



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

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## **Pharmacy Based User Manual Therapeutic Drug Monitoring (TDM)**

<b>Version</b>	<b>: 1.5</b>
<b>Document ID</b>	<b>: PB_U. MANUAL_THERAPEUTIC DRUG MONITORING</b>

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1.2	05/01/2014	Shalet Kana	Norlaileza Sidek (SA)	Changes of latest screen shot.
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## Verified and Acknowledged By:

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Name	Role / Designation	Organization	Signature & Date
		Bahagian Perkhidmatan Farmasi (BPF), KKM	

## Peer Review

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1.2	Michelle Foo/Juridah Ayob (QA)	Changes of latest screen shot.
1.3	Michelle Foo/Juridah Ayob (QA)	Updated to v1.3.
1.4	Michelle Foo/Juridah Ayob (QA)	Changes to latest update and screenshot version 1.4.1
1.5	Michelle Foo/Juridah Ayob (QA)	Changes to latest update and screenshot version 1.5.1



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*Reference ID : PB\_U. MANUAL\_THERAPEUTIC DRUG MONITORING-v1.5*

*Application reference: PhIS & CPS v1.5.1*

## Table of Contents

1.0	Introduction .....	1
1.1	Overview of PhIS.....	1
1.2	Purpose and Objectives .....	1
1.3	Organised Sections .....	1
2.0	Application Standard Features .....	2
2.1	PhIS Legend .....	2
3.0	Therapeutic Drug Monitoring (TDM) .....	4
	Overview .....	4
	User Group .....	4
	Functional Diagram.....	4
	Functional Description .....	4
3.1	Search Registered Patient.....	5
3.2	New Patient Registration .....	7
3.3	Therapeutic Drug Monitoring (TDM) Order .....	11
3.4	External TDM .....	21
3.4.1	External TDM Online .....	21
3.4.2	External TDM Offline .....	25
4.0	Acronyms.....	28
5.0	Links to Clinical Modules.....	28

## 1.0 Introduction

### 1.1 Overview of PhIS

Pharmacy Information System or better known as PhIS, is a complete and comprehensive system that integrates pharmacy related services geared towards pharmacy excellence. PhIS implementation would transform most of current manual process to electronic system would benefit facility end user in the health care sector.

There are 12 modules to assist services delivery by the health care sector which comprises of:

1. Order Management
2. Inpatient Pharmacy
3. Outpatient Pharmacy
4. Medication Counselling
5. Ward Pharmacy
6. Pharmacy Inventory
7. Manufacturing of Cytotoxic Drug Reconstitution, Parenteral Nutrition, IV Admixture & Eye Drop , Radiopharmaceuticals and Extemporaneous
8. Adverse Drug Reaction & Drug Allergic (ADR & DAC)
9. Clinical Pharmacokinetics Services (TDM)
10. Drug Information & Consumer Education (DICE)
11. Medication Therapy Adherence Clinic (MTAC)
12. Data Mining (PhARM)

### 1.2 Purpose and Objectives

This user manual outlines the Therapeutic Drug Monitoring (TDM) module and its key features/functionalities. The primary objective is to help guide user through the process of completing PhIS application process. User will understand the following activities in details:



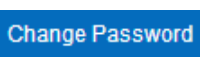





















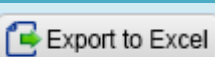
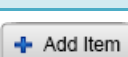


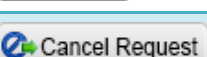
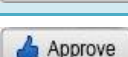

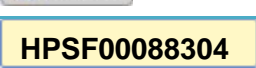


### 1.3 Organised Sections




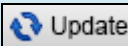

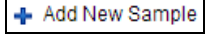
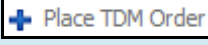
These are the sections within this document:

- Section 1 : Introduction
- Section 2 : Application Standard Features
- Section 3 : Therapeutic Drug Monitoring
- Section 4 : Acronyms
- Section 5 : Links To Clinical Modules

## 2.0 Application Standard Features

### 2.1 PhIS Legend

Standard Legend			
	Login to PhIS		Logout from PhIS
	Change Login Password		Reset Login Screen
	Expand Menu		Collapse Menu
	Display Home Tab		Expand Module
	Collapse Module		Close All Open Tabs
	Refresh Screen		Search Record
	Add/Create New Record		Show Help
	Print	*	Mandatory Field
	Calendar Icon		Search Icon
	Close Window		Radio Button
	Checkbox		Edit Record
	Cancel		Delete Record
	Save		Export and Open Report in Excel Format
	Add Item to the list		Delete Item from the list
	Request for Approval		Cancel the Request
	Approve Transaction		Reject Transaction
	Automatically Display/Retrieve Box		Empty Text Box
	Dropdown Box		

TDM Module Legend			
 Delete	Delete Record	 Update	Update Record
<a href="#">TDM Guidelines</a>	Display TDM Guidelines Details	 Add	Add Sampling Details
 Update	Update Sampling Details	<a href="#">Drug Info</a>	Display Selected TDM Drug Information
 New	Create New TDM Order	 Add New Sample	Add New Sampling Details
 Place TDM Order	Display TDM Order Screen to Place New TDM Order	<a href="#">Details</a>	Display Reporting Details Screen
<a href="#">Register Patient</a>	Register External Patient for Outsource	<a href="#">Manage Sample</a>	Display External TDM Resulting Screen

### **Note**

To learn more about Login Information, kindly click [Login Information](#) module for descriptive steps.

## 3.0 Therapeutic Drug Monitoring (TDM)

### Overview

The Order Management - Therapeutic Drug Monitoring (TDM) module handles all the information to specify the ordered items as per local drug formulary, MOH and non-MOH including registered and non-registered drugs. This function is to enable data mining. All medication orders must be prescribed by authorized personnel only and in compliance with guidelines on prescribing in the drug formulary (drug category, discipline / specialty) as defined by MOH.

### User Group

This module is intended for Pharmacist, Assistant Pharmacist and Nurse.

### Functional Diagram

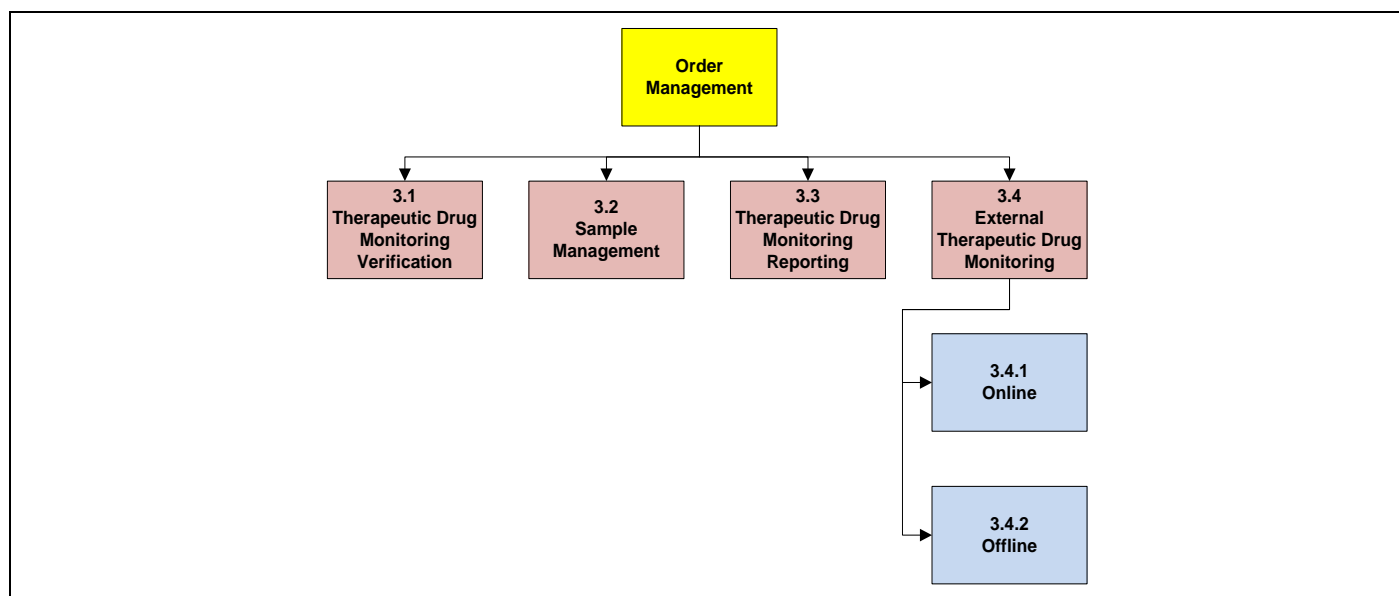


Figure 3.0-1

### Functional Description

Therapeutic Drug Monitoring (TDM) comprises of four (4) main functions:

- Verification**  
 Verification is for pharmacist to verify the prescriptions received from order management. This process is mandatory for all prescriptions receive before the user can proceed with reporting.
- Sample Management**  
 TDM Sampling Management is to record the sampling details into the system including information of the samples which need to be send outsource.
- Reporting**  
 TDM Reporting is to enter the TDM resulting and the interpretation to the Doctor.
- External TDM**  
 External TDM is for record TDM resulting received from other facility



### 3.1 Search Registered Patient

To view existing patient record, perform steps below:

#### STEP 1

Click on 'Order Management' menu followed by 'Transcribe Order' and screen will be displayed as per Figure 3.1-1

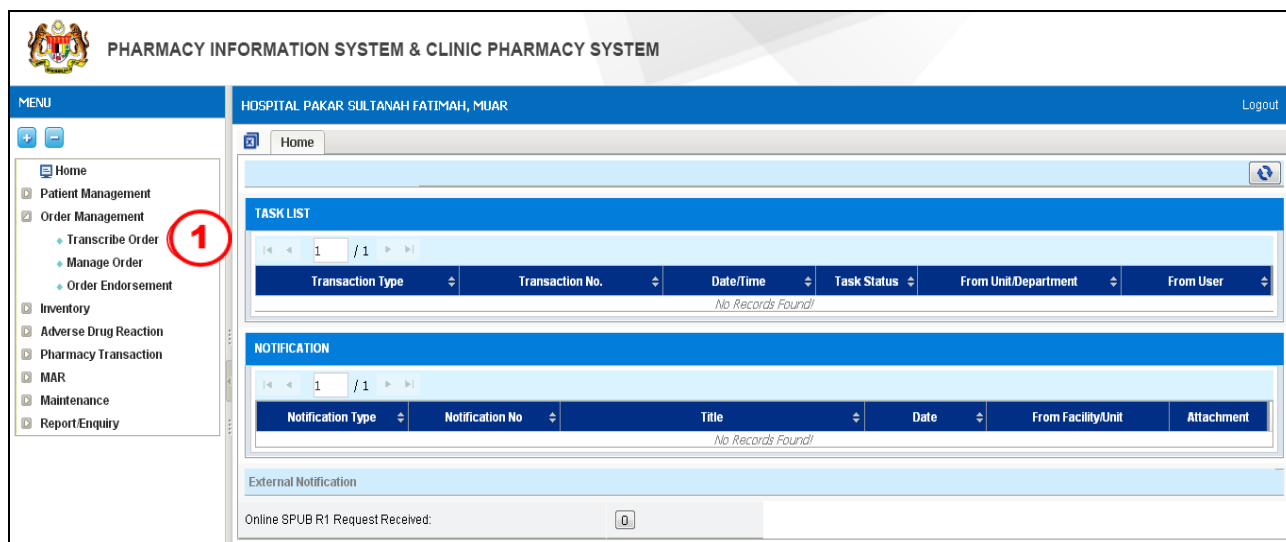



Figure 3.1-1 PhIS Home page


#### STEP 2

Enter registered patient name

#### STEP 3

Click on the  button to search for a registered patient

#### Note

- This page is used to search for a registered patient
- If the patient is not registered, click on the  button and the Patient Registration screen will be displayed.

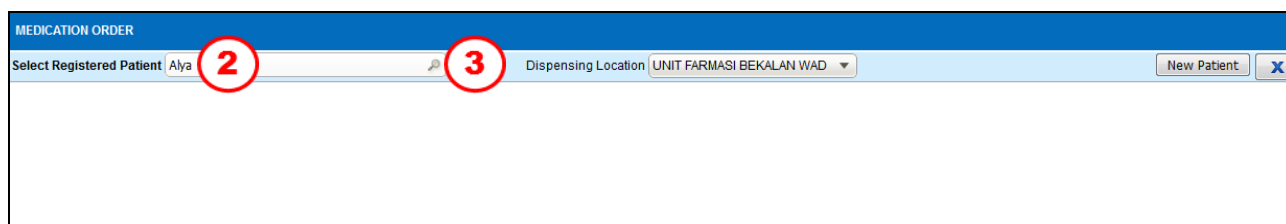
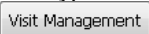


Figure 3.1-2 Medication Order

#### STEP 4

Double-click on the selected patient and the details will be displayed as per Figure 3.1-4

#### Note

- Click on the 'Renew Visit' hyperlink to renew a visit for the same location.
- Select the 'Visit Type' and 'Location' to create a new visit.
- Click on the  button to assess 'Visit Management' Screen. (Refer to Appendix 1).

**MEDICATION ORDER**

Select Registered Patient:  Dispensing Location:

Patient Search

1 < 5 / 5 > [ 41 - 46 / 46 ]

MRN Number	ID Number	Patient Name
HPSF00029460	860225015124M	NUR ALYA ADRIANA BT MOHD AZRI
HPSF00029472	800615016160	BIO SALLYANTI BINTI MD SALEH
HPSF00030656	S2166223B	KAMALAMKHI D/O N KALYAPARMAL
HPSF00031200	080526010194	PUTRI NUR ALYA ZAHIRAH BINTI MUHAMMAD NURHAFFIQ
<b>HPSF00031804</b>	<b>061202011138</b>	<b>ALYA NATASHA BINTI KHALID</b>
HPSF00031844	881024095052	NUR ALYA SOFEA SOO TENG

Figure 3.1-3 Search Patient

**MEDICATION ORDER**

Select Registered Patient:  Dispensing Location:

**ALYA NATASHA BINTI KHALID** MyKid:  Age:  Gender:  MRN:

Address:  Phone And Email:  Diagnosis:

Height:  cm Weight:  kg BMI/BSA:   (Last Updated: 17/07/2014)

[Lab Results](#) [Counselling History](#) [Demographic](#) [Pharmacist Notes](#) [Medication Profile](#) [Other Appointment](#)

**VISIT/ADMISSION**

Encounter No:  Visit Type:  Location:  Department:

☐ Breast Feeding ☐ Pregnant  Weeks

Encounter No	Visit/Admission Date	Visit Type	Visit Location	Discharge Date	Renew Visit
0214	17/07/2014	Outpatient	KLINIK PAKAR KANAK-KANAK		<a href="#">Renew Visit</a>

**PARTIAL SUPPLY**

Order Date	Order Location	Prescription No	Next Collection Date	Next Collection Mode	Prescription Status
No Records Found!					

Figure 3.1-4 Medication Order Screen

## STEP 5

Double-click on the selected visit as per Figure 3.1-5

**MEDICATION ORDER**

Select Registered Patient:  Dispensing Location:

**ALYA NATASHA BINTI KHALID** MyKid:  Age:  Gender:  MRN:

Address:  Phone And Email:  Diagnosis:

Height:  cm Weight:  kg BMI/BSA:   (Last Updated: 17/07/2014)

[Lab Results](#) [Counselling History](#) [Demographic](#) [Pharmacist Notes](#) [Medication Profile](#) [Other Appointment](#)

**VISIT/ADMISSION**

Encounter No:  Visit Type:  Location:  Department:

☐ Breast Feeding ☐ Pregnant  Weeks

Encounter No	Visit/Admission Date	Visit Type	Visit Location	Discharge Date	Renew Visit
0214	17/07/2014	Outpatient	KLINIK PAKAR KANAK-KANAK		<a href="#">Renew Visit</a>

**PARTIAL SUPPLY**

Order Date	Order Location	Prescription No	Next Collection Date	Next Collection Mode	Prescription Status
No Records Found!					

Figure 3.1-5 Visit/Admission Detail

### 3.2 New Patient Registration

This page is used to register new patient

To register new patient in to the system, perform the steps below:

#### STEP 1

Click on 'Order Management' menu followed by 'Transcribe Order and screen will be displayed as per Figure 3.2-1

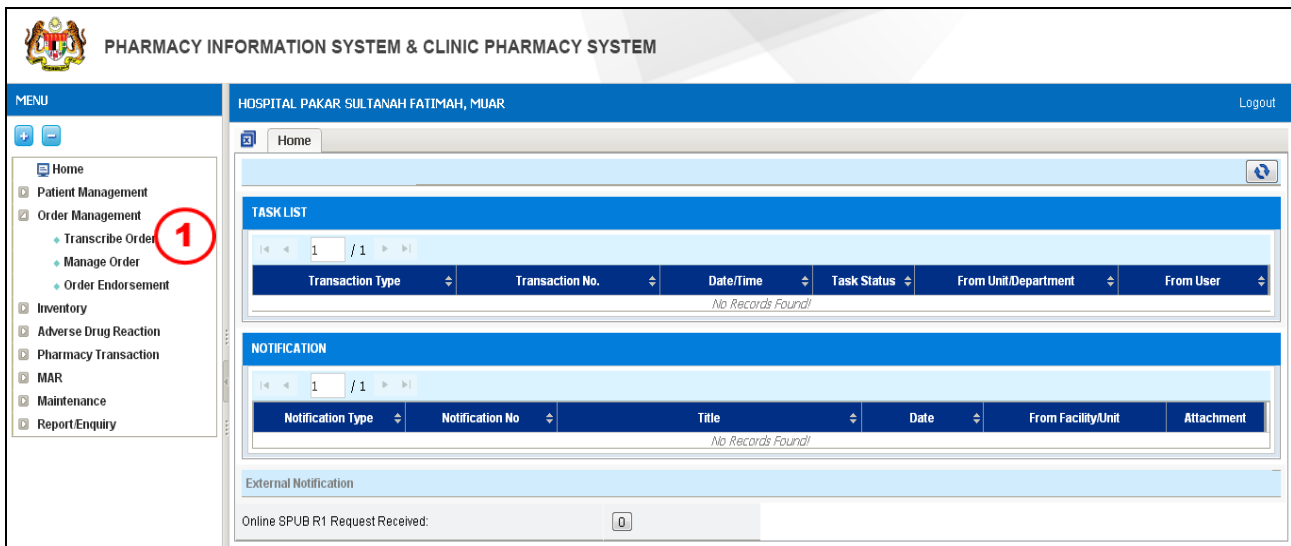


Figure 3.2-1 PhIS Home Page

#### STEP 2

Click on the **New Patient** to register for new patient

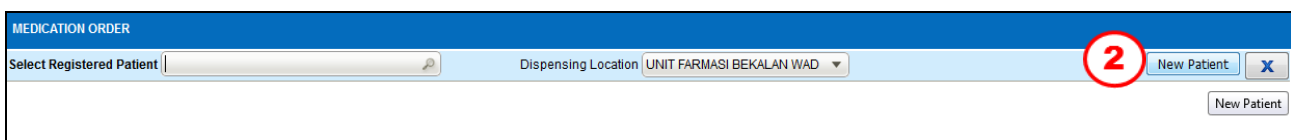


Figure 3.2-2 Transcribe Order Create New Patient

#### STEP 3

Enter **Patient Name**

#### STEP 4

Select from **Identification Card Number** drop down box:

- MYKAD
- MYKID

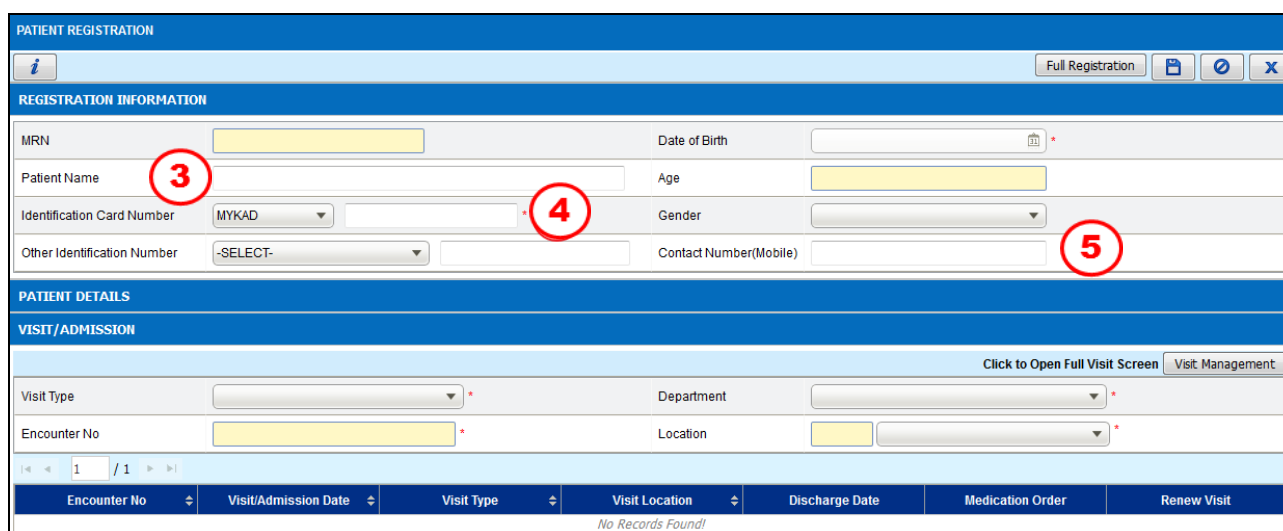
and enter the relevant number

### Note

- After enter the Identification Card Number the below details will be displayed:
  - Date of Birth (dd/mm/yy)
  - Age (Y M D)
  - Gender (Male/Female/Unknown)
- If MYKAD/MYKID is unavailable, user is required to select the Other Identification Number dropdown box:
  - BIRTH CERTIFICATE
  - DRIVING LICENSE
  - FATHER IC
  - MILITARY CARD NUMBER
  - MOTHER IC
  - OLD IC
  - PASSPORT
  - PENSION CARD
  - POLICE CARD NUMBER
  - UNKNOWN PATIENT
  - WORK PERMIT
 and enter the relevant number.

### STEP 5

Enter **Contact Number (Mobile)**



The screenshot shows the 'PATIENT REGISTRATION' form. The 'REGISTRATION INFORMATION' section contains the following fields:

- MRN: [Text Field]
- Date of Birth: [Date Picker]
- Patient Name: [Text Field] (Annotated with a red circle and the number 3)
- Age: [Text Field]
- Identification Card Number: [Dropdown Menu] MYKAD [Text Field] (Annotated with a red circle and the number 4)
- Gender: [Dropdown Menu]
- Other Identification Number: [Dropdown Menu] -SELECT- [Text Field]
- Contact Number(Mobile): [Text Field] (Annotated with a red circle and the number 5)

The 'PATIENT DETAILS' section contains the following fields:

- Visit Type: [Dropdown Menu]
- Department: [Dropdown Menu]
- Encounter No: [Text Field]
- Location: [Text Field]

At the bottom, there is a table with columns: Encounter No, Visit/Admission Date, Visit Type, Visit Location, Discharge Date, Medication Order, and Renew Visit. The status 'No Records Found!' is displayed below the table.

Figure 3.2-3 Registration Information

### STEP 6

Select the **Visit Type** from dropdown box:

- Daycare
- Emergency
- Inpatient
- Outpatient
- Outsource
- SPUB
- Walk-in

### STEP 7

Select the **Department** from dropdown box:

### Note

**Department** will tie to the selected **Visit Type**.

## STEP 8

Select **Location** from dropdown box



### Note

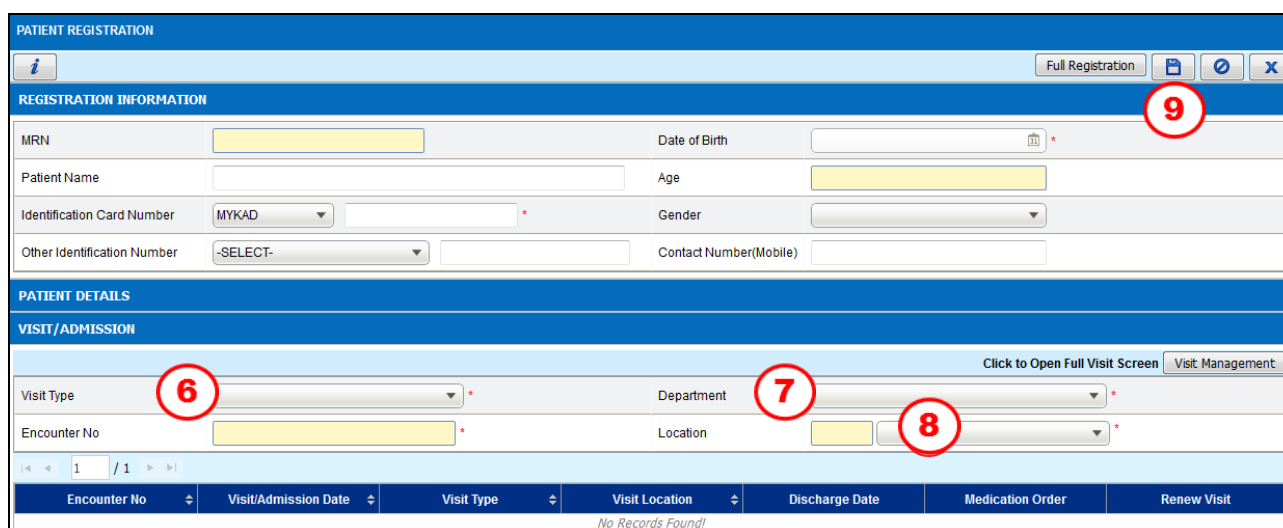
**Location** will tie to the selected **Department**.

## STEP 9

Click on the  button to save the record and medication order screen will display as per Figure 3.2.5

### Note

- After click the save button, system will automatically generate the MRN (Medical Record Number) and  and  buttons will be enabled.
- Click on the **Full Registration** button to assess 'Visit Management' Screen. (Refer to Appendix 2).
- Another option to register a new patient is to click on the **New Patient Registration** button located under Patient Quick Registration that will display the same screen as Figure 3.2-3.



The screenshot shows the 'PATIENT REGISTRATION' form. It is divided into several sections: 'REGISTRATION INFORMATION', 'PATIENT DETAILS', and 'VISIT/ADMISSION'. The 'VISIT/ADMISSION' section contains dropdown menus for 'Visit Type' (callout 6), 'Department' (callout 7), and 'Location' (callout 8). A 'Full Registration' button is located in the top right corner (callout 9). The form also includes fields for MRN, Date of Birth, Patient Name, Age, Identification Card Number, Gender, Other Identification Number, and Contact Number(Mobile). A table at the bottom shows a list of records with columns: Encounter No, Visit/Admission Date, Visit Type, Visit Location, Discharge Date, Medication Order, and Renew Visit. The status 'No Records Found!' is displayed below the table.

Figure 3.2-4 Visit/Admission

MEDICATION ORDER																																																																					
Select Registered Patient HPSF00032191			Dispensing Location			New Patient X																																																															
	AZLEEN BINTI ISMAIL		Mykad 750509145804		Age 39 Years 04 Months 24 Days		Gender Female		M/RN HPSF00032191																																																												
	Address		Phone And Email		Diagnosis		No known Allergies																																																														
	Height	158 cm	Weight	57 kg	BMI/BSA	22.8 / 1.6 m <sup>2</sup>	Update (Last Updated : )																																																														
Upload Photo																																																																					
Lab Results Counselling History Demographic Pharmacist Notes Medication Profile Other Appointment																																																																					
VISIT/ADMISSION																																																																					
Encounter No 0763		Visit Type Outpatient *		Location KLINIK PAKAR ORTOPEDIK *		Department Orthopaedic and Traum *		Clear Visit Management Patient Label																																																													
<input type="checkbox"/> Breast Feeding <input type="checkbox"/> Pregnant Weeks																																																																					
V VISIT RECORD																																																																					
Original Prescriber Name			Original Order Transaction Number			Clinic TCA																																																															
<div> <div>Patient Diagnosis</div> <div>Allergy</div> <div>Adverse Drug Reaction</div> <div>Nutritional Assessment</div> <div><b>Normal Order</b></div> <div>Infusion Order</div> <div>Parenteral Nutrition</div> <div>Cytotoxic Drug Reconstitution</div> <div>Therapeutic Drug Monitoring</div> <div>Radiopharmaceuticals</div> </div> <div> <b>NORMAL ORDER - DRUG DETAILS</b> <div>View Order Draft Confirm</div> </div>																																																																					
<table border="1"> <thead> <tr> <th>Alert</th> <th>Drug Name</th> <th>Order Details</th> <th>Order Qty</th> <th>Drug Info</th> </tr> </thead> <tbody> <tr> <td></td> <td>Drug</td> <td>Advanced Search</td> <td></td> <td></td> </tr> <tr> <td></td> <td>Dosage</td> <td>0</td> <td></td> <td></td> </tr> <tr> <td></td> <td>Admin Route</td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>Frequency</td> <td>Dosage Schedule</td> <td></td> <td></td> </tr> <tr> <td></td> <td>Duration</td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>Start Date / Time</td> <td>02/10/2014 11:55 AM</td> <td></td> <td></td> </tr> <tr> <td></td> <td>End Date / Time</td> <td>02/10/2014 11:55 AM</td> <td></td> <td></td> </tr> <tr> <td></td> <td>Order Quantity</td> <td>0</td> <td></td> <td></td> </tr> <tr> <td></td> <td>Drug Indication</td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td>Drug Remarks</td> <td colspan="3"></td> </tr> <tr> <td></td> <td>Available Qty</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <div> <input type="checkbox"/> Own Medication  <input type="checkbox"/> Ward Stock  <input type="checkbox"/> Patient Require Counselling         </div> <div> + Add    Modify    Clear         </div>										Alert	Drug Name	Order Details	Order Qty	Drug Info		Drug	Advanced Search				Dosage	0				Admin Route					Frequency	Dosage Schedule				Duration					Start Date / Time	02/10/2014 11:55 AM				End Date / Time	02/10/2014 11:55 AM				Order Quantity	0				Drug Indication					Drug Remarks					Available Qty			
Alert	Drug Name	Order Details	Order Qty	Drug Info																																																																	
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	Drug Remarks																																																																				
	Available Qty																																																																				

### Figure 3.2-5 Medication Order

### 3.3 Therapeutic Drug Monitoring (TDM) Order

Perform these steps below to create new order for TDM

TDM Order screen allows Prescriber to place TDM Services order. The order will be sent to Pharmacist for verification and reporting.

TDM Order User Groups:

- Authorised Pharmacist

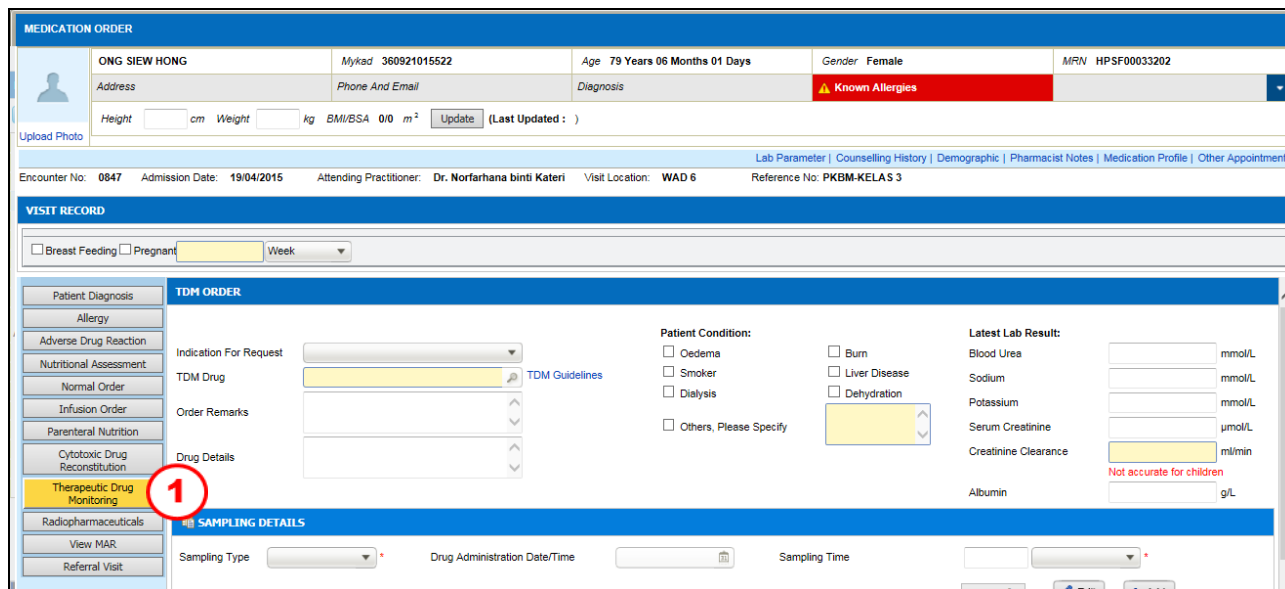


Figure 3.3-1 Medication Order

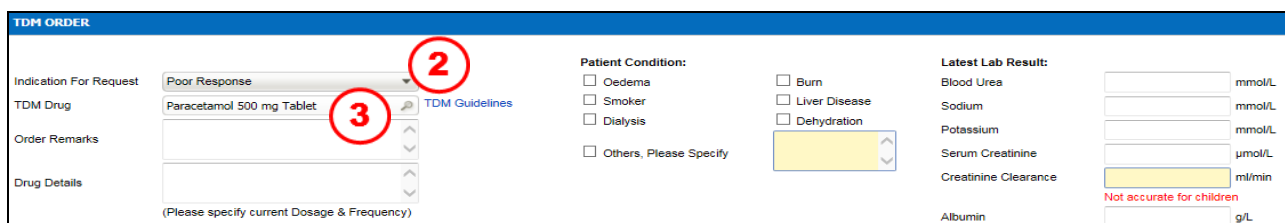


Figure 3.3-2 TDM Order

#### STEP 1

Click on the **Therapeutic Drug Monitoring** button to create TDM order

#### Note

- User is allowed to update patient's height and weight and click on the **Update** button and system will automatically calculate the BMI/BSA in  $m^2$ .
- Visit Record will display Breast Feeding and Pregnant checkboxes only if the patient is a female.

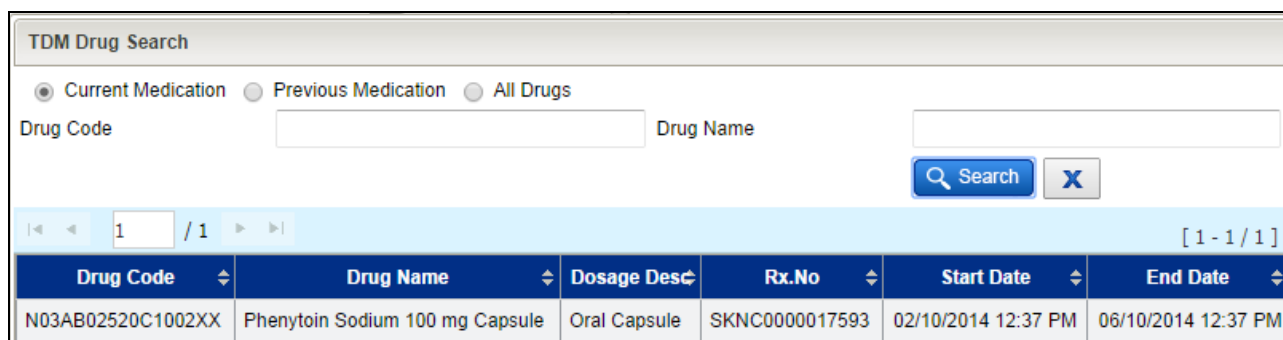
#### STEP 2

Select **Indication For Request** from dropdown box:

- Non Compliance
- Poor Response
- Therapeutic Monitoring
- Suspected Toxicity

**Note**

Selected Indication For Request will be the search key for TDM Drug field.



**TDM Drug Search**

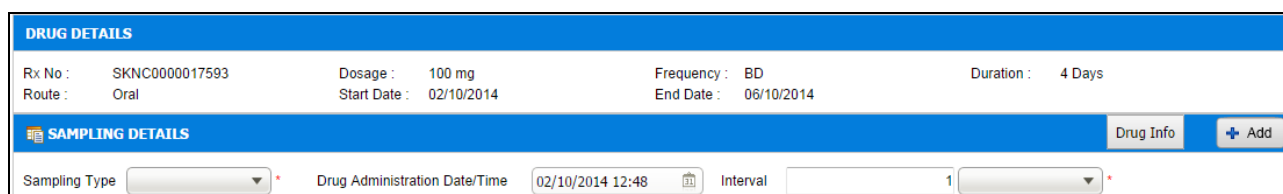
☒ Current Medication
 ☐ Previous Medication
 ☐ All Drugs

Drug Code:  Drug Name:

1 / 1  [ 1 - 1 / 1 ]

Drug Code	Drug Name	Dosage Desc	Rx.No	Start Date	End Date
N03AB02520C1002XX	Phenytoin Sodium 100 mg Capsule	Oral Capsule	SKNC0000017593	02/10/2014 12:37 PM	06/10/2014 12:37 PM

**Figure 3.3-3 Drug Search**



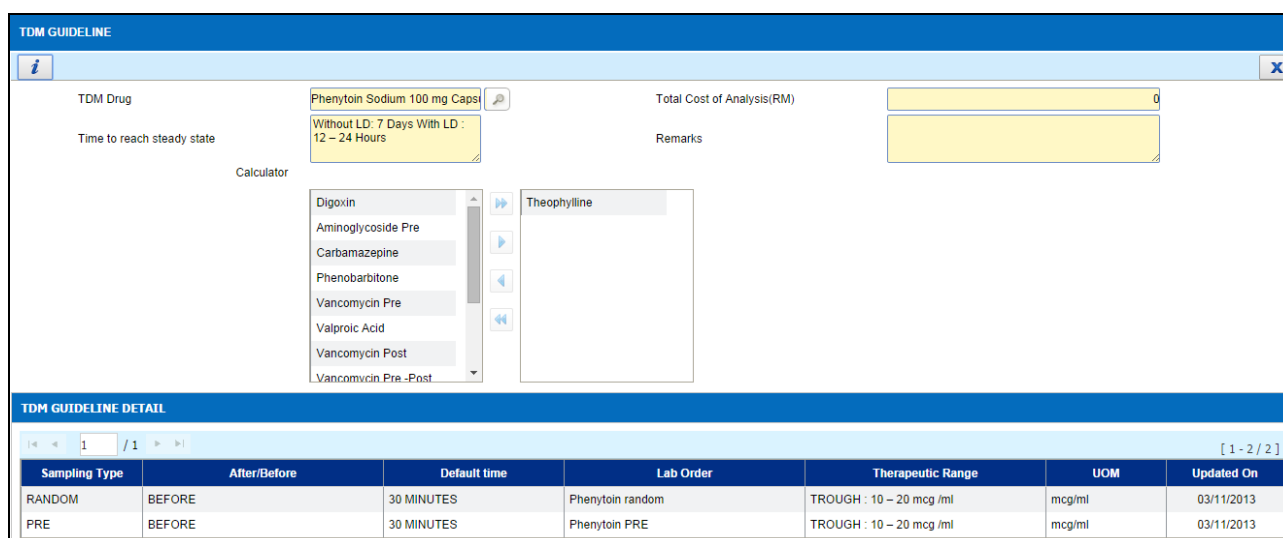
**DRUG DETAILS**

Rx No : SKNC0000017593 Dosage : 100 mg Frequency : BD Duration : 4 Days  
 Route : Oral Start Date : 02/10/2014 End Date : 06/10/2014

**SAMPLING DETAILS**

Sampling Type:  Drug Administration Date/Time: 02/10/2014 12:48 Interval: 1

**Figure 3.3-4 Drug Details**



**TDM GUIDELINE**

TDM Drug: Phenytoin Sodium 100 mg Capsule  
 Time to reach steady state: Without LD: 7 Days With LD: 12 – 24 Hours  
 Total Cost of Analysis(RM):  0  
 Remarks:

**Calculator**

Digoxin  
 Aminoglycoside Pre  
 Carbamazepine  
 Phenobarbitone  
 Vancomycin Pre  
 Valproic Acid  
 Vancomycin Post  
 Vancomycin Pre-Post

Theophylline

**TDM GUIDELINE DETAIL**

1 / 1  [ 1 - 2 / 2 ]

Sampling Type	After/Before	Default time	Lab Order	Therapeutic Range	UOM	Updated On
RANDOM	BEFORE	30 MINUTES	Phenytoin random	TROUGH : 10 – 20 mcg /ml	mcg/ml	03/11/2013
PRE	BEFORE	30 MINUTES	Phenytoin PRE	TROUGH : 10 – 20 mcg /ml	mcg/ml	03/11/2013

**Figure 3.3-5 TDM Guidelines**

**STEP 3**

Click on the  button to search for TDM drug based on:

- Current Medication
- Previous Medication
- All Drugs

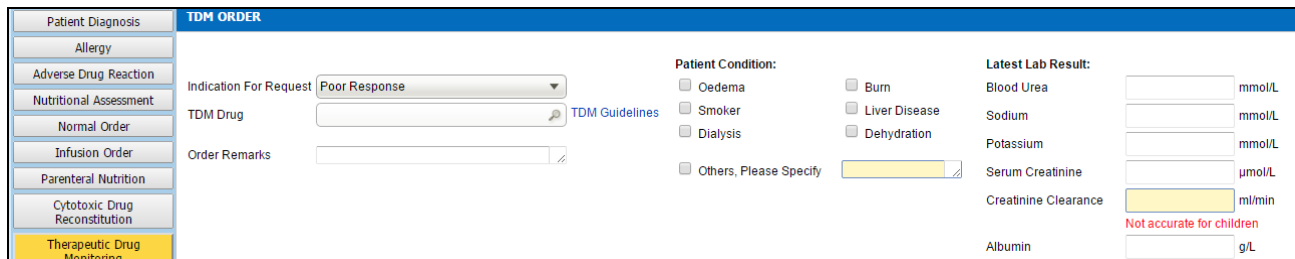
**Note**

- If the selected Indication for Request 'Non Compliance/ Poor Response/ Therapeutic Monitoring', TDM Drug search can be select from three (3) sources :
  - Current Medication
  - Previous Medication
  - All Drugs
- If the selected TDM Drug is the Current Medication or Previous Medication, system will automatically display the



Drug Details as per Figure 3.3-4.

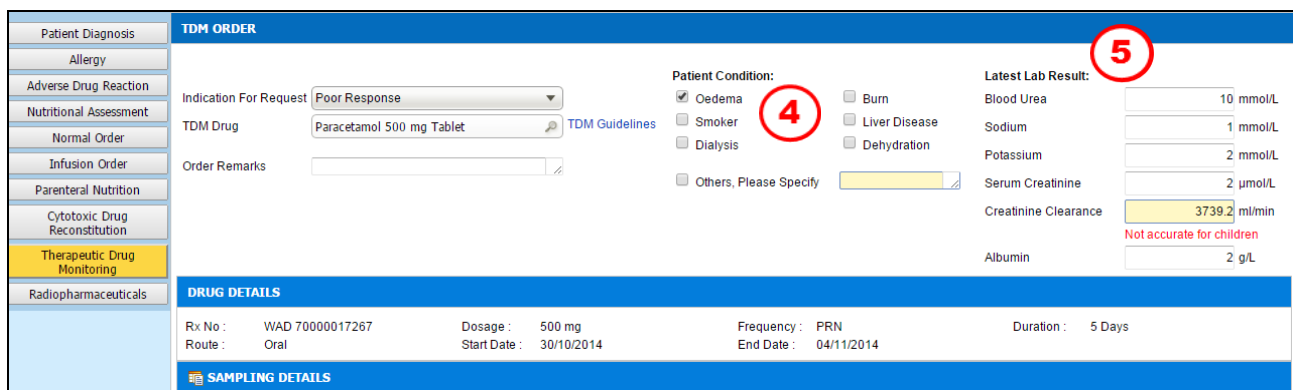
- Click on [TDM Guidelines](#) hyperlink to view TDM Guideline details on the selected TDM Drug as per Figure 3.3-5.
- TDM Guideline master setup is controlled by HQ.
- If the selected Indication for Request is 'Suspected Toxicity', TDM Drug search will default to 'All drugs' which comes from drugs that have been set in TDM Guideline master.
- The Drug Details field will be a free text field for user to enter the current dosage and frequency.



The form is titled 'TDM ORDER'. On the left is a vertical menu with options: Patient Diagnosis, Allergy, Adverse Drug Reaction, Nutritional Assessment, Normal Order, Infusion Order, Parenteral Nutrition, Cytotoxic Drug Reconstitution, Therapeutic Drug Monitoring (highlighted), and Radiopharmaceuticals. The main area contains:
 

- Indication For Request: Poor Response (dropdown)
- TDM Drug: (text field) with a 'TDM Guidelines' link.
- Order Remarks: (text field)
- Patient Condition: checkboxes for Oedema, Burn, Smoker, Liver Disease, Dialysis, Dehydration, and Others, Please Specify (text field).
- Latest Lab Result: fields for Blood Urea (mmol/L), Sodium (mmol/L), Potassium (mmol/L), Serum Creatinine (μmol/L), Creatinine Clearance (ml/min, with a note 'Not accurate for children'), and Albumin (g/L).

Figure 3.3-6 TDM Order

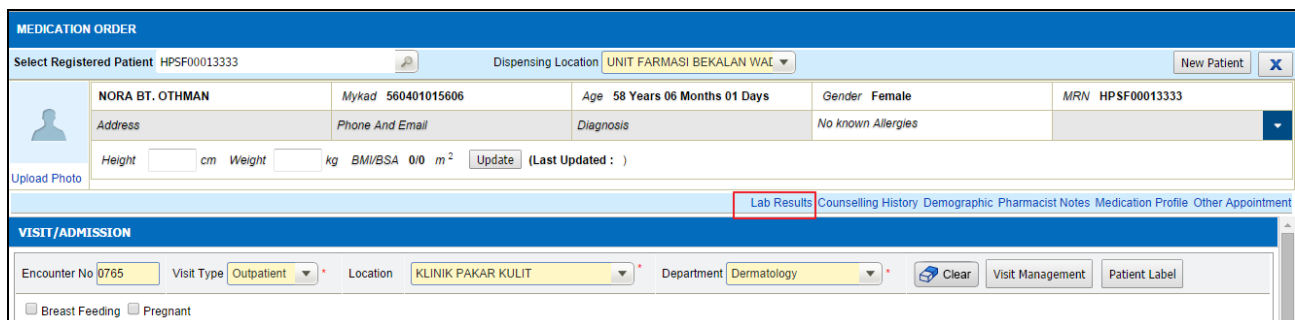


This form shows the 'TDM ORDER' section with additional details. The 'TDM Drug' is 'Paracetamol 500 mg Tablet'. The 'Patient Condition' section has 'Oedema' checked (marked with a red circle 4). The 'Latest Lab Result' section has values: Blood Urea (10 mmol/L), Sodium (1 mmol/L), Potassium (2 mmol/L), Serum Creatinine (2 μmol/L), Creatinine Clearance (3739.2 ml/min, with a note 'Not accurate for children'), and Albumin (2 g/L). A red circle 5 is around the 'Latest Lab Result' header. Below this is the 'DRUG DETAILS' section with:
 

- Rx No: WAD 70000017267
- Route: Oral
- Dosage: 500 mg
- Frequency: PRN
- Start Date: 30/10/2014
- End Date: 04/11/2014
- Duration: 5 Days

 At the bottom is a 'SAMPLING DETAILS' section.

Figure 3.3-7 Patient Condition



The form is titled 'MEDICATION ORDER'. It shows patient information for 'NORA BT. OTHMAN' (Mykad: 560401015606, Age: 58 Years 06 Months 01 Days, Gender: Female, MRN: HPSF00013333). Below this is a 'VISIT/ADMISSION' section with:
 

- Encounter No: 0765
- Visit Type: Outpatient
- Location: KLINIK PAKAR KULIT
- Department: Dermatology
- Buttons: Clear, Visit Management, Patient Label
- Checkboxes: Breast Feeding, Pregnant

 A red box highlights the 'Lab Results' link in the top navigation bar.

Figure 3.3-8 Lab Result Hyperlink

#### STEP 4

Select **Patient Condition** checkbox(es):

- Oedema
- Burn
- Smoker
- Liver Disease
- Dialysis
- Dehydration
- Others

#### Note

- User may select more than one condition.
- If 'Others' is selected, user needs to state the patient's condition in the text box provided.
- Fill in Order **Remarks** if applicable.

## STEP 5

Enter **Latest Lab Result** which consists of:

- Blood Urea
- Sodium
- Potassium
- Serum Creatinine
- Creatinine Clearance
- Albumin

### Note

*Creatinine Clearance will be automatically calculated by system in ml/min when Serum Creatinine is filled.  
Lab result data will be updated in the **Lab Result** hyperlink.*

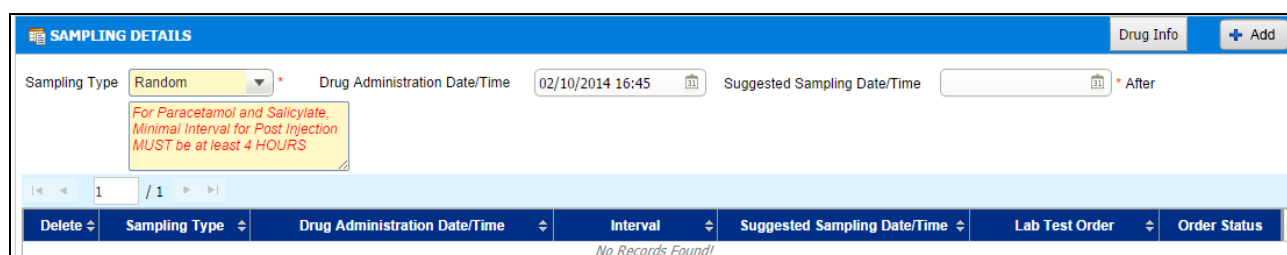


Figure 3.3-9 Sampling Details (Suspected Toxicity)

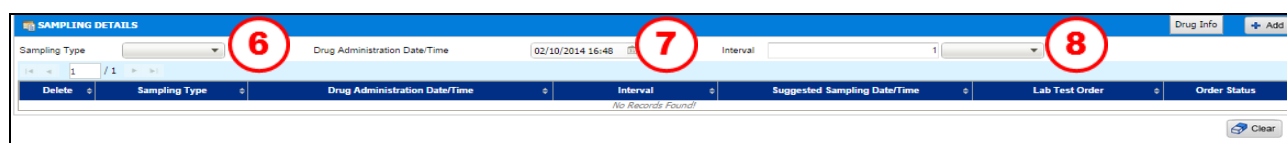


Figure 3.3-10 Sampling Details

### Note

- Screen for Sampling Details will be displayed differently based on selected 'Indication For Request' below:
- If 'Suspected Toxicity', Sampling Type is defaulted to 'Random' and the 'Suggested Sampling Date/Time' field will be displayed as per Figure 3.3-11.
- Click on the **Drug Info** button to view drug information on selected TDM drug.
- If 'Non Compliance/ Poor Response/ Therapeutic Monitoring', the 'Interval' field will be displayed as per Figure 3.3-12.

## STEP 6

Select **Sampling Type** from dropdown box:

- Pre
- Post
- Random

## STEP 7

Click on the  button to select Drug Administration Date/Time

### Note

*Drug Administration Date/Time can be edited by user and the format should be 'DD/MM/YYYY HH:MM'.*

## STEP 8

Select **Sampling Type** from dropdown box and enter **Interval** and select Hours/Minutes

### Note


*The Interval field is only enable if user choose the Indication for Request as Non Compliance/Poor*

## Response/Therapeutic Monitoring.


### STEP 9

Click on the  button to add sampling details




#### Note

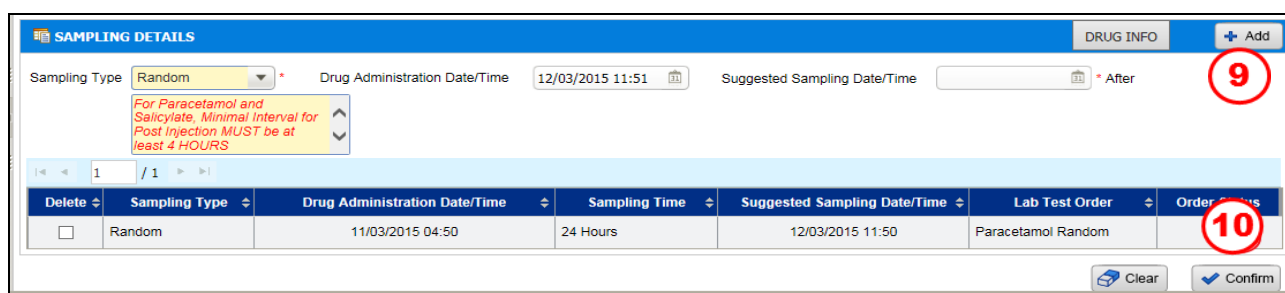
- Repeat Step 6 to Step 9 to add more samples (for Pre and Post Sampling).
- Click on the  button to see the information of the drug in details as per Figure 3.3-12.

### STEP 10

Click on the  to save TDM order and TDM Order No. will be generated

#### Note

- Click on the  button to print TDM Request Form
- Click on the  button to clear all entered data.
- Click on the  button to create a new TDM Order and the system will reset all fields in TDM Order screen
- To delete sampling details added, check on ☐ Delete checkbox.



The screenshot shows the 'SAMPLING DETAILS' form. At the top right, there is a 'DRUG INFO' button and an '+ Add' button, which is circled in red with a '9'. Below the form fields, there is a table with columns: Delete, Sampling Type, Drug Administration Date/Time, Sampling Time, Suggested Sampling Date/Time, Lab Test Order, and Order No. The first row shows a 'Random' sampling type, '11/03/2015 04:50' administration time, '24 Hours' sampling time, '12/03/2015 11:50' suggested time, and 'Paracetamol Random' lab test order. The 'Order No.' column is circled in red with a '10'. At the bottom right, there are 'Clear' and 'Confirm' buttons.

Figure 3.3-11 Add Drug for Sampling

DRUG INFORMATION	
Generic	
Phenytoin Sodium 100 mg Capsule	
Contents	phenytoin
Dosage	<p><b>Oral Epilepsy</b>  <b>Adult:</b> Initially, 3-4 mg/kg daily as single dose or in divided doses. Alternatively, 150-300 mg daily increased gradually to 600 mg daily if necessary. Maintenance: 200-500 mg daily.  <b>Child:</b> Initially, 5 mg/kg daily in 2-3 divided doses. Maintenance: 4-8 mg/kg daily in divided doses. Max dose: 300 mg daily.</p> <p><b>Intravenous Tonic-clonic status epilepticus</b>  <b>Adult:</b> Adjunctive therapy with a benzodiazepine (e.g. diazepam): 10-15 mg/kg by slow inj or intermittent infusion at a max rate of 50 mg/min. Maintenance: 100 mg IV (or orally) given every 6-8 hr.  <b>Child:</b> Neonates: 20 mg/kg as a loading dose, then 2.5-5 mg/kg bid; 1 mth-12 yr: 18 mg/kg as a loading dose, then 2.5-5 mg/kg bid; &gt;12 yr: 18 mg/kg as a loading dose, then up to 100 mg 3-4 times daily.</p>
Contraindications	Pregnancy. IV admin in sinus bradycardia, heart block, or Stokes-Adams syndrome.
Special precautions	Cardiovascular disease, e.g. sinus bradycardia, heart blocks; DM; hepatic impairment; hypoalbuminemia; porphyria; seizures (may increase frequency of petit mal seizures); debilitated patients; elderly. Caution in IV admin in hypotension, heart failure or MI, monitor BP and ECG during therapy. IV must be given slowly (too rapid admin may cause hypotension, CNS depression, cardiac arrhythmias and impaired heart conduction). Extravasation and intra-arterial admin must be avoided. Do not discontinue abruptly (may increase seizure frequency), unless safety concerns require a more rapid withdrawal. May impair ability to drive or operate machinery.
Adverse reactions	Hypersensitivity, lack of appetite, headache, dizziness, tremor, transient nervousness, insomnia, GI disturbances (e.g. nausea, vomiting, constipation), tenderness and hyperplasia of the gums, acne, hirsutism, coarsening of the facial features, rashes, osteomalacia. Phenytoin toxicity as manifested as a syndrome of cerebellar, vestibular, ocular effects, notably nystagmus, diplopia, slurred speech, and ataxia; also with mental confusion, dyskinesias, exacerbations of seizure frequency, hyperglycaemia. Solutions for inj may cause local irritation or phlebitis. Prolonged use may produce subtle effects on mental function and cognition, especially in children. <b>Potentially Life-Threatening Adverse Drug Reaction:</b> Toxic epidermal necrolysis, Stevens-Johnson syndrome.
Drug interactions	Effects with other sedative drugs or ethanol may be potentiated. Enhances toxic effects of paracetamol, lithium. Increased risk of osteomalacia with acetazolamide. Decreased serum levels/effects with acyclovir, antineoplastics, benzodiazepines, ciprofloxacin, CYP2C9 inducers (e.g. carbamazepine), CYP2C19 inducers (e.g. rifampin), folic acid, vigabatrin. Increased serum concentrations with allopurinol, capecitabine, cimetidine, CYP2C9 inhibitors (e.g. fluconazole), CYP2C19 inhibitors (e.g. delavirdine), disulfiram, methyphenidate, metronidazole, omeprazole, SSRIs, trazodone, trimethoprim. Increases metabolism of antiarrhythmics, anticonvulsants, antipsychotics, beta-blockers, calcium channel blockers, chloramphenicol, corticosteroids, doxycycline, oestrogens, HMG-CoA reductase inhibitors, methadone, theophylline, TCAs. Decreases levels/effects of clozapine, cyclosporin, tacrolimus, CYP2B6 substrates (e.g. bupropion, selegiline), CYP2C8 substrates (e.g. amiodarone), CYP2C9 substrates (e.g. celecoxib), CYP2C19 substrates (e.g. citalopram), CYP3A4 substrates (e.g. benzodiazepines), digoxin, itraconazole, levodopa, neuromuscular-blocking agents, thyroid hormones, topiramate. Increases levels/effect of dopamine, ticlopidine. Valproic acid may displace phenytoin from binding sites; and affect phenytoin serum concentrations. Transiently increases the hypothermia response to warfarin initially, followed by an inhibition of the response. <b>Potentially Hazardous Interaction:</b> Enhances the hypotensive properties of dopamine and the cardiac depressant properties of lidocaine.
Mechanism of action	Phenytoin acts as an anticonvulsant by increasing efflux or decreasing influx of sodium ions across cell membranes in the motor cortex during generation of nerve impulses; thus stabilising neuronal membranes and decreasing seizure activity. It acts as an antiarrhythmic by extending the effective refractory period and suppressing ventricular pacemaker automaticity, shortening action potential in the heart. <b>Absorption:</b> Slow but almost complete from the GI tract (oral); much slower absorption (IM). <b>Distribution:</b> Widely distributed. Protein-binding: 90%. <b>Metabolism:</b> Extensively hepatic; converted to inactive metabolites. <b>Excretion:</b> Via urine as hydroxylated metabolite; elimination half life at steady state: 22 hr.
MIMS Class	Anticonvulsants
ATC Classification	N03AB02 - phenytoin; Belongs to the class of hydantoin derivatives antiepileptics. Used in the management of epilepsy.

Figure 3.3-12 Drug Information

## STEP 11

Click on the  button to verify order

### Note

- Order Status changed to "Verified".
- Users not allowed to update sampling details if order status is "Verified".

## STEP 12

Enter details in these fields:

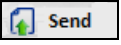

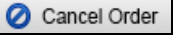
- Actual Admin Date/Time
- Actual Sampling Date/Time
- Sample Sent Date/Time
- Sample Accepted Date/Time
- Sent Through
- Sample Collected By
- Sent By
- Sample Accepted By

## STEP 13

Select **Process Type** from dropdown box:

- Lab Based
- Outsource
- Pharmacy Based

### Note

- If Process Type is "Outsource", user needs to select which facility to send the order to under Send To dropdown box and click on the  button.
- Click on the  button to reject the sampling details. User needs to place a new order.
- Click on the  button to cancel the order. User may not need to place new order.

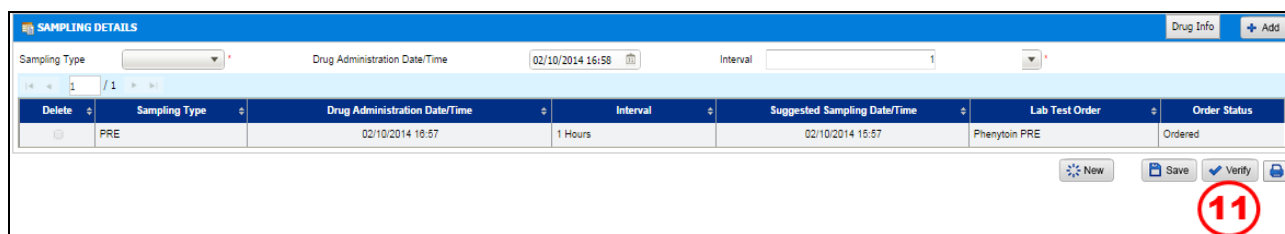


Figure 3.3-13 Verify Sampling Details

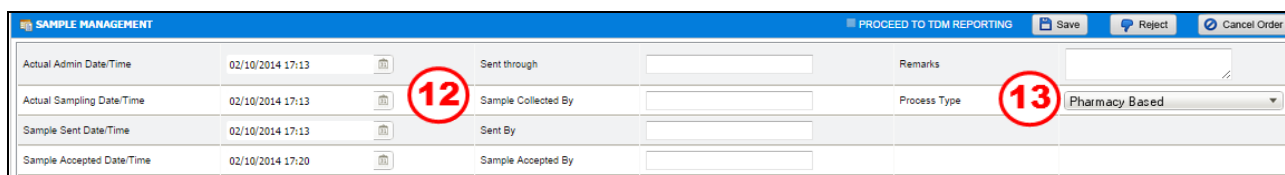


Figure 3.3-14 Sampling Management

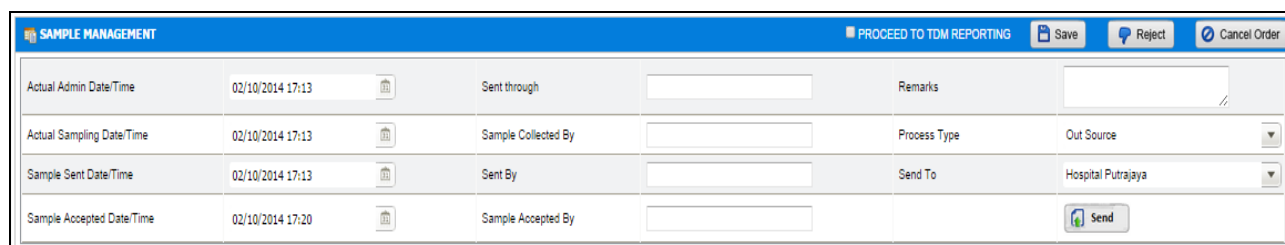


Figure 3.3-15 Sampling Management – Out Source

#### STEP 14

Click on the  button to save record and select the **PROCEED TO TDM REPORTING** to perform the TDM reporting

#### STEP 15

Click on [Details](#) hyperlink to display Reporting screen

#### Note

- User needs to enter sample details for pre sample, post sample or random sample based on TDM order.
- Latest Lab Result will display the latest lab results recorded for:
  - Blood Urea
  - Sodium
  - Potassium
  - Serum Creatinine
  - Creatinine Clearance
  - Albumin

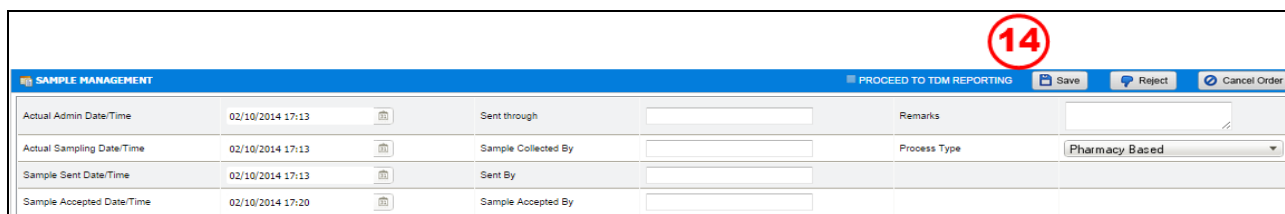


Figure 3.3-16 Save and Proceed to Reporting

**REPORTING**

**NORA BT. OTHMAN** Mykad: 560401015606 Age: 58 Years 06 Months 01 Days Gender: Female IIRN: HPSF00013333

Address: Phone And Email: Diagnosis: No known Allergies

Height: 152 cm Weight: 56 kg BMI/BSA: 24.2 / 1.57 m<sup>2</sup> [Update](#) (Last Updated: 02/10/2014)

Encounter No: 0765 Visit Date: 02/10/2014 Visit Location: KLINIK PAKAR KULIT Transcribed By: Nor Faezah

Lab Results Demographic Pharmacist Notes Medication Profile TDM Guidelines

[Add](#) [CP2](#)

[1 - 1 / 1]

TDM No.	Drug Name	Drug Details	Actual Drug Admin Date/Time	Reporting	Pre	Post	Random	Toxic	Recommendation Type	Recommendation accepted
TDM0000000136	Phenytoin Sodium 100 mg Capsule	100 mg, BD, Oral Capsule 02/10/2014 (4 Days), Start Date: 02/10/2014 End Date: 08/10/2014	02/10/2014 17:13	<a href="#">Details</a> <b>15</b>				NO		

Pharmacist Note

Remarks

Total Cost of Analysis

TDM service Charge in RM

[Save](#) [Confirm](#)

[Place TDM Order](#) [Save](#)

Figure 3.3-17 TDM Reporting

#### STEP 16

Enter sample details as below:

- Result Value
- Resulted By

#### Note

Click on [Details](#) hyperlink to view sample details. Sample Details consists of:

- Reference Range
- Sample Collected Date/Time
- Actual Drug Admin Date/Time
- Outsource

#### STEP 17

Select calculator from dropdown box. Please refer to [TDM Calculator](#) to view sample calculator calculation.

#### STEP 18

Enter **Pharmacokinetics Profile**

#### STEP 19

Select **Recommendation Type** from dropdown box:

- Increase The Dose
- Maintain The Dose
- Reduce The Dose
- Refer to Pharmacist Notes
- Stop The Dose
- Withhold The Dose

#### Notes

*Recommendation Type will be copied and displayed in Pharmacist Notes.*

#### STEP 20

Select **Toxic**:


- Yes
- No



### STEP 23

Click on the  button to confirm report

### Note

The  button and  button will be enabled.

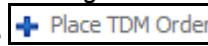
### STEP 24

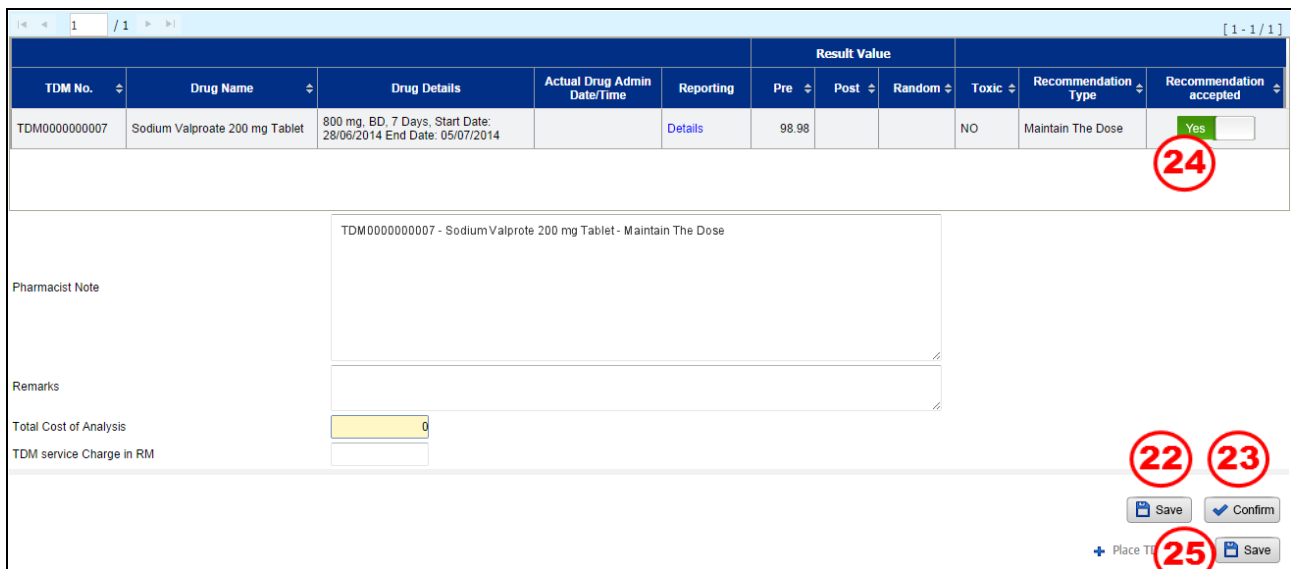
Click 'Yes' or 'No' at the  button under **Recommendation accepted**


### STEP 25

Click on the  button to authorize the report

### Note

- The status will change to "Result Viewed".
- Click on the  button to place new TDM order.



TDM No.	Drug Name	Drug Details	Actual Drug Admin Date/Time	Reporting	Pre	Post	Random	Toxic	Recommendation Type	Recommendation accepted
TDM0000000007	Sodium Valproate 200 mg Tablet	800 mg, BD, 7 Days, Start Date: 28/06/2014 End Date: 05/07/2014		<a href="#">Details</a>	98.98			NO	Maintain The Dose	

Pharmacist Note

Remarks

Total Cost of Analysis: 0

TDM service Charge in RM





Buttons:    

Figure 3.3-20 TDM Reporting



### 3.4 External TDM

#### 3.4.1 External TDM Online

External Notification	
External TDM Request Received:	<input type="text" value="1"/>
External TDM Result Received:	<input type="text" value="0"/>
Online SPUB R1 Request Received:	<input type="text" value="0"/>

**Figure 3.4.1-1 External Notification**

External TDM module is for user to record external TDM resulting (Outsource) via online or offline. It will be recorded online if both facilities use PhIS to perform TDM processes.

#### STEP 1

Click on the **External TDM Result Received**  button to view Outsource information

OUTSOURCE LISTING								
[ 1 - 2 / 2 ]								
<input type="checkbox"/>	Hosp/Clinic	Mrn No	Patient Name	Patient ID	TDM Drug	Sample Type	Date/Time	Register
<input type="checkbox"/>	Hospital Pakar Sultanah Fatimah, Muar	HPSF00007006	[REDACTED]	[REDACTED]	carBAMAZepine 200mg Tablet	RANDOM	22/07/2014 13:26	Register
<input type="checkbox"/>	Hospital Pakar Sultanah Fatimah, Muar	HPSF00017231	[REDACTED]	[REDACTED]	Sodium Valproate 200 mg Tablet	PRE	22/09/2014 15:48	Register

**Figure 3.4.1-2 Outsource Listing**

#### STEP 2

Click on **Register** hyperlink to register the patient in the system

#### Note

The status will change to 'Registered' as per Figure 3.4.1-2

OUTSOURCE LISTING								
[ 1 - 2 / 2 ]								
<input type="checkbox"/>	Hosp/Clinic	Mrn No	Patient Name	Patient ID	TDM Drug	Sample Type	Date/Time	Register
<input type="checkbox"/>	Hospital Pakar Sultanah Fatimah, Muar	HPSF00007006	[REDACTED]	910801126176	carBAMAZepine 200mg Tablet	RANDOM	22/07/2014 13:26	Register
<input checked="" type="checkbox"/>	Hospital Pakar Sultanah Fatimah, Muar	HPSF00017231	[REDACTED]	790719015422	Sodium Valproate 200 mg Tablet	PRE	22/09/2014 15:48	Registered

**Figure 3.4.1-3 Outsource Listing – Registered Patient**

#### STEP 3

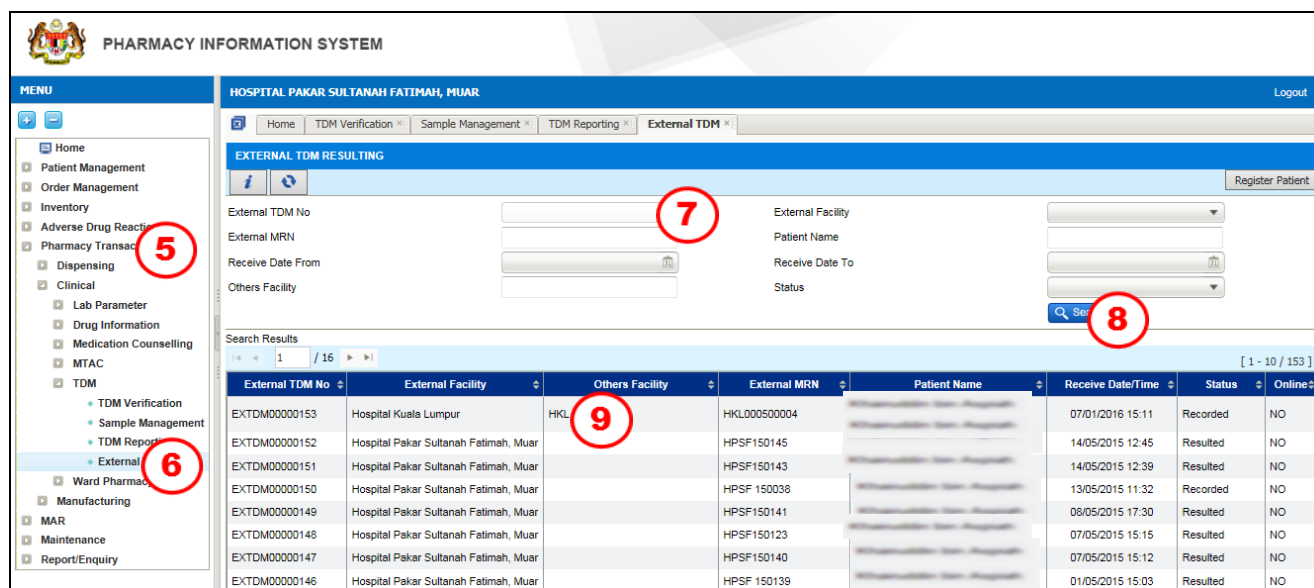
Click on the ☒ checkbox for selected patient

#### STEP 4

Click on the  button to save the record

#### Note

Registered patient will be uploaded to the External TDM listing page.



External TDM No	External Facility	Others Facility	External MRN	Patient Name	Receive Date/Time	Status	Online
EXTDM0000153	Hospital Kuala Lumpur	HKL	HKL000500004		07/01/2016 15:11	Recorded	NO
EXTDM0000152	Hospital Pakar Sultanah Fatimah, Muar		HPSF150145		14/05/2015 12:45	Resulted	NO
EXTDM0000151	Hospital Pakar Sultanah Fatimah, Muar		HPSF150143		14/05/2015 12:39	Resulted	NO
EXTDM0000150	Hospital Pakar Sultanah Fatimah, Muar		HPSF 150038		13/05/2015 11:32	Recorded	NO
EXTDM0000149	Hospital Pakar Sultanah Fatimah, Muar		HPSF150141		08/05/2015 17:30	Resulted	NO
EXTDM0000148	Hospital Pakar Sultanah Fatimah, Muar		HPSF150123		07/05/2015 15:15	Resulted	NO
EXTDM0000147	Hospital Pakar Sultanah Fatimah, Muar		HPSF150140		07/05/2015 15:12	Resulted	NO
EXTDM0000146	Hospital Pakar Sultanah Fatimah, Muar		HPSF 150139		01/05/2015 15:03	Resulted	NO

Figure 3.4.1-4 External TDM Listing Page

## STEP 5

Click on 'Pharmacy Transaction' menu follow by 'Clinical' sub-menu

## STEP 6


Click on 'TDM' and click on 'External TDM' function

## STEP 7

Search for patient records by:

- External TDM No.
- External Facility
- External MRN
- Patient Name
- Receive Date From
- Receive Date To
- Others Facility
- Status
  - Recorded
  - Rejected
  - Resulted

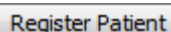
## STEP 8

Click on the  button to search for patient records

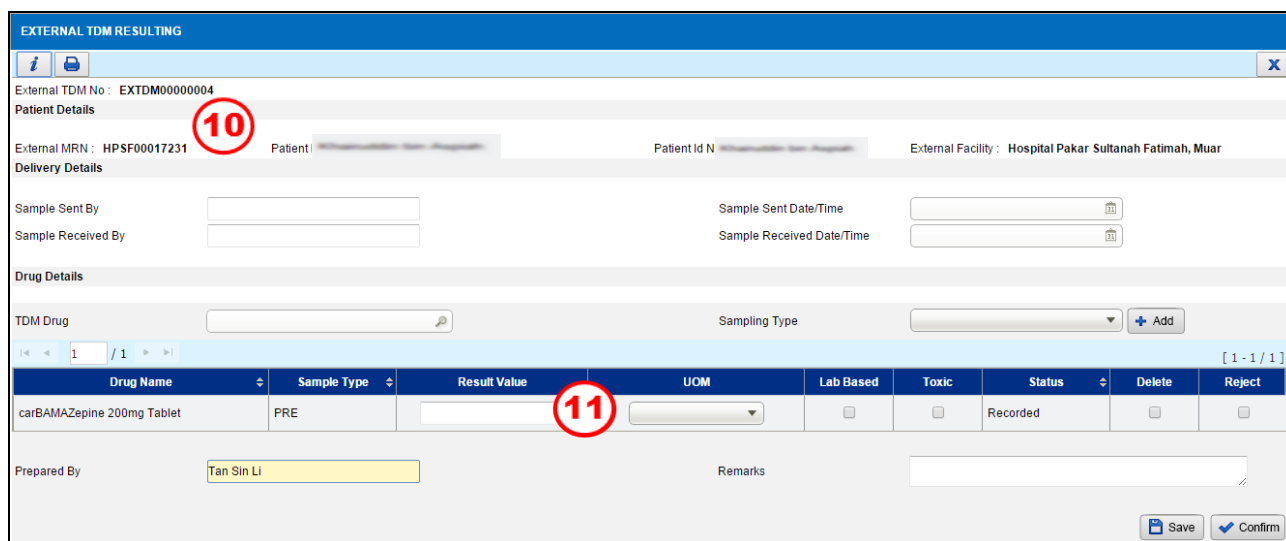
## STEP 9

Double-click on the selected patient and External TDM Resulting screen will be displayed as per Figure 3.4.1-5

## Note



button is for offline External TDM (refer to [section 3.2 External TDM Offline](#))



**EXTERNAL TDM RESULTING**

External TDM No : EXTDM00000004

**Patient Details**

External MRN : HPSF00017231 Patient: [Redacted] Patient Id N: [Redacted] External Facility : Hospital Pakar Sultanah Fatimah, Muar

**Delivery Details**

Sample Sent By: [Text Box] Sample Sent Date/Time: [Text Box]

Sample Received By: [Text Box] Sample Received Date/Time: [Text Box]

**Drug Details**

TDM Drug: [Text Box] Sampling Type: [Dropdown] + Add

Drug Name	Sample Type	Result Value	UOM	Lab Based	Toxic	Status	Delete	Reject
carBAMAZepine 200mg Tablet	PRE	[Text Box]	[Dropdown]	<input type="checkbox"/>	<input type="checkbox"/>	Recorded	<input type="checkbox"/>	<input type="checkbox"/>

Prepared By: Tan Sin Li Remarks: [Text Box]

Save Confirm

Figure 3.4.1-5 External TDM Resulting

#### STEP 10

Enter **Delivery Details** as below:

- Sample Sent By
- Sample Sent Date/Time
- Sample Received By
- Sample Received Date/Time

#### STEP 11

Enter **Result Value** and select **UOM** from dropdown box :

- mcg/ml
- mg/dl
- mmol/l
- ng/ml

#### Note

- Select on ☐ **Lab Based** checkbox if TDM resulting process is done at a laboratory.
- Select on ☐ **Toxic** checkbox if TDM results show toxicity for selected patient.
- Select on ☐ **Reject** checkbox to reject sampling received.
- Select on ☐ **Delete** checkbox to delete TDM order.
- Enter **Remarks** if applicable.

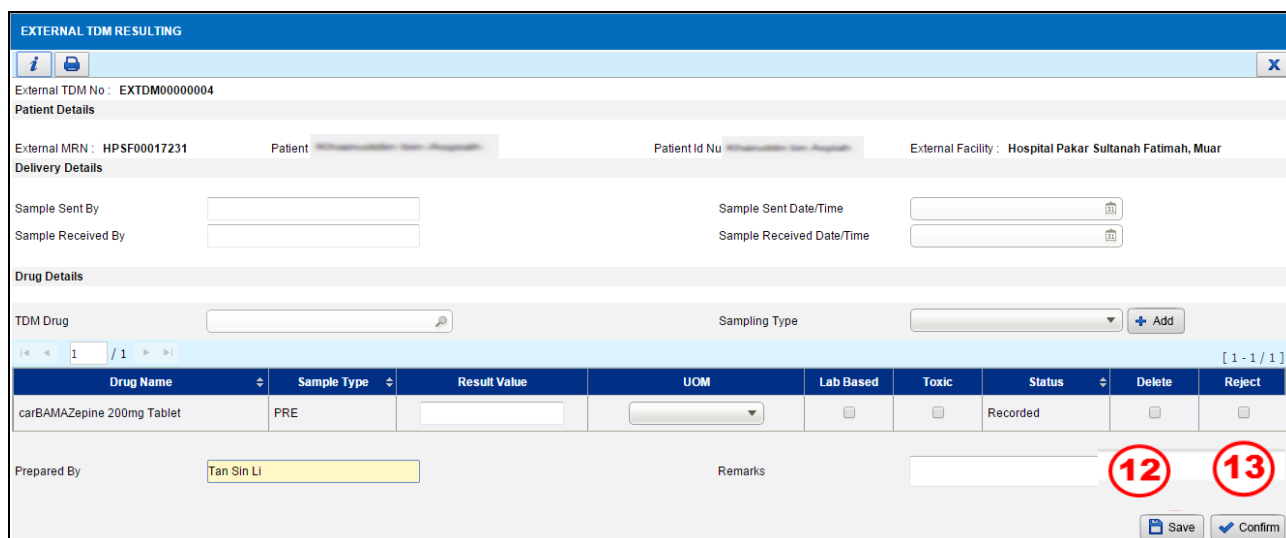




Figure 3.4.1-6 External TDM Resulting

#### STEP 12

Click on the  button to save external TDM resulting



#### STEP 13

Click on the  button to confirm external TDM resulting

#### Note

- The status will change to “Resulted”.
- Outsource TDM Resulting will be sent back to the requester.

To receive an **External TDM Result Received**:

- Click on the **External TDM Result Received**  button to view the outsource listing.
- Select on ☐ checkbox(es) on selected outsource request.
- Click on the  button to upload the patient record in order to proceed with TDM Reporting processes.(refer to [section 3.3 TDM Reporting](#))

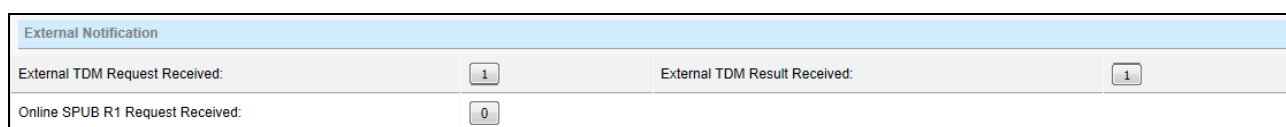
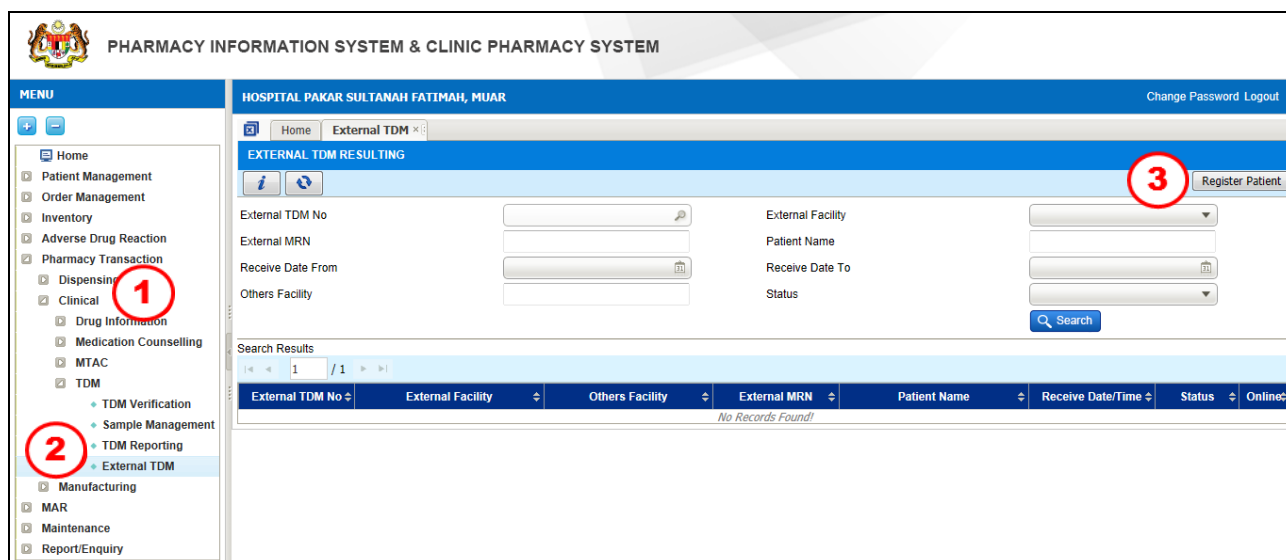


Figure 3.4.1-7 External Notification

OUTSOURCE LISTING									
TDM Order No	Mm No	Patient Name	Patient ID	TDM Drug	Sample Type	Result	UOM	Date/Time	
<input checked="" type="checkbox"/> EXTDM0000001	HPSF00017231		790719015422	Sodium Valproate 200 mg Tablet	PRE	13.3	mcg/ml	22/09/2014 16:22	

Figure 3.4.1-8 Outsource Listing

### 3.4.2 External TDM Offline



**Figure 3.4.2-1 External TDM Listing Page**

External TDM module is for user to record external TDM resulting (Outsource) via online and offline. It is recorded offline if one of the facility used PhIS to perform TDM processes.

#### STEP 1

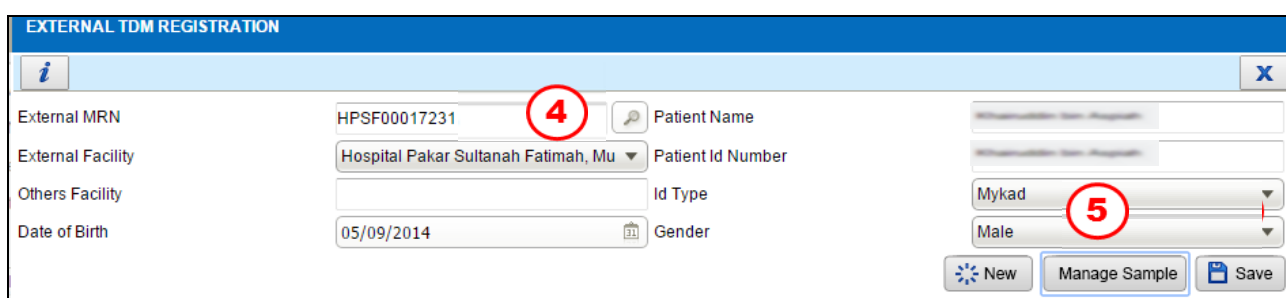
Click on 'Pharmacy Transaction' menu follow by 'Clinical' sub-menu

#### STEP 2

Click on 'TDM' and click on 'External TDM' function

#### STEP 3

Click on the **Register Patient** button to register external patient




**Figure 3.4.2-2 External TDM Registration**

#### STEP 4

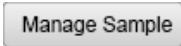
Enter details in the fields below:

- External MRN
- Patient Name
- External Facility
- Patient Id Number
- Other Facility  
(If the sample come from private sector or facility which is not listed under MOH facilities)
- Id Type

### Note

Click on the External MRN  button to search for registered patient and all fields will be automatically retrieved.

### STEP 5

Click on the  button and External TDM Resulting screen will be displayed as per Figure 3.4.2-3

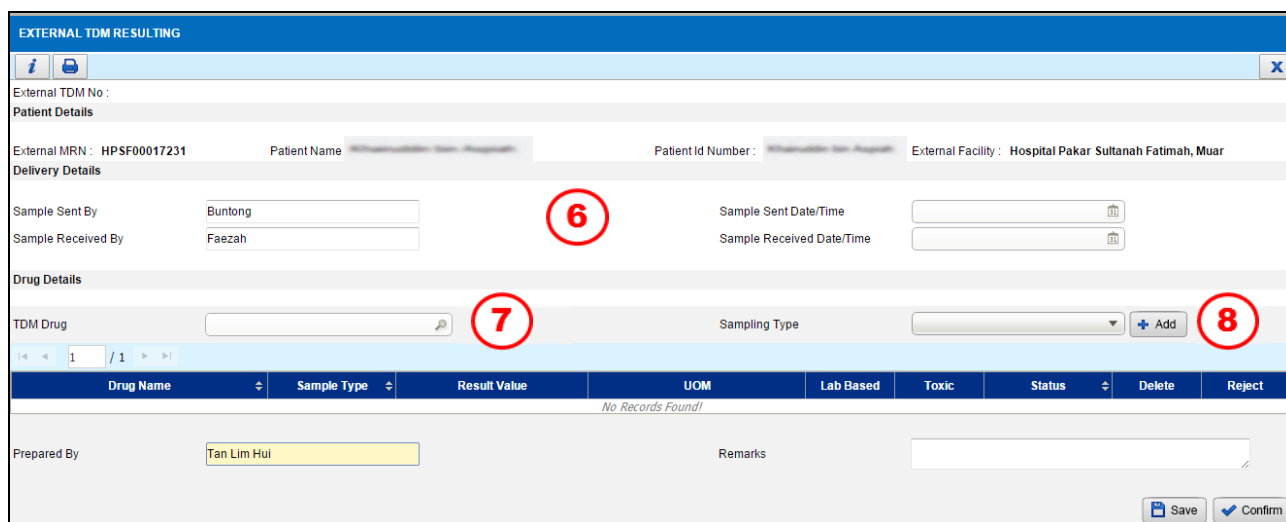


Figure 3.4.2-3 External TDM Resulting

### STEP 6

Enter **Delivery Details** as below:

- Sample Sent By
- Sample Sent Date/Time
- Sample Received By
- Sample Received Date/Time

### STEP 7

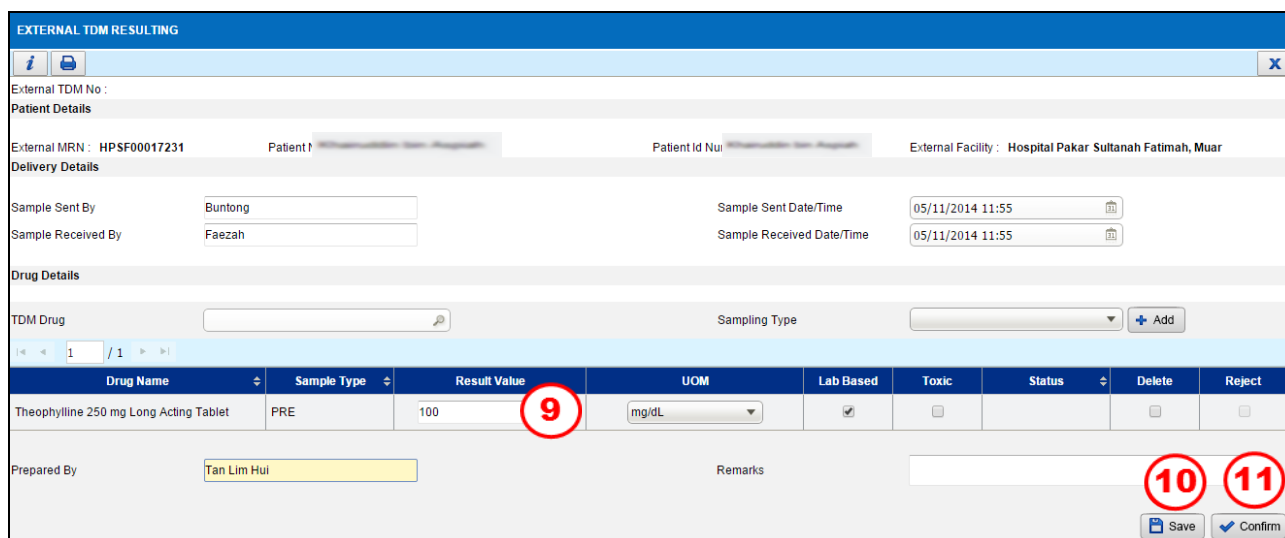
Click on the **TDM Drug**  button to search for drug

### STEP 8

Select **Sampling Type** from dropdown box:

- Pre
- Post
- Random

and click on the  button to add the information



**EXTERNAL TDM RESULTING**

External TDM No :   
 Patient Details

External MRN : HPSF00017231 Patient Name :   
 Patient Id Num :   
 External Facility : Hospital Pakar Sultanah Fatimah, Muar

**Delivery Details**

Sample Sent By : Buntong Sample Sent Date/Time : 05/11/2014 11:55   
 Sample Received By : Faezah Sample Received Date/Time : 05/11/2014 11:55

**Drug Details**

TDM Drug : Sampling Type : + Add

Drug Name	Sample Type	Result Value	UOM	Lab Based	Toxic	Status	Delete	Reject
Theophylline 250 mg Long Acting Tablet	PRE	100	mg/dL	<input checked="" type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

Prepared By : Tan Lim Hui Remarks :   
 Save Confirm

**Figure 3.4.2-4 External TDM Resulting**

### STEP 9


Enter **Result Value** and select **UOM** from dropdown box :

- mcg/ml
- mg/dl/ml


### Note

- Select on ☐ **Lab Based** checkbox if TDM resulting process is done at a laboratory.
- Select on ☐ **Toxic** checkbox if TDM results show toxicity for selected patient.
- Select on ☐ **Reject** checkbox to reject sampling received.
- Select on ☐ **Delete** checkbox to delete TDM order.
- Enter **Remarks** if applicable.

### STEP 10

Click on the  button to save external TDM resulting

### STEP 11

Click on the  button to confirm external TDM resulting

## 4.0 Acronyms

Abbreviation	Definition
PhIS	Pharmacy Information System
CPS	Clinical Pharmacy System
MOH	Ministry Of Health
TDM	Therapeutic Drug Monitoring

## 5.0 Links to Clinical Modules

No	Module	PDF Links	No	Module	PDF Links
1	Inpatient	<a href="#">Click Here</a>	12	CDR Dispensing	<a href="#">Click Here</a>
2	CDR Order	<a href="#">Click Here</a>	13	Methadone Dispensing	<a href="#">Click Here</a>
3	TDM Order	<a href="#">Click Here</a>	14	PN Dispensing	<a href="#">Click Here</a>
4	PN Order	<a href="#">Click Here</a>	15	Order Management	<a href="#">Click Here</a>
5	IV Order	<a href="#">Click Here</a>	16	Patient Management	<a href="#">Click Here</a>
6	Prepacking	<a href="#">Click Here</a>	17	Radiopharmaceuticals	<a href="#">Click Here</a>
7	Galenical	<a href="#">Click Here</a>	18	Outpatient	<a href="#">Click Here</a>
8	MTAC	<a href="#">Click Here</a>	19	Special Drug Request	<a href="#">Click Here</a>
9	ADR & DAC	<a href="#">Click Here</a>	20	MAR	<a href="#">Click Here</a>
10	Medication Counselling	<a href="#">Click Here</a>	21	DICE	<a href="#">Click Here</a>
11	Ward Pharmacy	<a href="#">Click Here</a>	22		