Medical History	To display Relevant Medical History recorded
7.	Reporter Details	To display Reporter Details as below: i. Name ii. Address iii. Designation iv. Tel No v. Email Address vi. Date of Report vii. Signature

3.1.4.8.3 Input Validation Rules

None

3.1.5 Integration

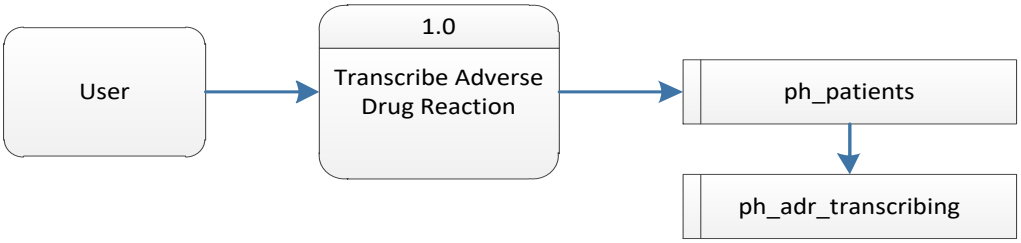
No	Name	Description
1.	NPRA	National Pharmaceutical Regulatory Agency

3.2 NPRA Feedback

3.2.1 Purpose

To get feedback of ADR reported from NPRA

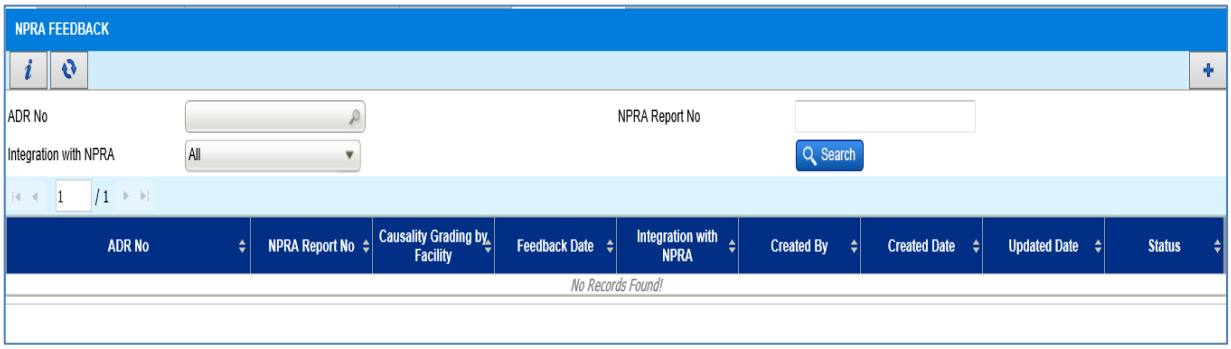
3.2.2 Screen Navigation Diagram



3.2.3 Detail Functionality and Screen

3.2.3.1 NPRA Feedback Listing

3.2.3.1.1 Screen Design

ID	NPRA.SD1
Description	NPRA Feedback Listing Screen
Diagram	
Notes	• Click on Search button to display record based on the criteria selected. • Click on Add button to add new record. • Double click on the record to show details record.
Cross References	None

3.2.3.1.2 Application Business Rules

No	Name	Description
1.	Search filter	ADR reporting listing screen allow user to display record according to the filtering data selected. This screen will allow user to search by the following criteria: i. ADR No – ADR Reporting listing shall be retrieved from the database based on matching ADR No. ii. NPRA Report No – NPRA Report No listing shall be retrieved from the database based on matching NPRA Report No. iii. Integration with NPRA – Drop down value to indicates whether the record is online or offline. Value provided = Yes/No
2.	NPRA List	Results of the search will listed below the search criteria section. The NPRA listing record will contain the following information: i. ADR No ii. NPRA Report No iii. Causality Grading by NPRA iv. Feedback Date v. Integration with NPRA vi. Created By vii. Created Date viii. Updated Date ix. Status
3.	Refresh Order Listing	Click on the Refresh button to reset all searched records and searching criteria's to default value.

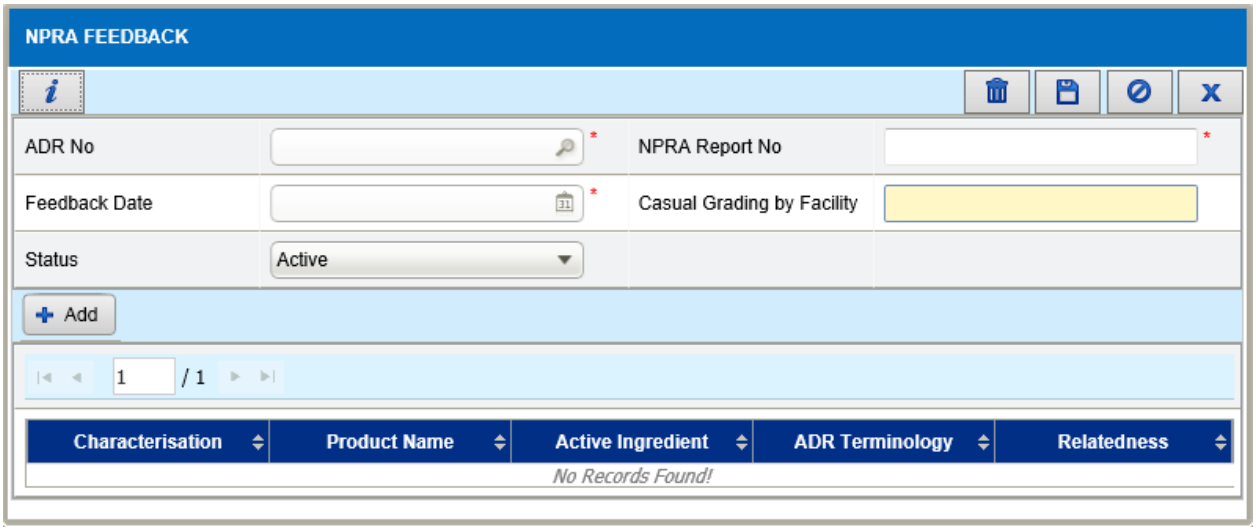
3.2.3.1.3 Input Validation Rules

None.

3.2.3.2 NPRA Feedback Record

3.2.3.2.1 Screen Design

ID	NPRA.SD2
Description	NPRA Feedback Record
Diagram	



Notes	• Click on the 'Cancel' button to cancel the task. • Click on the 'Save' button to save the record and system will go back to the NPRA feedback listing screen. • Click on 'Add' button to add new record
Cross References	None

3.2.3.2.2 Application Business Rules

No	Name	Description
1.	NPRA feedback screen	• This screen user can transcribe report/ feedback received from NPRA. • User need to select ADR No to record the feedback. • Field to be filled as below: i. ADR No ii. NPRA Report no iii. Feedback Date iv. Reaction Details v. Causality Grading by NPRA vi. Causality Grading by Facility • Causality Grading by Facility field shall be capture from the data selected in ADR reporting – drug details.

3.2.3.2.3 Input Validation Rules

No	Name	Description	Mandatory	Type
1.	ADR No	ADR No shall be searching field to search from the ADR No generated by system	Yes	Search field
2.	NPRA Report no	NPRA Report no shall be a free text field with a maximum of 500 characters capacity.	Yes	Text Box
3.	Feedback Date	Feedback Date is to be selected from calendar control. Should be in dd/mm/yyyy format.	Yes	Calendar
4.	Reaction Details	This shall be a free text field with a maximum of 2000 characters capacity.	No	Text Box
5.	Causality Grading by NPRA	This shall be a free text field with a maximum of 1000 characters capacity.	No	Text Box
6.	Causality Grading by Facility	Causality Grading by Facility shall capture from the grading selected during ADR recording.	No	Read Only

3.2.4 Integration

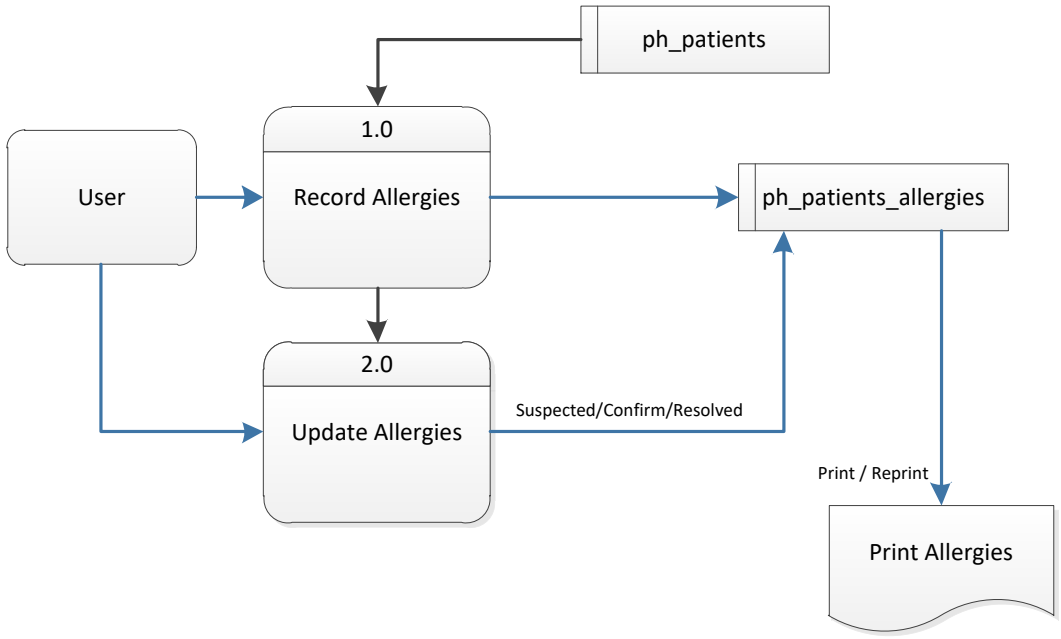
None.

3.3 Patient Drug Allergy

3.3.1 Purpose

To record patients drug allergy in the system and print the Drug allergy card

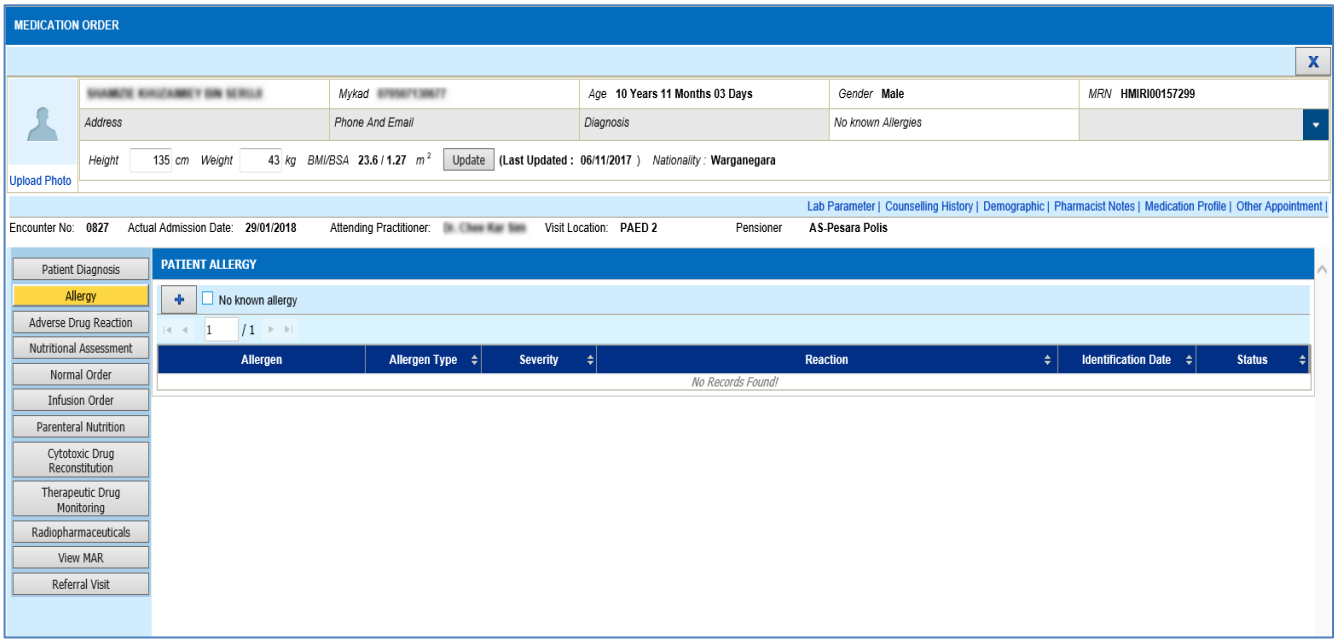
3.3.2 Screen Navigation Diagram



3.3.3 Detail Functionality and Screen

3.3.3.1 Medication Order (Patient Allergy)

3.3.3.1.1 Screen Design

ID	DAC.SD1
Description	Medication Order - Allergy
Diagram	
Notes	• Click on the 'Allergy' menu bar to open Patient Allergy screen. • Click on the Checkbox 'No know Allergies' to define there is No existence of allergy • Click on the 'Add' button to add the allergies, upon click on the 'Add' button system will prompt out Patient Allergy Screen.
Cross References	None

3.3.3.1.2 Application Business Rules

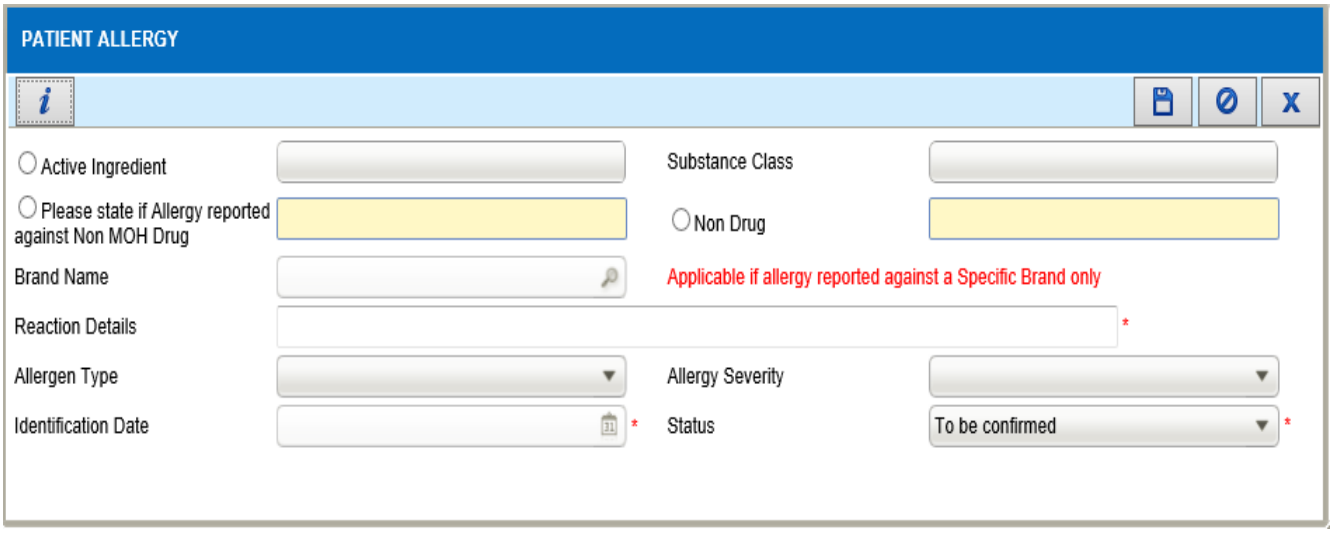
No	Name	Description
1.	Add New Allergy	Medication Order Screen provides "Allergy" menu. On click of the button will display Patient Allergy screen. Click on Add button to add new record.
2.	Allergy List	System shall list all the previous Patient Allergy recorded. Allergy record will contains the following information: i. Allergen ii. Allergen Type iii. Severity iv. Reaction v. Identification Date vi. Status

3.3.3.1.3 Input Validation Rules

None

3.3.3.2 *Record Patient Allergy*

3.3.3.2.1 *Screen Design*

ID	DAC.SD2
Description	Record Patient Allergy
Diagram	
Notes	• Click on 'Cancel' to cancel the task. • Click on 'Save' button to save the record
Cross References	None

3.3.3.2.2 *Application Business Rules*

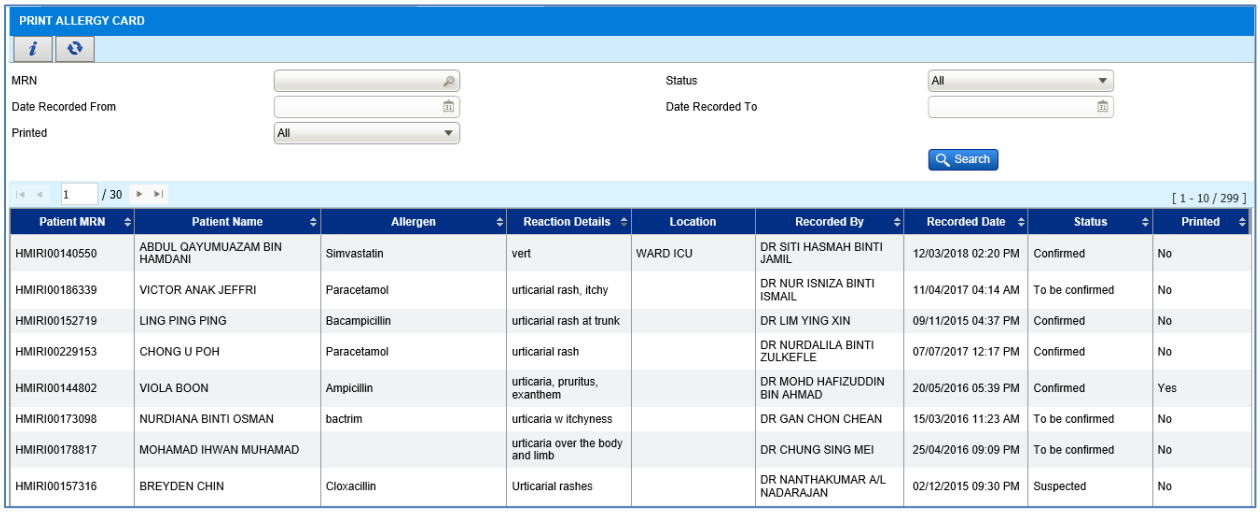
No	Name	Description
1.	Record Allergy	User is allowed to select only one allergen per record. Allergen can be define from below selection: i. Active Ingredient ii. Substance Class iii. Drug Allergy (Non MOH) iv. Non Drug
2.	Status	System will default the status as 'To be confirmed' if user did not select any status for the first time record. User with valid access right is allowed to change the status. Status available as below: i. Confirmed ii. Resolved iii. Suspected iv. To be confirmed

3.3.3.2.3 Input Validation Rules

No	Name	Description	Mandatory	Type
1.	Active Ingredient	Click on the radio button to activate the search active ingredient field. The values in the search are listed from the database based on Active Ingredient set up in drug master.	Yes	Radio button
2.	Drug Allergy (MOH)	Click on the radio button to activate the search drug allergy by MOH field. The values in the search are listed from the database based on the drug name set up in drug master.	Yes	Radio button
3.	Allergen - Others (O)	Click on the radio button to activate the allergen others free text field with capacity of 100 maximum values.	Yes	Radio button
4.	Drug Allergy (Non MOH)	Click on the radio button to activate the allergen others free text field with capacity of 200 maximum values.	No	Text Box
5.	Brand name	Brand name to be selected from the search field provided. The values are listed from the database based on brand associated with Generic name from Drug/Item master.	No	Search Field
6.	Allergen Type	A drop down combo box is provided to select the Allergen Type. The values are populated from system parameter, allergy-type.	No	Drop Down
7.	Allergy Severity	A drop down combo box is provided to select the Allergy Severity. The values are populated from system parameter, allergy-severity.	No	Drop Down
8.	Allergen Description	Allergen description shall be a free text field with a maximum of 100 characters capacity.	No	Text Box
9.	Reaction Details	Reaction details shall be a free text field with a maximum of 200 characters capacity.	Yes	Text Box
10.	Identification Date	Date Field with calendar popup. The date to be entered in dd/mm/yyyy format.	Yes	Calendar
11.	Status	This field shall show system defined values in a drop down combo box. i. To be Confirm (Default value) ii. Suspected iii. Confirmed iv. Resolved	Yes	Drop Down

3.3.3.3 *Drug Allergy Card Listing*

3.3.3.3.1 *Screen Design*

ID	DAC.SD2
Description	Drug Allergy card- Print allergy Card listing
Diagram	
Notes	• Click on 'Search' button to list the results. • The list will display the following columns. i. MRN No. ii. Patient Name iii. Allergen iv. Reaction Details v. Date Recorded vi. Recorded By vii. Status • The list will display the following columns. i. Type ii. Allergens iii. Reaction Details iv. Date/Time Recorded v. Recorded By vi. Status vii. Printed viii. Date/Time Printed
Cross References	None

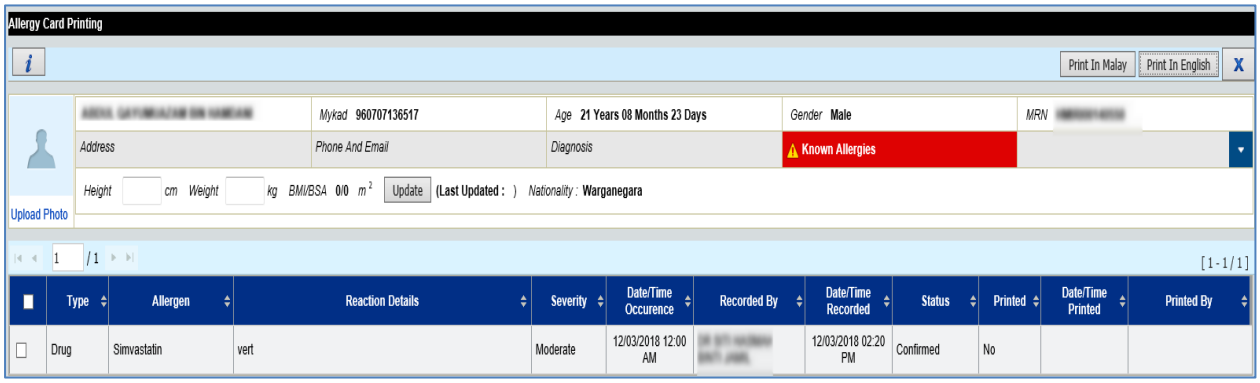
Patient MRN	Patient Name	Allergen	Reaction Details	Location	Recorded By	Recorded Date	Status	Printed
HMIRI00140550	ABDUL QAYUMUAZAM BIN HAMDANI	Simvastatin	vert	WARD ICU	DR SITI HASMAH BINTI JAMIL	12/03/2018 02:20 PM	Confirmed	No
HMIRI00186339	VICTOR ANAK JEFFRI	Paracetamol	urticarial rash, itchy		DR NUR ISNIZA BINTI ISMAIL	11/04/2017 04:14 AM	To be confirmed	No
HMIRI00152719	LING PING PING	Bacampicillin	urticarial rash at trunk		DR LIM YING XIN	09/11/2015 04:37 PM	Confirmed	No
HMIRI00229153	CHONG U POH	Paracetamol	urticarial rash		DR NURDALILA BINTI ZULKEFLE	07/07/2017 12:17 PM	Confirmed	No
HMIRI00144802	VIOLA BOON	Ampicillin	urticaria, pruritus, exanthem		DR MOHD HAFIZUDDIN BIN AHMAD	20/05/2016 05:39 PM	Confirmed	Yes
HMIRI00173098	NURDIANA BINTI OSMAN	bactrim	urticaria w itchyness		DR GAN CHON CHEAN	15/03/2016 11:23 AM	To be confirmed	No
HMIRI00178817	MOHAMAD IHWAN MUHAMAD		urticaria over the body and limb		DR CHUNG SING MEI	25/04/2016 09:09 PM	To be confirmed	No
HMIRI00157316	BREYDEN CHIN	Cloxacillin	Urticarial rashes		DR NANTHAKUMAR A/L NADARAJAN	02/12/2015 09:30 PM	Suspected	No

3.3.3.3.2 Application Business Rules

No	Name	Description	Mandatory	Format
1.	MRN	Patient Search is provided. The patient listing will be from the database.	No	Text field
2.	Status	This field will show system defined values in a drop down combo box. i. All ii. Pending for Confirmation iii. To Print iv. Re print	No	Text field
3.	Date Recorded From	Date Field with calendar popup. The date to be entered in dd/mm/yyyy format.	No	Calendar
4.	Date Recorded To	Date Field with calendar popup. The date to be entered in dd/mm/yyyy format.	No	Calendar

3.3.3.4 Print Drug Allergy Card

3.3.3.4.1 Screen Design

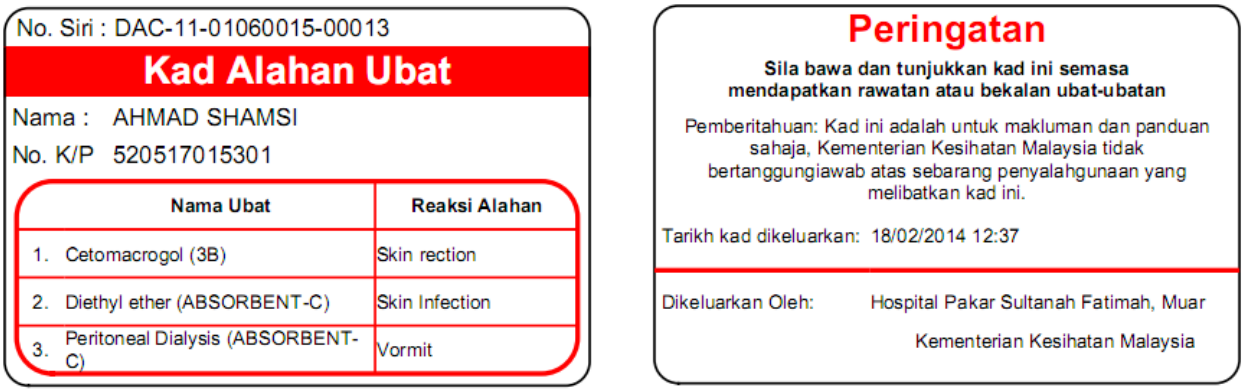
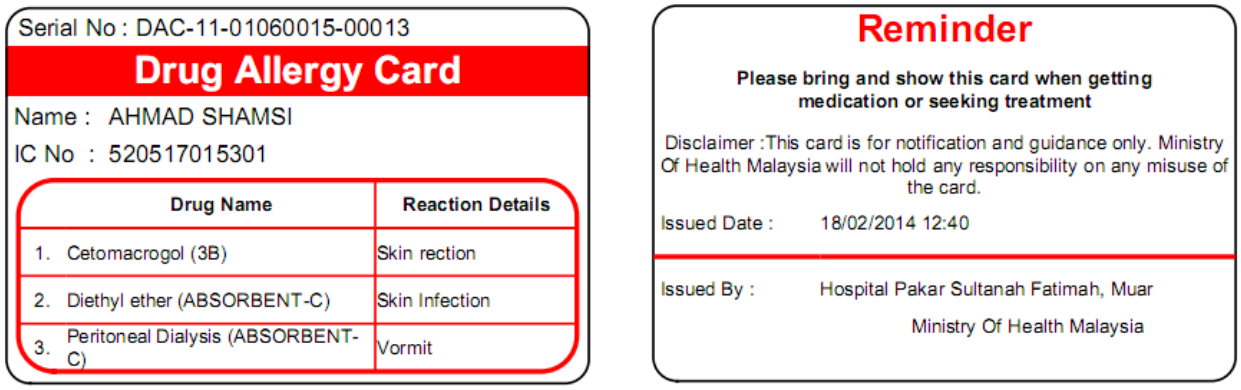
ID	DAC.SD2
Description	Allergy card Printing
Diagram	
Notes	• Click on the check box to select record to be print in the card. • Click on 'Print in Malay' button to print an allergy card in Malay. Click on 'Print in English' button to print an allergy card in English. • The list will display the following columns. i. Type ii. Allergens iii. Reaction Details iv. Recorded By v. Date/Time Recorded vi. Status vii. Printed viii. Date/Time Printed • Previous printed allergic details against each allergen are displayed with the date and printed status for information so that user can decide whether to reprint where necessary. However the allergic reactions which are not confirmed by the doctors are not allowed to be selected for printing.
Cross References	None

3.3.3.4.2 Application Business Rules

None

3.3.3.5 *Drug Allergy Card*

3.3.3.5.1 *Screen Design*

ID	DAC.SD2
Description	Drug Allergy Card
Diagram	 DAC printed in Malay  DAC printed in English
Notes	• DAC shall display maximum three records per card. If the patient have more than three records, then shall print another card • The card is print according to 'credit card' size. It is printed side by side which can be folded. • For new allergies added, a new date for the Card Printed is generated.
Cross References	None

3.3.3.5.2 *Application Business Rules*

None

3.3.4 Integration

None

4. References

Document	Description/ Expansion

5. Acronyms

Item	Description

6. Appendix