



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

System Design Document (SDD)

Therapeutic Drug Monitoring

Version	: v1.2
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**REVISION HISTORY**

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0.1	15.03.2012	Norlaileza Sidek	G. Shenoy (SME)/ Maxine Wong (QA)	Initial 1st draft
0.2	16.03.2012	Norlaileza Sidek	G. Shenoy	Review comments added
1.1	29/03/2012	Norlaileza Sidek	MOH	
1.2	06.04.2018	Norlaileza Sidek	MOH	Updated based on version 1.7 released

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Date :		Date :	



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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.

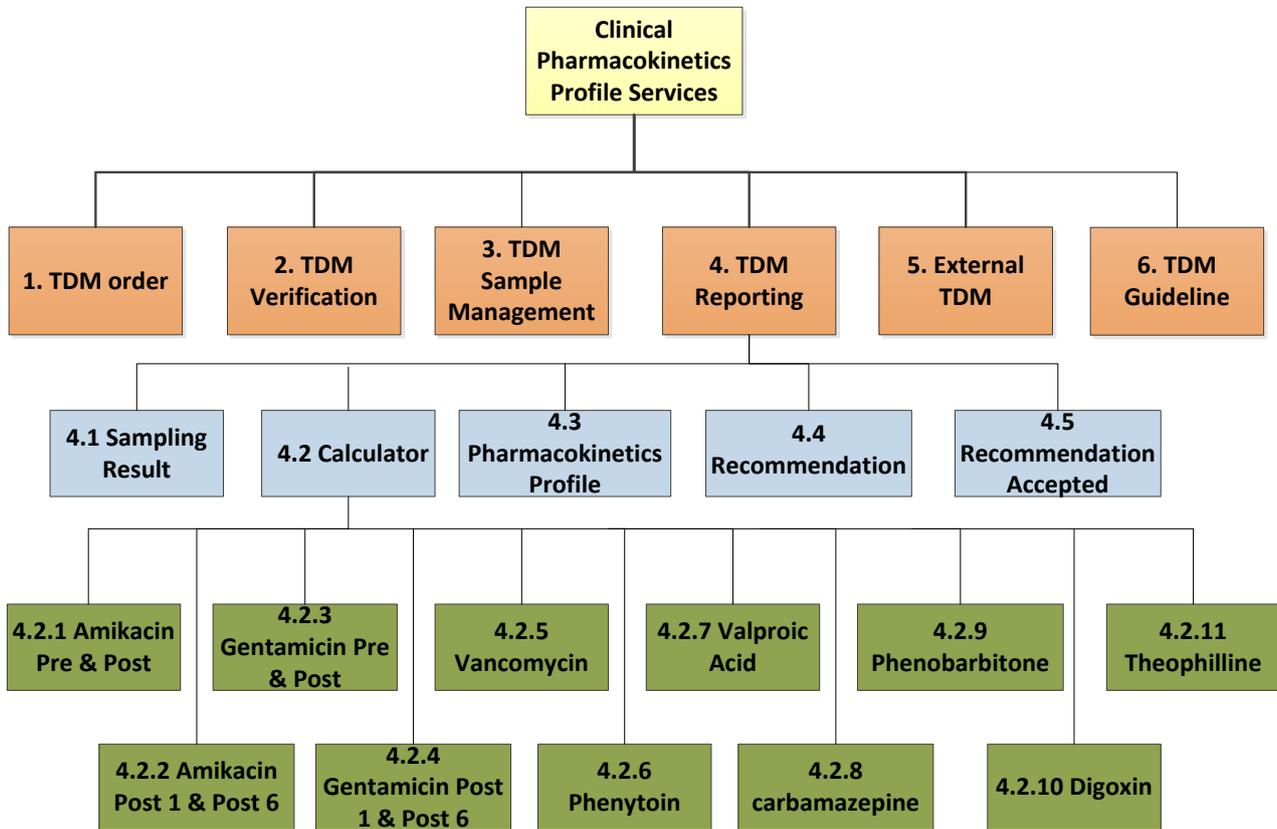
2 Purpose

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.

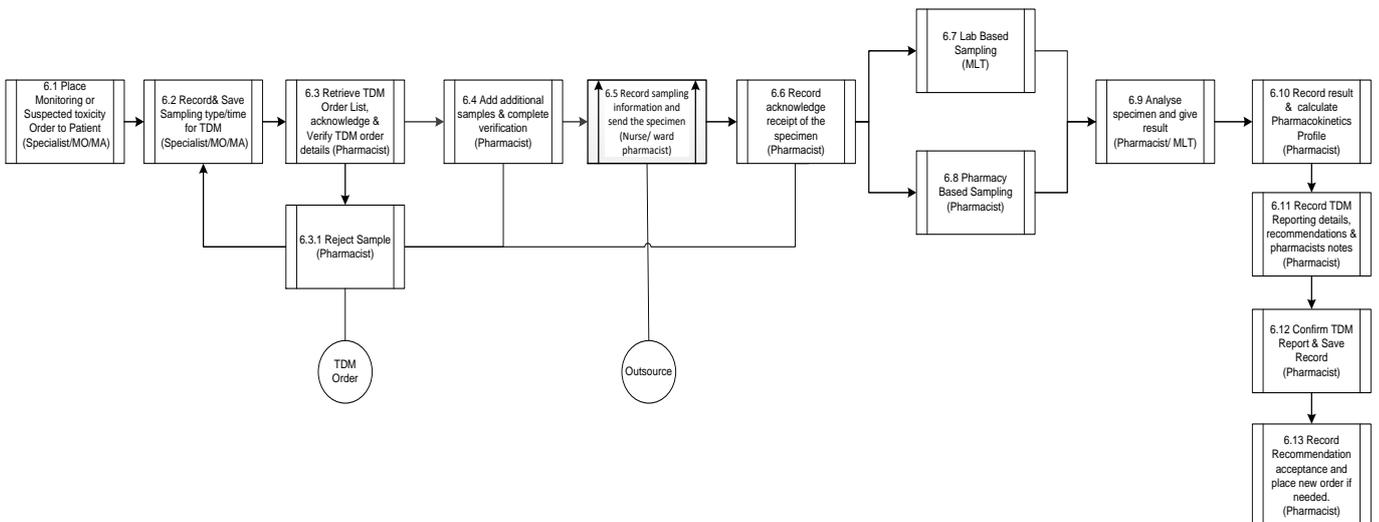


3 Detailed System Design

3.1 Clinical Pharmacokinetics Service (TDM) Overview



3.1.1 Block Diagram



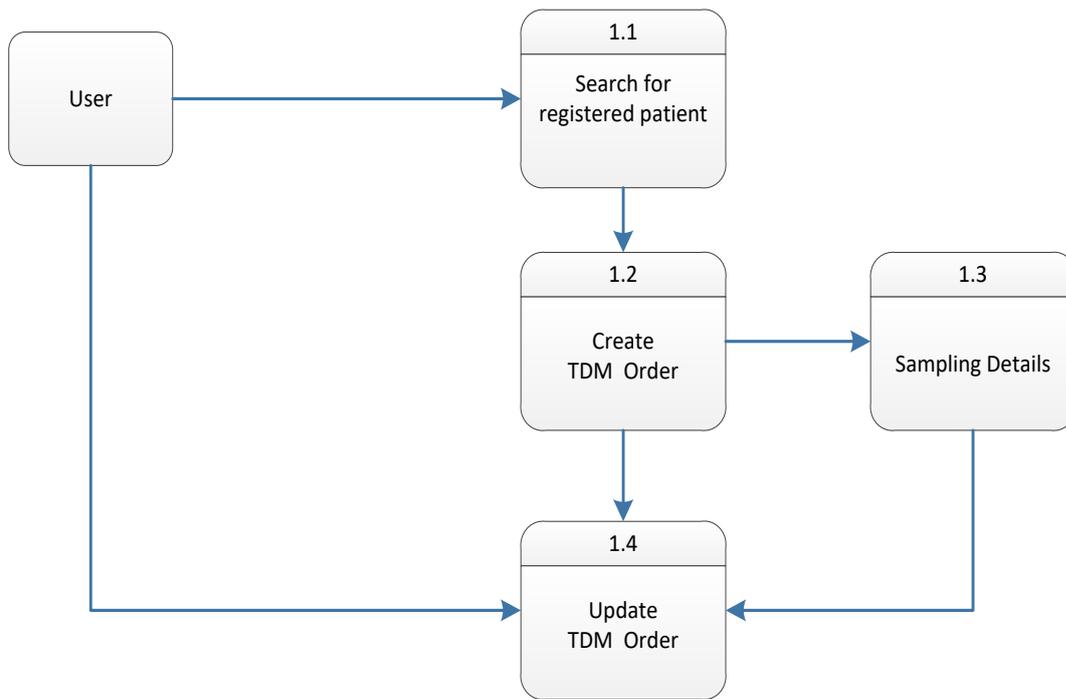


3.2 TDM Order

3.2.1 Purpose

This module shall be used to create a new clinical pharmacokinetics services or therapeutic drug monitoring (TDM) order for PhIS full based facilities.

3.2.2 Screen Navigation Diagram



TDM.SND1: TDM Order



3.2.3 Detail Functionality and Screen

3.2.3.1 Medication Order Listing

3.2.3.1.1 Screen Design

ID	TDMMO.SD1
Description	Medication Order Listing
Diagram	
Notes	<ul style="list-style-type: none"> Click on search button to search for the patient. Double click on patient record to add new TDM order.
Cross References	None

3.2.3.1.2 Application Business Rules

No.	Name	Description
1.	Search Patient	<p>Medication Order listing screen is displayed for user to select patient based on user's granted location and patient's visit location. Listing is sorted in ascending order based on visit date.</p> <p>By default, patient's record is displayed based on the visit type as below:</p> <ol style="list-style-type: none"> Inpatient: Patient record is displayed until the patient discharge. Outpatient/SPUB/Outsource/Walk In: Patient record is displayed only for one day. Daycare: Patient record is displayed until the patient discharge. Emergency: Patient record is displayed until the patient discharge. System auto discharge after 24 hours.
2.	Refresh 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*

No.	Name	Description	Mandatory	Format
1.	MRN	Medication order listing shall be retrieved from the database for all registered patients with visit based on matching MRN.	No	Text box
2.	Patient Name	Medication order listing shall be retrieved from the database for all registered patients with visit based on matching Patient Name.	No	Text box
3.	Location	By default, location is default to user's login location. The listed location values are based on the user's granted location as setup in User Profile screen.	Yes	Drop down list
4.	Show All checkbox	Display patient records assigned to the login user.	No	Checkbox
5.	Show All by Location	Display patients records assigned to user's login location.	No	Checkbox



3.2.3.2 TDM Order

3.2.3.2.1 Screen Design

ID	TDMMO.SD2
Description	Create New TDM Order Record

Diagram

i. TDM Order Screen

MEDICATION ORDER

Mykad: [redacted] Age: 10 Years 10 Months 26 Days Gender: Male MRN: [redacted]
 Address: [redacted] Phone And Email: [redacted] Diagnosis: [redacted] No known Allergies
 Height: 135 cm Weight: 43 kg BMI/BSA: 23.6 / 1.27 m² Update (Last Updated: 06/11/2017) Nationality: Warganegara

Encounter No: 0827 Actual Admission Date: 29/01/2018 Attending Practitioner: [redacted] Visit Location: PAED 2 Pensioner: AS-Pesara Polis

TDM ORDER

Patient Condition:
 Oedema Burn
 Adverse Drug Reaction Liver Disease
 Nutritional Assessment Smoker
 Normal Order Dehydration
 Infusion Order Others, Please Specify: test
 Parenteral Nutrition

Latest Lab Result:
 Blood Urea: 4 mmol/L Serum Creatinine: 45 µmol/L
 Sodium: 2 mmol/L Creatinine Clearance: 152.79 ml/min
 Potassium: 2 mmol/L Albumin: 2 g/L
 Not accurate for children

DRUG DETAILS

Indication For Request: Non Compliance
 TDM Drug: [redacted] TDM Guidelines
 Order Remarks:
 Drug Details:
 (Please specify current Dosage, Frequency, Start Date & End Date)

ii. Add Sample button

	Drug Name	Drug Details	Order Remarks	Drug Info
+ Add Sample	Carbamazepine 100 mg/5 ml (2% w/v) Syrup	80 mg/5 ml BD (02/04/2018 - 07/04/2018)	testing only	i

iii. Add Sample Details

SAMPLING DETAILS

Sampling Type: [dropdown] Drug Administration Date/Time: [calendar] Sampling Time: 1 [dropdown]

iv. Sampling Details

	Drug Name	Drug Details	Order Remarks	Drug Info
-	Carbamazepine 100 mg/5 ml (2% w/v) Syrup	80 mg/5 ml BD (02/04/2018 - 07/04/2018)	testing only	i
	Sampling Type	Drug Administration Date/Time	Suggested Sampling Date/Time	Suggested Sampling Date/Time
	Pre	02/04/2018 12:15 PM	30 Minutes	02/04/2018 11:45 AM
				Lab Test Order
				Carbamazepine PRE



Notes	<ul style="list-style-type: none"> Click on 'New' button to place new order Click on the 'Clear' button to cancel the task. Click on the 'Add sample' button to add sample. Click on the 'Confirm' button to save the order. New TDM order No will be generated. Format : TDMXXXXXXXXXX (10 digits running number) Click on Prescription button to print the TDM order form.
Cross References	None

3.2.3.2.2 Application Business Rules

No.	Name	Description
1.	Create multiple drug in one order	During creation of new order: i. User can add more drug by click on 'Add' button
2.	TDM Guideline	Click on TDM Guideline hyperlink to check on the therapeutic range. For TDM guideline master setup refer to this section : 3.7 TDM Guideline Listing Screen (Master Setup)
3.	Drug Details	User can select drug from option as below: i. Current Medication ii. Previous Medication iii. All Drugs
4.	Sampling Details	<p>This section will be based on the selection of the 'Indication for request' field. If the selected value is:</p> <ul style="list-style-type: none"> <i>Suspected toxicity</i> <ul style="list-style-type: none"> Sampling type will be show only 'Random'. Date and time will be default to current date and time with provision to change. Calendar to be provided. 'Interval' will be default to '1 minutes after' with provision to change. Sampling Date/time will be calculate as 'selected date/time + interval'  <ul style="list-style-type: none"> <i>Therapeutic Monitoring or Poor Response or Non Compliance</i> <ul style="list-style-type: none"> Sampling type can be 'Pre ,Post or Random' User can select either only pre or post, pre and post, or random. (If user select random, information of Pre and Post will be clear). Sampling Details will be show as "Random" Only. From the selected Drug Administration Date/Time system will auto calculate the 'Sampling Date/Time' which is based on the Interval selected. The Sampling Details will be shown based on the selected



No.	Name	Description
		<p>Drug Administration Date/Time entered.</p> <ul style="list-style-type: none"> User can always click on 'Clear' button to clear back the entered data. Click on 'Add' button to add more samples. If the selected TDM Drug is 'Paracetamol' or 'Salicylate' the format to do sampling will always be "Random" <p>Sample Id will be generated once complete the order transaction.</p>
5.	Modify order record	<p>User can edit the patient condition and order remarks</p> <p>On click of Update button, modification on the record will be updated in order details section.</p>
6.	Delete order record	<p>On click of Delete button:</p> <ol style="list-style-type: none"> Confirmation message will be displayed before user proceeds to delete the drug Once user confirms to delete the record, system will delete order and all drugs record. Screen will refresh and user is allowed to create new CDR order.
7.	Confirm order record	<p>On click of Confirm button:</p> <ol style="list-style-type: none"> Order status is updated to 'Ordered'. Order information will be displayed in the TDM Verification Screen. Print button is enabled after saving the record.
8.	Print Prescription	<p>On click of Print button:</p> <ol style="list-style-type: none"> Prescription with all the ordered drugs is displayed in PDF format. User able to print the displayed prescription.

3.2.3.2.3 Input Validation Rules

ID	Name	Description	Mandatory	Format
1.	Indication for Request	<p>A drop down combo box with values populated from 'Indication for Request' ph_ref_code. The value contains as below:</p> <ol style="list-style-type: none"> Therapeutic Monitoring Suspected Toxicity Poor Response Non Compliance <ul style="list-style-type: none"> These value will be the search key of the TDM Drug field 	Yes	Drop Down
2.	TDM Drug	<p>TDM Drug is captured based on the selection of the 'Indication for Request' field.</p> <ul style="list-style-type: none"> Suspected toxicity – <ul style="list-style-type: none"> List of drugs master from 'ph_tdm_guideline_hdrs'. 	Yes	Searching Field



ID	Name	Description	Mandatory	Format
		<ul style="list-style-type: none"> • Therapeutic Monitoring / Poor response / Non Compliance <ul style="list-style-type: none"> - List of drugs from patient's Medication Profile where tdm_yn is checked (ph_order_normal_drugs) - The drug details will be shown as below: <ul style="list-style-type: none"> ○ Rx No - Order no ○ Dosage - dosage ○ Frequency – ph_frequencies ○ Duration - duration ○ Route – drug_route_seqno ○ Start Date - start_date_time_ori ○ End Date - end_date_time_ori 		
3.	Oedema	This field set to be checked or unchecked.	No	Check box
4.	Smoker	This field set to be checked or unchecked.	No	Check box
5.	Dialysis	This field set to be checked or unchecked.	No	Check box
6.	Burn	This field set to be checked or unchecked.	No	Check box
7.	Liver Disease	This field set to be checked or unchecked.	No	Check box
8.	Dehydration	This field set to be checked or unchecked.	No	Check box
9.	Others	This field set to be checked or unchecked.	No	Check box
10.	Others free text	A free text field to enter the text with capacity maximum of 100 characters. This field should enable once user checked on 'Others' check box.	No	Free text
11.	Order Remarks	A free text field to enter the text with capacity maximum of 100 characters.	No	Free text
12.	Drug Details	This will appear if the selection of drug is from option 'All Drugs' or if the Indication of Request selected is 'Suspected Toxicity'	Yes	Free Text
13.	Sampling Type	<p>A drop down combo box with values populated from 'sampling type' ph_ref_code. The value contain as below:</p> <ol style="list-style-type: none"> 1) Pre 2) Post 3) Random <p>*If the indication of request selected as 'Suspected Toxicity' the value will always be 'Random' and the selected drug also must have 'Random' sample type in the TDM Guideline. Else, a pop up alert message will appear.</p> <ul style="list-style-type: none"> - Alert message as below: "The selected drug doesn't have 'Random Sample'. Do you want to proceed". 	Yes	Drop Down
14.	Drug Administration Date/Time	<p>Calendar option with default to current date and time but, user can change accordingly.</p> <p>* If the order comes from Medication Drug Profile</p>	Yes	Calendar



ID	Name	Description	Mandatory	Format
		<p>the calendar selection will be within the start date and end date defined in the order only.</p> <p>* If the order is come from the Drug Master, the calendar option will be following to current date and time.</p> <p>* If the drug route is by Infusion, interval should be calculated by the end time of the infusion given.</p>		
15.	Interval	<ul style="list-style-type: none"> An alphanumeric free text field with maximum capacity of 10 characters. If sampling type is 'Random' - Default to '1' with provision to change. <p>*If TDM Drug selected is "Paracetamol", default to '4' with provision to edit.</p>	Yes	Free Text
16.	Interval Description	<p>A drop down combo box with values populated from 'interval' ph_ref_code. The value contain as below:</p> <ol style="list-style-type: none"> Minute(s) Hour 	Yes	Drop Down
17.	Sampling Date/Time	<p>Sampling Date/Time will be auto calculated in dd/mm/yyyy format.</p> <ul style="list-style-type: none"> Pre <ul style="list-style-type: none"> Drug administration - Interval time. <i>E.g : 15/05/2012 - 30 mins</i> Post <ul style="list-style-type: none"> Drug administration + Interval time. <i>E.g : 15/05/2012 + 30 mins</i> Random <ul style="list-style-type: none"> Drug administration + Interval time. <i>E.g : 15/05/2012 + 30 mins</i> 	Yes	Auto Display
18.	Lab Test Order	Auto display based on the selected "lab_order" in "ph_tdm_guideline"	Yes	Auto Display
19.	Sample ID	<p>Auto generated running number when sampling details (ph_sampling_details) is added.</p> <p>The format of the Sample ID is: Hospital prefix/SM/running no. e.g. HSDG/SM/000001</p>	Yes	Auto Display
20.	Status	<p>This field will capture status for the order.</p> <p>Ordered – Once user save the record</p>	Yes	Auto Display
21.	Status By	This field will capture the person names who update the status.	Yes	Auto Display
22.	Status Updated Date	This field will capture the date/time of updated status.	Yes	Auto Display

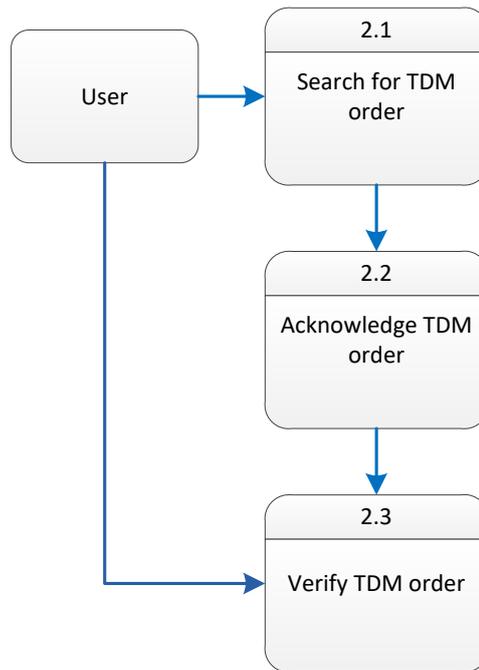


3.3 TDM Acknowledge & Verification

3.3.1 Purpose

This module shall be used by Pharmacist to acknowledge and verify clinical pharmacokinetics services or therapeutic drug monitoring (TDM) order.

3.3.2 Screen Navigation Diagram



TDM.SND2: TDM Acknowledge & Verification



3.3.3 Detail Functionality and Screen

3.3.3.1 TDM Acknowledge & Verification Listing

3.3.3.1.1 Screen Design

ID	TDMAV.SD1
Description	TDM Acknowledge & Verification Listing Screen
Diagram	
Notes	<ul style="list-style-type: none"> Click on the 'Search' button to search the order. The Basic search as below: <ul style="list-style-type: none"> Ordered Date From Ordered Date To Status TDM Order No The Advance search as below: <ul style="list-style-type: none"> Location Type Location TDM Drug Ordered By Acknowledge By MRN Double on the patient record to open TDM verification screen
Cross References	None

3.3.3.1.2 Application Business Rules

No.	Name	Description
1.	Search Transaction	Click on the 'Search' button to search the existing record: <ol style="list-style-type: none"> By default filter record by : <ul style="list-style-type: none"> Latest TDM Order date/time If user enters multiple search criteria, system will display the search results based on the specified criteria If no criteria entered, system will display all transactions



No.	Name	Description
2.	View search result in listing page	Columns in search result listing are displayed based on: i. TDM Order No: Display TDM Order No ii. TDM Drug: Display TDM drug iii. MRN: Display patient MRN No. iv. Patient Name: Display patient registered name. v. IC No/ other identification: Display patient IC No or Other identification no as registered in patient management screen. vi. Ordered By: Display name of the prescriber vii. Ordered Date/time: Display ordered date/time viii. Order Status: Display value from 'Status' field in transaction screen. ix. Drug Info: Display drug information for the selected drug

3.3.3.1.3 Input Validation Rules

ID	Name	Description	Mandatory	Format
1.	Ordered Date From	Ordered Date From to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
2.	Ordered Date To	Ordered Date To to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
3.	Location Type	Location Type to be selected from the dropdown combo box with values as configured in the 'Location Type' ph_ref_code. The list as below: - Clinic - ER - Nursing Unit - Pharmacy - Day Care	No	Drop Down
4.	Location	Location to be selected from the dropdown combo box with values as configured in the master setup. (ph_location_setup)	No	Drop Down
5.	TDM Order No	An enterable lookup field which will display list of TDM Order No in popup screen.	No	Free Text
6.	Status	A drop down combo box with values populated from 'tdm_status_verify' ph_ref_code Value as below: 1) Ordered 2) Acknowledge 3) Verified *The query's criteria also will be depends on the user role. If the user got verify role then the Verify button should appear, else the verify button will disappear.	No	Drop Down



ID	Name	Description	Mandatory	Format
7.	TDM Drug	An enterable lookup field which will display list of TDM Drugs in popup screen. TDM Drugs is capture from ph_tdm_guideline_hdrs.tdm_drug	No	Searching Field
8.	Ordered By	An enterable lookup field which will display list of user name (ph_user_details) in popup screen.	No	Searching Field
9.	Acknowledged By	An alphanumeric free text field with maximum capacity of 20 characters.	No	Free Text
10.	MRN	MRN No should be selected from patient search box	No	Searching Field



3.3.3.1 TDM Acknowledge & Verification Screen

3.3.3.1.1 Screen Design

ID	TDMAV.SD2
Description	TDM Acknowledge & Verification Screen
Diagram	
Notes	<ul style="list-style-type: none"> Click on  button to activate the 'Acknowledge' and 'Verify' button Double click on the sample record to edit the sampling details Click on 'Cancel Order' button to cancel the order and status will be 'Cancelled' Click on 'Acknowledge' button to acknowledge the order and status will be 'Acknowledge' Click on 'Verify' button to verify the order and status will be 'Verified' Click on Print button to print the TDM order form.
Cross References	None

3.3.3.1.2 Application Business Rules

No.	Name	Description
1.	Acknowledge	After click on "Acknowledge" button, will display "Verify" button and will display Acknowledged by name and Acknowledge Date/Time based on user login id and current date and time.
2.	Verify	After click on "Verify" button, system will display Verified by name and Verified Date/Time based on user login id and current date and time.



3.3.3.1.3 Input Validation Rules

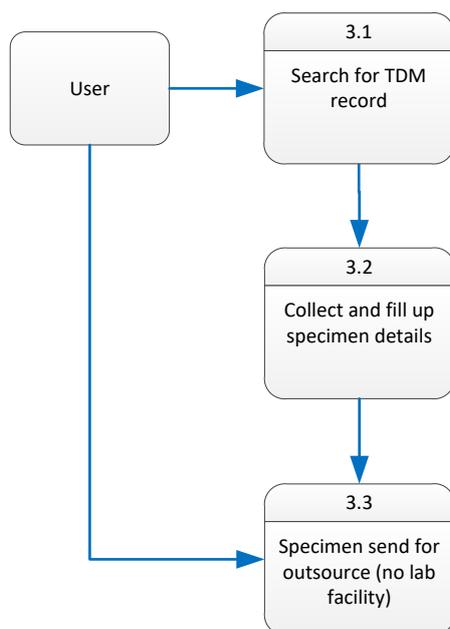
No	Name	Description	Mandatory	Format
1	Acknowledge	Click on 'Acknowledge' button to acknowledge the order and 'Verify' button will appear. The status will be Acknowledge . System will capture acknowledge person name and the acknowledge date/time.	Yes	Others
2.	Verify	This button will appear upon click on 'Acknowledge' button, the status will be Verified	Yes	Others

3.4 TDM Sample Management

3.4.1 Purpose

This module shall be used by Pharmacist to record sample management for clinical pharmacokinetics services or therapeutic drug monitoring (TDM) order. Sample can be either processes in lab based, pharmacy based or outsourced to other facility.

3.4.2 Screen Navigation Diagram





3.4.3 Detail Functionality and Screen

3.4.3.1 TDM Sample Management Listing

3.4.3.1.1 Screen Design

ID	TDMSM.SD1
Description	TDM Sample Management Listing Screen
Diagram	
Notes	<ul style="list-style-type: none"> Click on the 'Cancel' button to cancel the task. Click on the 'Search' button to search the order. The Basic search as below: <ul style="list-style-type: none"> Ordered Date From Ordered Date To Location type Location MRN IC No/Other Identification Status The Advance search as below: <ul style="list-style-type: none"> TDM Drug Ordered By Acknowledge By TDM Order No
Cross References	None

3.4.3.1.2 Application Business Rules

No.	Name	Description
1.	Search Transaction	Click on the 'Search' button to search the existing record: <ul style="list-style-type: none"> ii. By default filter record by : <ul style="list-style-type: none"> Latest TDM Order date/time If user enters multiple search criteria, system will display the search results based on the specified criteria If no criteria entered, system will display all transactions



No.	Name	Description
2.	View search result in listing page	Columns in search result listing are displayed based on: <ol style="list-style-type: none"> i. TDM Order No: Display TDM Order No ii. TDM Drug: Display TDM drug iii. MRN: Display patient MRN No. iv. Patient Name: Display patient registered name. v. IC No/ other identification: Display patient IC No or Other identification no as registered in patient management screen. vi. Ordered Date/time: Display ordered date/time vii. Acknowledge By: Display name of user who acknowledge the record viii. Verified By: Display name of user who verify the record ix. Status: Display value from 'Status' field in transaction screen. x. Drug Info: Display drug information for the selected drug

3.4.3.1.3 Input Validation Rules

ID	Name	Description	Mandatory	Format
1.	Ordered Date From	Ordered Date From to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
2.	Ordered Date To	Ordered Date To to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
3.	Location Type	Location Type to be selected from the dropdown combo box with values as configured in the 'Location Type' ph_ref_code. The list as below: <ul style="list-style-type: none"> - Clinic - ER - Nursing Unit - Pharmacy - Day Care 	No	Drop Down
4.	Location	Location to be selected from the dropdown combo box with values as configured in the master setup.	No	Drop Down
5.	TDM Order No	An enterable lookup field which will display list of TDM Order No in popup screen.	No	Free Text
6.	Status	A drop down combo box with values populated from 'tdm_status_verify' ph_ref_code Value as below: <ol style="list-style-type: none"> 4) Ordered 5) Acknowledge 6) Verified <p>*The query's criteria also will be depends on the user role. If the user got verify role then the Verify button should appear, else the verify button will disappear.</p>	No	Drop Down



ID	Name	Description	Mandatory	Format
7.	TDM Drug	An enterable lookup field which will display list of TDM Drugs in popup screen. TDM Drugs is capture from ph_tdm_guideline_hdrs.tdm_drug	No	Searching Field
8.	Ordered By	An enterable lookup field which will display list of user name (ph_user_details) in popup screen.	No	Searching Field
9.	Acknowledged By	An alphanumeric free text field with maximum capacity of 20 characters.	No	Free Text
10.	MRN	MRN No should be selected from patient search box	No	Searching Field

3.4.3.2 Sample Management Screen

ID	TDMSM.SD2
Description	TDM Sample Management Screen

Diagram

The screenshot shows the 'SAMPLE MANAGEMENT' interface. At the top, there are buttons for 'Save', 'Reject', and 'Cancel Order'. Below this, patient information is displayed: Name (WENDY CHUA WAN CHING), Mykad (910531135418), Age (26 Years 10 Months 06 Days), Gender (Female), and MRN (HUS00122971). There are also fields for Address, Phone And Email, and Diagnosis. A section for 'Sampling Details' includes a table with columns: Schedule Administration Date/Time, Drug Administered By, Sample Id, Lab Test Ordered, Sampling Type, Suggested Sampling Date/Time, Outsource, and Status. The table contains one row with data: 27/11/2017 10:00 PM, OTHERS (not specific), HUS/SIM/0000011803, Phenytoin PRE, Pre, 27/11/2017 09:30 PM, and Verified.

- Double click on the record to “Manage Sample”. Screen as below will appear.

The screenshot shows the 'Manage Sample' form. It has a 'Save' button and an 'X' button. The form contains several input fields with calendar icons: 'Actual Admin Date/Time', 'Actual Sampling Date/Time', 'Sample Sent Date/Time', and 'Sample Accepted Date/Time'. There are also dropdown menus for 'Sent through', 'Sample Collected By', 'Sent By', and 'Sample Accepted By'. A 'Remarks' field with a scroll bar is at the bottom.

Notes	<ul style="list-style-type: none"> • Click on the ‘Cancel’ button to cancel the task. • Click on the context menu to “Reject Sample” or to “Manage Sample”.
Cross References	None



3.4.3.2.1 Application Business Rules

No.	Name	Description
1.	Cancel Order	Click on cancel button to cancel the order
2.	Reject Sample	Upon click on the "Reject Sample", a pop up message will be prompted to validate the action, if Yes then the sample status will be 'Sample Rejected'.

3.4.3.2.2 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Drug Administered By	This field will auto captured from drug administered person name in MAR. Currently MAR system is still not ready yet.	No	Text Field
2.	Sent by	A free text field to enter the text with capacity maximum of 50 characters	No	Text Field
3.	Specimen Sent Date	Specimen sent date to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
4.	Sample Accepted By	A free text field to enter the text with capacity maximum of 50 characters	No	Text Field
5.	Sample Accepted Date / Time	Sample Accepted date to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
6.	Sent Through	A free text field to enter the text with capacity maximum of 50 characters	No	Text Field
7.	Remark	A free text field to enter the text with capacity maximum of 100 characters	No	Text Field
8.	Outsource	Selection of 'Yes' and 'No'	No	Text Field
9.	Status	According to the selection in Manage sample function in context menu, If: - Sample collected by – Status will be "Sample Collected" - Sent by – Status will be "Sample Sent" - Sample Accepted by – Status will be "Sample Accepted".	No	Text Field
10.	Actual Admin Date/Time	Actual admin date/time to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar

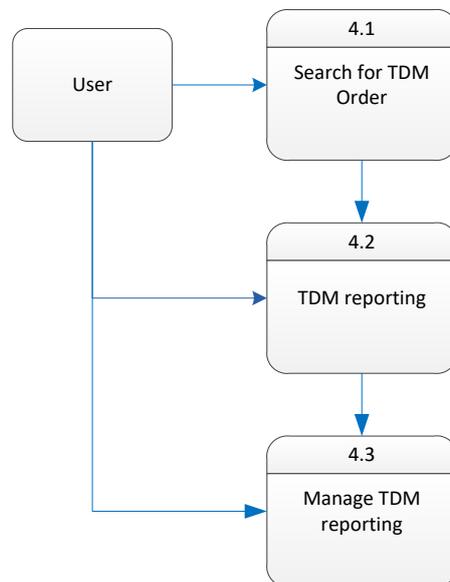


3.5 TDM Reporting

3.5.1 Purpose

This module shall be used by Pharmacist to record result reporting for clinical pharmacokinetics services or therapeutic drug monitoring (TDM) services. Provided also TDM calculator based on drug ordered.

3.5.2 Screen Navigation Diagram





3.5.3 Detail Functionality and Screen

3.5.3.1 TDM Result Reporting Listing Screen

3.5.3.1.1 Screen Design

ID	TDMRR.SD1
Description	TDM Result Reporting Listing Screen
Diagram	
<p>*Select patient and click on Add button to add new report.</p>	
Notes	<ul style="list-style-type: none"> Click on the 'Cancel' button to cancel the task. Click on the 'Search' button to search the order. The Basic search as below: <ul style="list-style-type: none"> MRN Patient name Status The Advance search as below: <ul style="list-style-type: none"> Report No Toxic
Cross References	None

3.5.3.1.2 Application Business Rules

None

3.5.3.1.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Status	A drop down combo box with values populated from 'tdm_status_report' ph_ref_code Value as below: 1) In-Process 2) TDM Resulted 3) Result Authorised	No	Drop Down



2.	Patient Name	Free text field to enter patient name.	No	Text Field
3.	Report No	An enterable lookup field which will display list of Report No in popup screen.	No	Searchi ng Field
4.	MRN	An enterable lookup field which will display list of values in popup screen. (ph_patients)	No	Searchi ng Field
5.	IC No/Other Identification	Free text field	No	Free Text
6.	Toxic	Drop Down field with value as below: <ul style="list-style-type: none">- All- Non Toxic- Toxic	No	Drop Down



3.5.3.2 TDM Result Reporting Screen

3.5.3.2.1 Screen Design

ID	TDMRR.SD2
Description	TDM Result Reporting Screen
1) Diagram	<p>The screenshot displays the 'REPORTING' interface for a patient named Mykad. It includes fields for patient demographics (Age: 17 Years 07 Months 12 Days, Gender: Male, MRN: HUS00251634), physical attributes (Height: 175 cm, Weight: 67 kg, BMI/BSA: 21.9 / 1.8 m²), and a 'Known Allergies' warning. A table lists drug details for Phenytoin Sodium 100 mg Capsule, including sampling and administration times. Below the table are sections for 'Pharmacist Note', 'Remarks', and 'Total Cost of Analysis' (0). Buttons for 'Save', 'Confirm', and 'Place TDM Order' are visible at the bottom.</p>
Notes	<ul style="list-style-type: none"> • Click on the 'Cancel' button to cancel the task. • Click on the 'Save' button and save the order, the order will still open for editing. The status will be "In Process". • Click on 'Reporting "Details"', system will pop up screen for reporting. • Click on 'Add' button to add another TDM order. Pop up screen will appear. • 'Result value' with "pre, post or random" column is based on the selected 'sample type' during order transaction. • Result value and calculator field is blocked for editing. User may click on Reporting 'Details' hyperlink to insert/edit data • Click on 'Confirm' button and the order will be final and cannot be editing. The status will be "TDM Resulted".
Cross References	None



3.5.3.2.2 Application Business Rules

No.	Name	Description
1.	Record TDM Result Reporting	<ul style="list-style-type: none"> User may select multiple orders for one reporting. Selected TDM orders will listed in the TDM reporting screen contains as below field/information: <ul style="list-style-type: none"> - TDM No - Drug Name - Actual Admin Date/Time *The other field will be empty. Click on 'Details' hyperlink to proceed with the reporting process. Upon click on the 'Details' hyperlink, a pop screen will appear.

3.5.3.2.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
TDM Listing				
1.	TDM No	This field come from the TDM order no for the selected order. ph_tdm_order.tdm_order_no	Yes	Auto display
2.	Drug Name	This field captured from the drug name from the TDM order. ph_tdm_order.tdm_drug	Yes	Auto display
3.	Actual Admin Date/Time	This field will capture "Actual Admin Date/Time" entered in the "sample management" screen. ph_sampling_details.actual_admin	Yes	Auto display
4.	Reporting	Click on the 'Details' hyperlink to start the reporting. A pop up screen will be prompted.	Yes	Auto display
5.	Result Value (Pre Sample, Post Sample and Random Sample)	These fields will capture value entered in the reporting screen (Result Value). If the order contains only one sample, the order field will be 'N/A'	Yes	Auto display
6.	Toxic	This field will capture value selected in the reporting screen (Toxic).	Yes	Auto display
7.	Recommendation Type	This field will capture value selected in the reporting screen (Recommendation Type).	Yes	Auto display
8.	Recommendation Accepted	<ul style="list-style-type: none"> - This field will only appear after user click on 'Confirm' (Status = TDM Resulted). - Selection of Yes or No. 	Yes	Auto display
Reporting				
9.	Pharmacist Note	- This field will contains 'Recommendation Type' value	No	Text Field



No.	Name	Description	Mandatory	Type
		and this also is an enterable free text field with capacity of 1000 characters maximum - This field will combine 'Recommendation Type' from all selected Order.		
10.	Remarks	A free text field to enter the text with maximum of 500 characters capacity	No	Text Field
11.	TDM Service Charge	A numeric field to enter the TDM Service charge	No	Text Field
12.	Total Cost of Analysis	This field will show cost of analysis which is set in TDM guideline master based on selected drug. (if there are more than one drugs, will show total of the analysis cost)	No	Text Field



3.5.3.3 TDM Result Reporting Pop up Screen

3.5.3.3.1 Screen Design

ID	TDMRR.SD3
Description	TDM Result Reporting Pop up Screen
Diagram	
Notes	<ul style="list-style-type: none"> • This is pop up screen appears upon clicking on “Details” hyperlink in Reporting tab at the reporting main screen. • Result value “pre, post or random” is based on the selected ‘sample type’ during order transaction. • Click on ‘Details’ hyperlink will pop up screen with details information about the sample. • Calculator section will list down the calculator type from the TDM guideline. • Click on the calculator name, it will expand/pop up the screen of calculator. Calculator appears based on the guideline setup. If the drug don’t have calculator, then no calculator pop up screen will appear and the ‘Pharmacokinetic Profile’ will be free text.
Cross References	None

3.5.3.3.2 Application Business Rules

None



3.5.3.3.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
Reporting Details				
1.	Result Value (Pre Sample, Post Sample or Random)	A numeric field to enter the result value.	No	Text Field
2.	Resulted by Value (Pre Sample, Post Sample or Random)	A free text field to enter the text with capacity maximum of 100 characters	No	Text Field
3.	Calculator	<ul style="list-style-type: none"> List name of calculator captured from TDM Guideline for the selected drug. (based on the guideline setup) Click on the calculator name, screen for calculator will be prompted. Result from the calculation will be copied over to the "Pharmacokinetics Profile" field. 	No	Text Field
4.	Pharmacokinetics Profile	<p>This field will capture result value from the calculator. This is non-editable field. Format for each result calculation define under the calculator screen.</p> <p>* If the drug don't have calculator, the 'Pharmacokinetic Profile' will be free text.</p>	No	Text Field
5.	Recommendation Type	<p>A drop down combo box with values populated from the master data,</p> <p>The value as below:</p> <ol style="list-style-type: none"> 1) Maintain the Dose 2) Withhold the Dose 3) Increase the Dose 4) Reduce the Dose 5) Stop the Dose 6) Refer to Pharmacist Notes <p>Data selected in the 'Recommendation Type' field will be display in the 'Pharmacist Note' field.</p>	Yes	Drop Down
6.	Toxic	Selection of Yes or No	No	Radio button



3.5.3.4 TDM Result Reporting (Sampling Result Details Screen)

3.5.3.4.1 Screen Design

ID	TDMRR.SD3
Description	Sampling Result Details Screen
Diagram	
<p>The screenshot shows a pop-up window titled 'DETAILS'. It contains the following information:</p> <ul style="list-style-type: none"> Reference Range : ASTHMA /COPD : 10 ? 20 mcg /ml APNEA / BRADYCARDIA IN NEONATES : 5 ? 15 mcg /ml VENTILATOR WEANING IN NEONATES : 5 ? 20 mcg /ml Sample Collected Date/Time : 06/04/2018 05:36 Actual Drug Admin Date/Time : 06/04/2018 05:36 Out Source : NO 	
Description	<ul style="list-style-type: none"> Each sample detail contains information captured from sample management screen. This pop up screen is for view purpose only. One sample type will only have one "Details" hyperlink. Eg: Pre Sample – Details Post Sample – Details Random Sample – Details
Cross References	None

3.5.3.4.2 Application Business Rules

None

3.5.3.4.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Reference Range	Values come from ph_tdm_guideline.range_from and range_to	Yes	Auto display
2.	Sample Collected Date/Time	Values come from ph_sampling_details.collection_date_time	Yes	Auto display
3.	Actual Drug Admin Date/Time	Values come from ph_sampling_details.actual_admin	Yes	Auto display
4.	Outsource	Values come from ph_sampling_details.outsource	Yes	Auto display



3.5.3.5 Calculator For Aminoglycoside Pre

3.5.3.5.1 Screen Design

ID	CAL1
Description	TDM Calculator screen (Aminoglycoside Pre)
Diagram	
Notes	<ul style="list-style-type: none"> • This pop up screen appears upon clicking on “calculator” hyperlink at the Reporting screen. • Click on ‘Close’ button to close the screen and go back to the reporting screen. • Field with yellow colour is an auto calculated field based on formula has been set.
Cross References	None

3.5.3.5.2 Application Business Rules

No.	Name	Description
1.	Pharmacokinetics Profile	Result format to be displayed in ‘Pharmacokinetics Profile’ field as below: 1) Total Dose 2) Creatinine Clearance 3) pKe 4) t1/2 5) Expected Cmax 6) Expected Cmin 7) Pre Level Expected Cmax
2.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field



3.5.3.5.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the below: 1) Actual (Default value) 2) Adjusted 3) Ideal	Yes	Drop Down
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 45.5$ 3) Adjusted Body Weight: Ideal Body Weight + $[0.4 \times (\text{Actual Body Weight} - \text{Ideal Body Weight})]$	Yes	Auto calculated
3.	Dose	Free text (user key in) (3 decimal)	No	Free Text
4.	Interval	Free text (user key in) (3 decimal)	No	Free Text
5.	Total dose	Formula as below: $= (24 / \text{Interval}(3)) \times \text{Dose}$	Yes	Auto calculated
6.	Pre level	Free text (user key in) (3 decimal)	No	Free Text
7.	Serum Creatinine	Free text (user key in) (3 decimal)	No	Free Text
8.	Creatinine Clearance	Formula as below: $N(13) \times (140 - \text{Age}) \times \text{Weight}(1) / \text{Serum Creatinine}(6)$ where N = see No. 13) (2 decimal)	Yes	Auto calculated
9.	Vd	Free text (user key in) (3 decimal)	No	Free Text
10.	pKe	Formula as below: $(0.00239 \times \text{Creatinine Clearance}(7)) + 0.014$	Yes	Auto calculated
11.	t1/2	Formula as below: $0.693 / \text{pKe}(9)$	Yes	Auto



				calculated
12.	Expected Cmax	Formula as below: $Dose(2) / (Weight(1) * Vd(8) * (1 - \exp(-pKe(9) * Interval(3))))$	Yes	Auto calculated
13.	Expected Cmin	Formula as below: $\exp(-pKe(9) * Interval(3)) * Expected\ Cmax(11)$	Yes	Auto calculated
14.	N	Male = 1.23 ; Female = 1.04	Yes	Others
To calculate Expected Cmax if assuming Expected Cmin = pre level result				
15.	Expected Cmin	Free text (user key in) (3 decimal)	No	Free Text
16.	Expected Cmax	Formula as below: $Expected\ Cmin / (\exp(-pKe * Interval\ T))$	Yes	Auto calculated



3.5.3.6 Calculator For Aminoglycoside Post

3.5.3.6.1 Screen Design

ID	CAL2
Description	TDM Calculator screen (Aminoglycoside Post)
Diagram	
Notes	<ul style="list-style-type: none"> • This pop up screen appears upon clicking on “calculator” hyperlink at the Reporting screen. • Click on ‘Close’ button to close the screen and go back to the reporting screen. • Field with yellow colour is an auto calculated field based on formula has been set.
Cross References	None

3.5.3.6.2 Application Business Rules

No.	Name	Description
1.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
2.	Pharmacokinetics Profile	Result format to be displayed in ‘Pharmacokinetics Profile’ field as below: 1) Total Dose 2) Creatinine Clearance 3) Vd 4) pKe 5) t ¹ / ₂ 6) Cmax 7) Cmin 8) Expected Cmax 9) New Dose 10) Expected Cmin



3.5.3.6.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the below: 1) Actual (Default value) 2) Adjusted 3) Ideal	Yes	Drop Down
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 45.5$ 3) Adjusted Body Weight: Ideal Body Weight + $[0.4 \times (\text{Actual Body Weight} - \text{Ideal Body Weight})]$	Yes	Auto calculated
3.	Dose	Free text (user key in)	No	Free Text
4.	Interval	Free text (user key in)	No	Free Text
5.	Total dose	$= (24 / \text{Interval}, T(3)) \times \text{Dose}$	Yes	Auto calculated
6.	t	Free text (user key in) (2 decimal)	No	Free Text
7.	Post level	Free text (user key in) (2 decimal)	No	Free Text
8.	Serum Creatinine	Free text (user key in) (2 decimal)	Yes	Auto calculated
9.	Creatinine Clearance	$N(22) \times (140 - \text{Age}) \times \text{Weight}(1) / \text{Serum Creatinine}(7)$ where N = see No. 22	No	Free Text
10.	Vd	$\text{Dose}(2) / ((\text{Weight}(1) \times \text{Cmax}(12)) \times (1 - \text{EXP}((-p\text{Ke}(10) \times \text{Interval}, T(3))))))$	Yes	Auto calculated
11.	pKe (population)	$(0.00239 \times \text{Creatinine Clearance}(8)) + 0.014$	Yes	Auto calculated



12.	t1/2	$0.693 / pKe(10)$	Yes	Auto calculated
13.	Cmax	$Post\ level(6) * EXP((pKe(10) * t(5)))$	Yes	Auto calculated
14.	Cmin	$Cmax(12) * EXP((-pKe(10) * Interval, T(3)))$	Yes	Others
15.	New Suggested Dose (NSD)	Free text (user key in)	No	Free Text
16.	New Interval (hr) (NI)	Free text (user key in)	Yes	Auto calculated
17.	Expected Cmax	$NSD(14) / ((Weight(1) * Vd(9)) * (1 - Exp((-pKe(10) * New Interval, NI(15))))$	Yes	Auto calculated
18.	Expected Cmin	$Exp((-pKe(10) * New Interval, NI(15))) * Expected Cmax(16)$	Yes	Auto calculated
19.	Desired Cmax	Free text (user key in)	No	Free Text
20.	New Interval (hr) (NIT)	Free text (user key in)	No	Free Text
21.	New Dose (ND)	$Desired\ Cmax(18) * Weight(1) * Vd(9) * (1 - Exp(-pKe(10) * New Interval, NIT(19)))$	Yes	Auto calculated
22.	Expected Cmin	$Desired\ Cmax(18) * Exp((-pKe(10) * New Interval, NIT(19)))$	Yes	Auto calculated
23.	N	Male = 1.23 ; Female = 1.04	Yes	Others



3.5.3.7 Calculator For Aminoglycoside Pre & Post

3.5.3.7.1 Screen Design

ID	CAL3
Description	TDM Calculator screen (Aminoglycoside Pre & Post)
<p>Diagram</p>	
Notes	<ul style="list-style-type: none"> • This pop up screen appears upon clicking on “calculator” hyperlink at the Reporting screen. • Click on ‘Close’ button to close the screen and go back to the reporting screen. • Field with yellow colour is an auto calculated field based on formula has been set.
Cross References	None

3.5.3.7.2 Application Business Rules

No.	Name	Description
1.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
2.	Pharmacokinetics Profile	Result format to be displayed in ‘Pharmacokinetics Profile’ field as below: <ol style="list-style-type: none"> 1) Total Dose 2) Creatinine Clearance 3) Ke 4) Vd 5) t_{1/2} 6) Cmax



No.	Name	Description
		7) Cmin 8) Expected Cmax 9) Expected Cmin 10) New Dose 11) Expected Cmin

3.5.3.7.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the below: 1) Actual (Default value) 2) Adjusted 3) Ideal	Yes	Drop Down
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150) / 30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150) / 30] \times 12 \times 2.3\} + 45.5$ 3) Adjusted Body Weight: $\text{Ideal Body Weight} + [0.4 \times (\text{Actual Body Weight} - \text{Ideal Body Weight})]$	Yes	Auto calculated
3.	Dose	Free text (user key in)	No	Free Text
4.	Interval	Free text (user key in)	No	Free Text
5.	Total dose	$= (24 / \text{Interval}(3)) \times \text{Dose}(2)$	Yes	Auto calculated
6.	t	Free text (user key in)	No	Free Text
7.	t2-t1	Free text (user key in)	No	Free Text
8.	Pre level	Free text (user key in)	No	Free Text
9.	Post level	Free text (user key in)	No	Free Text



10.	Serum Creatinine	Free text (user key in)	No	Free Text
11.	Creatinine Clearance	$N(24) \times (140 - \text{Age}) \times \text{Weight}(1) / \text{Serum Creatinine}(9)$ where N = see No. 24	Yes	Auto calculated
12.	Ke	$(\text{LN}(\text{Post level}(8)) - \text{LN}(\text{Pre Level}(7))) / (\text{Interval}(3) - (t2-t1)(6))$	Yes	Auto calculated
13.	Vd	$\text{Dose}(2) / (\text{Weight}(1) * \text{Cmax}(14) * (1 - \text{EXP}(-\text{Ke}(11) * \text{Interval}(3))))$	Yes	Auto calculated
14.	t1/2	$0.693 / \text{Ke}(11)$	Yes	Auto calculated
15.	Cmax	$\text{Post level}(8) * \text{EXP}((\text{Ke}(11) * t(5)))$	Yes	Auto calculated
16.	Cmin	$\text{Cmax}(14) * \text{EXP}((- \text{Ke}(11) * \text{Interval}(3)))$	Yes	Auto calculated
17.	New Suggested Dose (NSD)	Free text (user key in)	No	Free Text
18.	New Interval (hr) (NI)	Free text (user key in)	No	Free Text
19.	Expected Cmax	$\text{NSD}(16) / (\text{Weight}(1) * \text{Vd}(12) * (1 - \text{Exp}(-\text{Ke}(11) * \text{New Interval,NI}(17))))$	Yes	Auto calculated
20.	Expected Cmin	$\text{Exp}((- \text{Ke}(11) * \text{New Interval,NI}(17))) * \text{Expected Cmax}(18)$	Yes	Auto calculated
21.	Desired Cmax	Free text (user key in)	No	Free Text
22.	New Interval (hr) (NIT)	Free text (user key in)	No	Free Text
23.	New Dose (ND)	$\text{Desired Cmax}(20) * \text{Weight}(1) * \text{Vd}(12) * (1 - \text{Exp}(-\text{Ke}(11) * \text{New Interval,NIT}(21)))$	Yes	Others
24.	Expected Cmin	$\text{Desired Cmax}(20) * \text{Exp}((- \text{Ke}(11) * \text{New Interval,NIT}(21)))$	Yes	Auto calculated
25.	N	Male = 1.23 ; Female = 1.04	Yes	Others



3.5.3.8 Calculator For Aminoglycoside Post1 & Post6

3.5.3.8.1 Screen Design

ID	CAL4
Description	TDM Calculator screen (Aminoglycoside Post1 & Post6)
<p>Diagram</p>	
Notes	<ul style="list-style-type: none"> • This pop up screen appears upon clicking on “calculator” hyperlink at the Reporting screen. • Click on ‘Close’ button to close the screen and go back to the reporting screen. • Field with yellow colour is an auto calculated field based on formula has been set.
Cross References	None

3.5.3.8.2 Application Business Rules

No.	Name	Description
1.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
2.	Pharmacokinetics Profile	Result format to be displayed in ‘Pharmacokinetics Profile’ field as below: <ol style="list-style-type: none"> 1) Total Dose : 0 mg/daily 2) Creatinine Clearance : 0 ml/min 3) To calculate Vd , Ke and t1/2 Ke : 0 L/Kg Vd : 0 hr-1 t½ : 0 hour Cmax : 0 mcg/ml



No.	Name	Description
		<p>Cmin : 0 mcg/ml</p> <p>4) To calculate expected Cmin and Cmax based on new suggested dose: Expected Cmax : 0 mcg/ml Expected Cmin : 0 mcg/ml</p> <p>5) To calculate new dose and Cmin based on desired Cmax: New Dose : 0 mg Expected Cmin : 0 mcg/ml</p>

3.5.3.8.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	<p>A drop down field to indicate the patient body weight based on the below:</p> <p>1) Actual (Default value) 2) Adjusted 3) Ideal</p>	Yes	Drop Down
2.	Body Weight 2	<p>Display patient body weight based on selected body weight 1:</p> <p>1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner</p> <p>2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150) / 30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150) / 30] \times 12 \times 2.3\} + 45.5$</p> <p>3) Adjusted Body Weight: $\text{Ideal Body Weight} + [0.4 \times (\text{Actual Body Weight} - \text{Ideal Body Weight})]$</p>	Yes	Auto calculated
3.	Dose	Free text (user key in)	No	Free Text
4.	Interval	Free text (user key in)	No	Free Text
5.	Total dose	$= (24 / \text{Interval}(3)) * \text{Dose}(2)$	Yes	Auto calculated
6.	t	Free text (user key in)	No	Free



				Text
7.	T6-t1	Free text (user key in)	No	Free Text
8.	Post 1 level	Free text (user key in)	No	Free Text
9.	Post 6 level	Free text (user key in)	No	Free Text
10.	Serum Creatinine	Free text (user key in)	No	Free Text
11.	Creatinine Clearance	$N(24) \times (140 - \text{Age}) \times \text{Weight}(1) / \text{Serum Creatinine}(9)$ where N = see No. 24	Yes	Auto calculated
12.	Ke	$(\text{LN}(\text{Post 1 level}(7)) - \text{LN}(\text{Post 6 Level}(8))) / ((t6-t1)(6))$	Yes	Auto calculated
13.	Vd	$\text{Dose} / (\text{Weight}(1) * \text{Cmax}(14) * (1 - \text{EXP}(-\text{Ke}(11) * \text{Interval}(3))))$	Yes	Auto calculated
14.	t1/2	$0.693 / \text{Ke}(11)$	Yes	Auto calculated
15.	Cmax	$\text{Post 1 level}(7) * \text{EXP}((\text{Ke}(11) * t(5)))$	Yes	Auto calculated
16.	Cmin	$\text{Cmax}(14) * \text{EXP}((- \text{Ke}(11) * \text{Interval}(3)))$	Yes	Auto calculated
17.	New Suggested Dose (NSD)	Free text (user key in)	No	Free Text
18.	New Interval (hr) (NI)	Free text (user key in)	No	Free Text
19.	Expected Cmax	$\text{NSD}(16) / (\text{Weight}(1) * \text{Vd}(12) * (1 - \text{Exp}(-\text{Ke}(11) * \text{New Interval,NI}(17))))$	Yes	Auto calculated
20.	Expected Cmin	$\text{Exp}((- \text{Ke}(11) * \text{New Interval,NI}(17))) * \text{Expected Cmax}(18)$	Yes	Auto calculated
21.	Desired Cmax	Free text (user key in)	No	Free Text
22.	New Interval (hr) (NIT)	Free text (user key in)	No	Free Text
23.	New Dose (ND)	$\text{Desired Cmax}(20) * \text{Weight}(1) * \text{Vd}(12) * (1 - \text{Exp}(-\text{Ke}(11) * \text{New Interval,NIT}(21)))$	Yes	Others
24.	Expected Cmin	$\text{Desired Cmax}(20) * \text{Exp}((- \text{Ke}(11) * \text{New Interval,NIT}(21)))$	Yes	Auto calculated



25.	N	Male = 1.23 ; Female = 1.04	Yes	Others
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3.5.3.9 Calculator For Carbamazepine

3.5.3.9.1 Screen Design

ID	CAL5
Description	TDM Calculator screen (Carbamazepine)

Diagram Monotherapy

Polytherapy

Notes

- This pop up screen appears upon clicking on "calculator" hyperlink at the Reporting screen.



	<ul style="list-style-type: none"> Click on 'Close' button to close the screen and go back to the reporting screen. Field with yellow colour is an auto calculated field based on formula has been set. There are to tab/option can be select: <ul style="list-style-type: none"> Monotherapy Polytherapy
Cross References	None

3.5.3.9.2 Application Business Rules

No.	Name	Description
1.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
2.	Pharmacokinetics Profile result if Monotherapy selected	Result format to be displayed in 'Pharmacokinetics Profile' field as below: Monotherapy :-- <ol style="list-style-type: none"> 1) Clearance CP measured 2) \approx : 0 L/hr 3) Clearance (Population) 4) \approx : 0 L/hr 5) Vd 6) Ke 7) $t_{1/2}$ 8) Cpss 9) New Dose 10) Expected Cp
3.	Pharmacokinetics Profile result if Polytherapy selected	Result format to be displayed in 'Pharmacokinetics Profile' field as below: Polytherapy :-- <ol style="list-style-type: none"> 1) Clearance CP measured 2) \approx : 0 L/hr 3) Clearance (Population) 4) \approx : 0 L/hr 5) Vd 6) Ke 7) $t_{1/2}$ 8) Cpss 9) New Dose 10) Expected Cp

3.5.3.9.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the	Yes	Drop Down



		below: 1) Actual (Default value) 2) Adjusted 3) Ideal		
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 45.5$ 3) Adjusted Body Weight: Ideal Body Weight + [0.4 x (Actual Body Weight – Ideal Body Weight)]	Yes	Auto calculated
3.	Dose	Free text (user key in)	No	Free Text
4.	Interval	Free text (user key in)	No	Free Text
5.	Total dose	$= (24 / \text{Interval}(3)) * \text{Dose}(2)$	Yes	Auto calculated
6.	Cp measured	Free text (user key in)	No	Free Text
7.	Clearance Cp measured	$((S) (F) (\text{Total Dose } (4))) / \text{Cp measured } (5)$	Yes	Auto calculated
8.	Clearance (pop)	$0.064 * \text{Body Weight } (1)$	Yes	Auto calculated
9.	Cl	Free text (user key in)	No	Free Text
10.	Cpss	$((S) (F) (\text{Total Dose } (4) / 24 \text{ hr})) * T / \text{Cl } (8) \quad T = 1 \text{ day}$	Yes	Auto calculated
11.	Cp desired	Free text (user key in)	No	Free Text
12.	Cl	Free text (user key in)	No	Free Text
13.	New Dose	$(\text{Clearance } (12)) (\text{Cp desired } (10)) (\text{Interval}) / (S) (F) \text{ where Interval is default as 1 day}$	Yes	Auto calculated



14.	Cl	Free text (user key in)	No	Free Text
15.	Suggested dose	Free text (user key in)	Yes	Auto calculated
16.	Expected Cp	$((S) (F) (Dose (15))) / (Clearance (14))$	Yes	Auto calculated
17.	Cl	Free text (user key in)	No	Free Text
18.	Vd	$1.4 * Body weight (1)$	Yes	Auto calculated
19.	Ke	$Cl (17) / Vd (18)$	Yes	Auto calculated
20.	t1/2	$0.693 / Ke (19)$	Yes	Auto calculated
21.	S	1	No	Others
22.	F	0.8	No	Others



3.5.3.10 Calculator For Digoxin

3.5.3.10.1 Screen Design

ID	CAL6
Description	TDM Calculator screen (Digoxin)

Diagram

Without CHF and not renally impaired

The screenshot shows the 'CALCULATOR FOR DIGOXIN' interface. At the top, there are input fields for 'Body Weight' (set to 60 kg), 'Total Dose', 'Serum Creatinine', and 'Creatinine Clearance' (set to 0 ml/min). Below these are checkboxes for 'To calculate CI based on Patient's Factor(s)', 'To calculate Vd based on Patient's Factor(s)', 'To calculate Ke and t1/2 based on CI', 'To calculate Loading Dose(LD) based on Vd and Cp desired', 'To calculate Cpss level based on current dose and CI', and 'To calculate New Maintenance Dose(NMD) based on CI and Cp desired'. The 'Without CHF and not renally impaired' tab is selected. The interface includes various calculation notes and a 'New Suggested Dose(NSD)' section at the bottom.

Without CHF and renally impaired

This screenshot is identical to the one above, but with the 'Without CHF and renally impaired' tab selected. The 'Creatinine Clearance' field is now set to 0 ml/min, and the 'Expected Cp' field at the bottom is set to 0.0000 mg/L.



With CHF and not renally impaired

CALCULATOR FOR DIGOXIN

Body Weight **Actual** Body Weight kg

Total Dose mg/day

Serum Creatinine umol/L Creatinine Clearance ml/min

F

Note : Tablet = 0.7; Elixir = 0.8; Soft Gelatin capsule / Injection = 1

Select Patient's Condition

Without CHF and not renally impaired Without CHF and renally impaired With CHF and not renally impaired With CHF and renally impaired

Cp measured ng/ml

Note : mcg/ml = mg/L, ng/ml = 10⁻³ mcg/ml = 10⁻³ mg/L

~ mg/L

To calculate CI based on Patient's Factor(s)

Factor CI

Note : None = 1 Quinidine= 0.5 Amiodarone=0.50 Verapamil=0.75 Clinically hypothyroid=0.7 Clinically hyperthyroid=1.3

Clearance CP measured L/day

Clearance (Population) L/day

To calculate Vd based on Patient's Factor(s)

Factor Vd

Note : None = 1 Quinidine= 0.7 Clinically hypothyroid=0.7 Clinically hyperthyroid=1.3

Vd (pop) L

To calculate Ke and t1/2 based on CI

CI L/day

Ke hr⁻¹

t 1/2 hour

To calculate Loading Dose(LD) based on Vd and Cp desired

Cp Desired ng/ml

LD mg/day

To calculate Cps level based on current dose and CI

CI L/day

Cps mg/L

~ ng/ml

To calculate New Maintenance Dose(NMD) based on CI and Cp desired

CI L/day

Cp Desired ng/ml

New Dose mg/day

To calculate Expected Cp based on CI and New Suggested Dose(NSD)

CI L/day

New Suggested dose mg/day

Expected Cp mg/L ~ ng/ml

With CHF and renally impaired

CALCULATOR FOR DIGOXIN

Body Weight **Actual** Body Weight kg

Total Dose mg/day

Serum Creatinine umol/L Creatinine Clearance ml/min

F

Note : Tablet = 0.7; Elixir = 0.8; Soft Gelatin capsule / Injection = 1

Select Patient's Condition

Without CHF and not renally impaired Without CHF and renally impaired With CHF and not renally impaired With CHF and renally impaired

Cp measured ng/ml

Note : mcg/ml = mg/L, ng/ml = 10⁻³ mcg/ml = 10⁻³ mg/L

~ mg/L

To calculate CI based on Patient's Factor(s)

Factor CI

Note : None = 1 Quinidine= 0.5 Amiodarone=0.50 Verapamil=0.75 Clinically hypothyroid=0.7 Clinically hyperthyroid=1.3

Clearance CP measured L/day

Clearance (Population) L/day

To calculate Vd based on Patient's Factor(s)

Factor Vd

Note : None = 1 Quinidine= 0.7 Clinically hypothyroid=0.7 Clinically hyperthyroid=1.3

Vd (pop) L

To calculate Ke and t1/2 based on CI

CI L/day

Ke hr⁻¹

t 1/2 hour

To calculate Loading Dose(LD) based on Vd and Cp desired

Cp Desired ng/ml

LD mg/day

To calculate Cps level based on current dose and CI

CI L/day

Cps mg/L

~ ng/ml

To calculate New Maintenance Dose(NMD) based on CI and Cp desired

CI L/day

Cp Desired ng/ml

New Dose mg/day

To calculate Expected Cp based on CI and New Suggested Dose(NSD)

CI L/day

New Suggested dose mg/day

Expected Cp mg/L ~ ng/ml

Notes

- This pop up screen appears upon clicking on "calculator" hyperlink at the Reporting screen.
- Click on 'Close' button to close the screen and go back to the reporting screen.
- Field with yellow colour is an auto calculated field based on formula has been set.
- There are to tab/option can be select:



	<ul style="list-style-type: none"> - Without CHF and not renally impaired - Without CHF and renally impaired - With CHF and not renally impaired - With CHF and renally impaired
Cross References	None

3.5.3.10.2 Application Business Rules

No.	Name	Description
1.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
2.	Pharmacokinetics Profile result if Without CHF and not renally impaired selected	<p>Result format to be displayed in 'Pharmacokinetics Profile' field as below:</p> <ol style="list-style-type: none"> 1) Creatinine Clearance : 0 ml/min 2) \approx : 0 ng/ml 3) Clearance CP measured : 0 L/day 4) Clearance (Population) : 0 L/day 5) Vd : 0 L 6) Ke : 0 hr⁻¹ 7) t_{1/2} : 0 hour 8) LD : 0 mg/day 9) Cpss : 0 mg/L 10) \approx : 0 ng/ml 11) New Dose : 0 mg/day 12) Expected Cp : 0 mg/L 13) \approx : 0 ng/ml
3.	Pharmacokinetics Profile result if Without CHF and renally impaired selected	<p>Result format to be displayed in 'Pharmacokinetics Profile' field as below:</p> <ol style="list-style-type: none"> 1) Creatinine Clearance : 0 ml/min 2) \approx : 0 ng/ml 3) Clearance CP measured : 0 L/day 4) Clearance (Population) : 0 L/day 5) Vd : 0 L 6) Ke : 0 hr⁻¹ 7) t_{1/2} : 0 hour 8) LD : 0 mg/day 9) Cpss : 0 mg/L 10) \approx : 0 ng/ml 11) New Dose : 0 mg/day 12) Expected Cp : 0 mg/L 13) \approx : 0 ng/ml
4.	Pharmacokinetics Profile result if With CHF and not renally impaired selected	<p>Result format to be displayed in 'Pharmacokinetics Profile' field as below:</p> <ol style="list-style-type: none"> 1) Creatinine Clearance : 0 ml/min



No.	Name	Description
		2) \approx : 0 ng/ml 3) Clearance CP measured : 0 L/day 4) Clearance (Population) : 0 L/day 5) Vd : 0 L 6) Ke : 0 hr-1 7) $t_{1/2}$: 0 hour 8) LD : 0 mg/day 9) Cpss : 0 mg/L 10) \approx : 0 ng/ml 11) New Dose : 0 mg/day 12) Expected Cp : 0 mg/L 13) \approx : 0 ng/ml
5.	Pharmacokinetics Profile result if With CHF and renally impaired selected	Result format to be displayed in 'Pharmacokinetics Profile' field as below: 1) Creatinine Clearance : 0 ml/min 2) \approx : 0 ng/ml 3) Clearance CP measured : 0 L/day 4) Clearance (Population) : 0 L/day 5) Ke : 0 hr-1 6) $t_{1/2}$: 0 hour 7) LD : 0 mg/day 8) Cpss : 0 mg/L 9) \approx : 0 ng/ml 10) New Dose : 0 mg/day 11) Expected Cp : 0 mg/L 12) \approx : 0 ng/ml

3.5.3.10.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the below: 1) Actual (Default value) 2) Adjusted 3) Ideal	Yes	Drop Down
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm})-150)/30] \times 12 \times 2.3\} + 50$	Yes	Auto calculated



		<p>ii. Female= $\{[(\text{Height}(\text{cm})-150)/30] \times 12 \times 2.3\} + 45.5$</p> <p>3) Adjusted Body Weight: Ideal Body Weight + [0.4 x (Actual Body Weight – Ideal Body Weight)]</p>		
3.	F	Free text (user key in)	No	Free Text
4.	Total dose	Free text (user key in)	No	Free Text
5.	Serum Creatinine	Free text (user key in)	No	Free Text
6.	Creatinine Clearance	$N \times (140 - \text{Age}) \times \text{Weight} / \text{Serum Creatinine}$ where N = see No. 25	Yes	Auto calculated
7.	Cp measured	Free text (user key in)	No	Free Text
8.	Cp measured (mg/L)	$\text{Cp measured (6)} \times 10^{-3}$	Yes	Auto calculated
9.	Factor Cl	Free text (user key in)	No	Free Text
10.	Factor Vd	Free text (user key in)	No	Free Text
11.	Clearance Cp measured	$\text{Factor Cl (7)} \times ((\text{S (F(2)) (Total Dose (3))}) / \text{Cp measured (6A)})$	Yes	Auto calculated
12.	Clearance (pop)	$\text{Factor Cl (7)} \times (((0.33 \times \text{Body Weight (1)} + (0.9 \times \text{CrCl (5)})) \times 1440) / 1000$	Yes	Auto calculated
13.	Vd	$\text{Factor Vd (8)} \times ((3.8 \times \text{Body Weight (1)} + (3.1 \times \text{CrCl (5)}))$	Yes	Auto calculated
14.	Cpdesired	Free text (user key in)	No	Free Text
15.	LD	$\text{Vd (11)} \times (\text{Cpdesired (12)} \times 10^{-3} / \text{F (2)})$	Yes	Auto calculated
16.	Cl	Free text (user key in)	No	Free Text
17.	Cpss	$(((\text{S (F(2)) (Total Dose (3)) } / \text{Cl (14)}) \times 1000$	Yes	Auto calculated
18.	Cp desired	Free text (user key in)	No	Free Text
19.	Cl	Free text (user key in)	No	Free Text



20.	New Dose	$(\text{Clearance (17)}) (\text{Cp desired (16)} * 10^{-3}) (\text{Interval}) / (\text{S}) (\text{F(2)})$ where Interval is default as 1 day	Yes	Auto calculated
21.	CI	Free text (user key in)	No	Others
22.	Suggested dose	Free text (user key in)	No	Others
23.	Expected Cp	$((\text{S}) (\text{F(2)}) (\text{Dose (20)})) / (\text{Clearance (19)})$	Yes	Auto calculated
24.	CI	Free text (user key in)	No	Free Text
25.	Ke	$\text{CI (22)} / \text{Vd (11)}$	Yes	Auto calculated
26.	t1/2	$0.693 / \text{Ke (23)}$	Yes	Auto calculated
27.	N	Male = 1.23 ; Female = 1.04	No	Others



3.5.3.11 Calculator For Phenobarbitone

3.5.3.11.1 Screen Design

ID	CAL5
Description	TDM Calculator screen (Phenobarbitone)
<p>Diagram</p>	
Notes	<ul style="list-style-type: none"> • This pop up screen appears upon clicking on “calculator” hyperlink at the Reporting screen. • Click on ‘Close’ button to close the screen and go back to the reporting screen. • Field with yellow colour is an auto calculated field based on formula has been set.
Cross References	None

3.5.3.11.2 Application Business Rules

No.	Name	Description
1.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
2.	Pharmacokinetics Profile result	Result format to be displayed in ‘Pharmacokinetics Profile’ field as below: <ol style="list-style-type: none"> 1) Clearance CP measured : 0 L/day 2) \approx : 0 L/hr 3) Clearance (Population) : 0 L/day 4) \approx : 0 L/hr 5) Vd : 0 L 6) Ke : 0 hr-1 7) $t_{1/2}$: 0 hour



No.	Name	Description
		8) Cpss : 0 mcg/ml 9) New Dose : 0 mg/day 10) Expected Cp : 0 mcg/ml

3.5.3.11.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the below: 1) Actual (Default value) 2) Adjusted 3) Ideal	Yes	Drop Down
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150) / 30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150) / 30] \times 12 \times 2.3\} + 45.5$ 3) Adjusted Body Weight: $\text{Ideal Body Weight} + [0.4 \times (\text{Actual Body Weight} - \text{Ideal Body Weight})]$	Yes	Auto calculated
3.	Dose	Free text (user key in)	No	Free Text
4.	Interval	Free text (user key in)	No	Free Text
5.	Total dose	Free text (user key in)	No	Free Text
6.	Cp measured	Free text (user key in)	No	Free Text
7.	Clearance Cp measured	$((S (22)) (F) (\text{Total Dose} (4))) / \text{Cp measured} (5)$	Yes	Auto calculated
8.	Constant	Free text (user key in)	No	Free Text
9.	Clearance (pop)	$(\text{Constant} (7) * \text{Body Weight} (1)) / 1000$	Yes	Auto calculated
10.	Cl	Free text (user key in)	Yes	Auto



				calculated
11.	Cpss	$((S(22)) (F) (Total\ Dose\ (4) / 24\ hr)) / CI(9)$	Yes	Auto calculated
12.	Cp desired	Free text (user key in)	No	Free Text
13.	CI	Free text (user key in)	No	Free Text
14.	New Dose	$(Clearance(12) (Cp\ desired(10)) (Interval) / (S(22)) (F)$ where Interval is default as 1 day (times 1 day not 24hrs)	Yes	Auto calculated
15.	CI	Free text (user key in)	No	Free Text
16.	Suggested dose	Free text (user key in)	No	Free Text
17.	Expected Cp	$((S(22)) (F) (Dose(15))) / (Clearance(14))$	Yes	Auto calculated
18.	CI	Free text (user key in)	Yes	Auto calculated
19.	Constant	Free text (user key in)	No	Free Text
20.	Vd	Constant (18) * Body weight (1)	Yes	Auto calculated
21.	Ke	CI (17) / Vd (19)	Yes	Auto calculated
22.	t _{1/2}	0.693 / Ke (20)	Yes	Auto calculated
23.	S	Free text (user key in)	No	Others
24.	F	0.95	No	Others



3.5.3.12 Calculator For Phenytoin

3.5.3.12.1 Screen Design

ID	CAL5
Description	TDM Calculator screen (Phenytoin)

Diagram
Without Hypoalbuminemia

Select Patients Condition

Without Hypoalbuminemia **Hypoalbuminemia** Hypoalbuminemia with ESRF

Cp measured mcg/ml
Note: mcg/ml = mg/L

Vmax (Measured) 0.000 mg/day

To calculate Vmax (population)

Constant Vmax mg/kg/day
Note: Adult = 5-15 mg/kg/day, 6mo-6yrs = 10-13 mg/kg/day, 7yrs-16yrs = 8-10 mg/kg/day

Vmax (pop) 0.000 mg/day

To calculate Vd, Ke, t1/2 and CI based on Vmax

Constant Vd L/kg
Note: Adult: 0.65-0.74 L/kg, Children: 0.7-1.0 L/kg

Vmax mg/day

Vd 0.000 L CI 0.000 L/hr

Ke 0.000 hr⁻¹ t1/2 0.000 hour

To calculate Cps level based on Vmax

Vmax mg/day

Cps 0.000 mcg/ml
Note: mcg/ml = mg/L

To calculate Loading Dose (LD) based on Cp desired

Cp Desired mcg/ml
Note: mcg/ml = mg/L

LD 0.000 mg

To calculate Incremental Loading Dose (ILD) based on Cp desired and Cp measured

Cp Desired mcg/ml
Note: mcg/ml = mg/L

ILD 0.000 mg

To calculate New Maintenance Dose (NMD) based on Vmax and Cp desired

Vmax mg/day
Note: mcg/ml = mg/L

Cp Desired mcg/ml

New Dose 0.000 mg/day

To calculate therapy withold period (T) when level is toxic

Vmax mg/day
Note: mcg/ml = mg/L

Cp Desired mcg/ml

T 0.000 day

Hypoalbuminemia



CALCULATOR FOR PHENYTOIN

Body Weight: kg

Total Dose: mg/day

Albumin: g/dL

Note: $g/dL = 10^{-1} g/L$

Km: mg/L

Note: Adult = 4, Children = 7

S:

Note: Capsule/Injection=0.92, Suspension/Tablet=1

Select Patients Condition

Without Hypoalbuminemia Hypoalbuminemia Hypoalbuminemia with ESRF

Cp measured: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp Measured: mcg/ml

Vmax (Measured): mg/day

To calculate Vmax (population)

Constant Vmax: mg/kg/day

Note: Adult = 5-15 mg/kg/day, 6mo-6yrs = 10-13 mg/kg/day, 7yrs-16yrs = 8-10 mg/kg/day

Vmax (pop): mg/day

To calculate Vd, Ke, t1/2 and CI based on Vmax

Constant Vd: L/kg

Note: Adult: 0.65-0.74 L/kg, Children: 0.7-1.0 L/kg

Vmax: mg/day

Vd: L

CI: L/hr

Ke: hr⁻¹

t1/2: hour

To calculate Cpss level based on Vmax

Vmax: mg/day

Cpss: mcg/ml

Note: $mcg/ml = mg/L$

To calculate Incremental Loading Dose (ILD) based on Cp desired and Cp measured

Cp Desired: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp desired: mcg/ml

ILD: mg

To calculate New Maintenance Dose (NMD) based on Vmax and Cp desired

Vmax: mg/day

Cp Desired: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp desired: mcg/ml

New Dose: mg/day

To calculate therapy without period (T) when level is toxic

Vmax: mg/day

Cp Desired: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp desired: mcg/ml

T: day

Hypoalbuminemia with ESRF

CALCULATOR FOR PHENYTOIN

Body Weight: kg

Total Dose: mg/day

Albumin: g/dL

Note: $g/dL = 10^{-1} g/L$

Km: mg/L

Note: Adult = 4, Children = 7

S:

Note: Capsule/Injection=0.92, Suspension/Tablet=1

Select Patients Condition

Without Hypoalbuminemia Hypoalbuminemia Hypoalbuminemia with ESRF

Cp measured: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp Measured: mcg/ml

Vmax (Measured): mg/day

To calculate Vmax (population)

Constant Vmax: mg/kg/day

Note: Adult = 5-15 mg/kg/day, 6mo-6yrs = 10-13 mg/kg/day, 7yrs-16yrs = 8-10 mg/kg/day

Vmax (pop): mg/day

To calculate Vd, Ke, t1/2 and CI based on Vmax

Constant Vd: L/kg

Note: Adult: 0.65-0.74 L/kg, Children: 0.7-1.0 L/kg

Vmax: mg/day

Vd: L

CI: L/hr

Ke: hr⁻¹

t1/2: hour

To calculate Cpss level based on Vmax

Vmax: mg/day

Cpss: mcg/ml

Note: $mcg/ml = mg/L$

To calculate Incremental Loading Dose (ILD) based on Cp desired and Cp measured

Cp Desired: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp desired: mcg/ml

ILD: mg

To calculate New Maintenance Dose (NMD) based on Vmax and Cp desired

Vmax: mg/day

Cp Desired: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp desired: mcg/ml

New Dose: mg/day

To calculate therapy without period (T) when level is toxic

Vmax: mg/day

Cp Desired: mcg/ml

Note: $mcg/ml = mg/L$

Corrected Cp desired: mcg/ml

T: day

Notes

- This pop up screen appears upon clicking on "calculator" hyperlink at the Reporting screen.



	<ul style="list-style-type: none"> Click on 'Close' button to close the screen and go back to the reporting screen. Field with yellow colour is an auto calculated field based on formula has been set. There are to tab/option can be select: <ul style="list-style-type: none"> Without Hypoalbuminemia Hypoalbuminemia Hypoalbuminemia with ESRF
Cross References	None

3.5.3.12.2 Application Business Rules

No.	Name	Description
1.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
2.	Pharmacokinetics Profile result	Result format to be displayed in 'Pharmacokinetics Profile' field as below: <ol style="list-style-type: none"> Vmax (Measured) : 0 mg/day To calculate Vmax (population) Vmax (pop) : 0 mg/day To calculate Vd, Ke, t1/2 and CI based on Vmax Vd : 0 L CI : 0 L/hr Ke : 0 hr-1 t½ : 0 hour To calculate Cpss level based on Vmax Cpss : 0 mcg/ml To calculate Loading Dose (LD) based on Cp desired LD : 0 mg To calculate Incremental Loading Dose (ILD) based on Cp desired and Cp measured ILD : 0 mg To calculate New Maintenance Dose (NMD) based on Vmax and Cp desired New Dose : 0 mg/day To calculate therapy withhold period (T) when level is toxic T : 0 day

3.5.3.12.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the below: <ol style="list-style-type: none"> Actual (Default value) 	Yes	Drop Down



		2) Adjusted 3) Ideal		
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 45.5$ 3) Adjusted Body Weight: $\text{Ideal Body Weight} + [0.4 \times (\text{Actual Body Weight} - \text{Ideal Body Weight})]$	Yes	Auto calculated
3.	Km	Free text (user key in)	No	Free Text
4.	Albumin	Free text (user key in)	No	Free Text
5.	S	Free text (user key in)	No	Free Text
6.	Dose	Free text (user key in)	No	Free Text
7.	Cp measured	Free text (user key in)	No	Free Text
8.	Patient's Vmax	$((S(4)) (F) (Dose (5)) / (Km (2) + Cp \text{ measured } (6))) / Cp \text{ measured } (6)$	Yes	Auto calculated
9.	Constant Vmax	Free text (user key in)	No	Free Text
10.	Vmax (pop)	Constant (8) * Body Weight (1)	Yes	Auto calculated
11.	Vmax	Free text (user key in)	No	Free Text
12.	Cpss	$((Km (2)) (S(4)) (F) (Dose (5))) / (Vmax (10) - [(S(4)) (F) (Dose (5))])$	Yes	Auto calculated
13.	Constant Vd	Free text (user key in)	No	Free Text
14.	Vd	Constant Vd(12) * Body Weight (1)	Yes	Auto calculated
15.	Vmax	Free text (user key in)	No	Free Text



16.	Cl	$(V_{max} (14) / (K_m (2) + C_p \text{ measured } (6))) / 24$	Yes	Auto calculated
17.	Ke	$Cl (15) / V_d (13)$	Yes	Auto calculated
18.	T1/2	$0.693 / K_e(16)$	Yes	Auto calculated
19.	Cp desired	Free text (user key in)	No	Free Text
20.	LD	$V_d (13) * C_p \text{ desired } (18)$	Yes	Auto calculated
21.	Cp desired	Free text (user key in)	No	Free Text
22.	ILD	$V_d (13) * (C_p \text{ desired } (20) - C_p \text{ measured } (6))$	Yes	Auto calculated
23.	Cp desired	Free text (user key in)	No	Free Text
24.	New Maintenance Dose	$(V_{max} (23A) * C_p \text{ desired } (22) * T) / (S(5)) (F) (K_m (2) + C_p \text{ desired } (22))$ where T = Interval = 1 day	Yes	Auto calculated
25.	Vmax	Free text (user key in)	No	Free Text
26.	Cp desired	Free text (user key in)	No	Free Text
27.	T	$((K_m (2)) (LN (C_p \text{ measured } (6) / C_p \text{ desired } (24))) + (C_p \text{ measured } (6) - C_p \text{ desired } (24))) * (V_d (13) / V_{max} (7))$	Yes	Auto calculated
28.	F	1	No	Others



3.5.3.13 Calculator For Theophylline

3.5.3.13.1 Screen Design

ID	CAL5
Description	TDM Calculator screen (<i>Theophylline</i>)

Diagram
Theophylline Oral

CALCULATOR FOR THEOPHYLLINE

Body Weight (Actual) kg Body Weight kg

Dose mg Interval(T) hour

S

Theophylline Monohydrate = 0.91 Theophylline = 1

Select Calculator:

Oral **IV**

Cp Measured mcg/ml
Note: mcg/ml = mg/L

To calculate Clearance based on patient's factor(s)

Factor Q
Note: For multiple factors, Q = Q1 x Q2 x Q3

Clearance Cp Measured L/hr

Clearance(pop) L/hr

To calculate Vd based on patient's factor(s)

Factor Vd
Note: Adult = 0.5 Premature = 0.7

Vd (pop) L

Note: Q=

Smoking History	1.6	Phenobarbitone	1.3
Cystic Fibrosis	1.5	Phenytoin	1.6
Severe COPD	0.8	Rifampicin	1.3
Acute Pulmonary Oedema	0.5	Erythromycin	0.75
Hepatic Cirrhosis	0.5	Ciprofloxacin	0.7
Acute Pulmonary Edema	0.5	Cimetidine	0.6
Acute Viral Illness	0.5	Propranolol	0.6
Chronic Heart Failure	0.4	Influenza Vaccine	0.5
None	1	Elderly > 70 y.o	0.8

To calculate Ke and t1/2 based on CI

CI L/hr

Ke hr-1

t1/2 hour

To calculate C_{ss} level based on current dose and CI

CI L/hr

Note: mcg/ml = mg/L

C_{ss} mcg/ml

To calculate Loading Dose (LD) based on Cp desired and Vd

Cp desired mcg/ml
Note: mcg/ml = mg/L

Vd L

LD mg

To calculate Incremental Loading Dose (ILD) if level is SUB-therapeutic based on Cp desired and Vd

Cp desired mcg/ml
Note: mcg/ml = mg/L

Vd L

ILD mg

To calculate New Maintenance Dose (IMD) based on Cp desired and CI

Cp desired mcg/ml
Note: mcg/ml = mg/L

CI L/hr

T hr

New Dose mg every hr

To calculate New Dose (Ko) based on Cp and CI when convert Oral to IV Aminophylline

Cp mcg/ml
Note: mcg/ml = mg/L

CI L/hr

Ko(IV) mg/hr

Theophylline IV



CALCULATOR FOR THEOPHYLLINE

Body Weight: Body Weight:

Dose: mg/hr

S:

Aminophylline Anhydrous = 0.8 Aminophylline hydrates = 0.84

Select Calculator: **Oral** IV

Cp Measured: mcg/ml
Note: mcg/ml = mg/L

To calculate Clearance based on patient's factor(s)

Factor Q:
Note: For multiple factors, Q = Q1 x Q2 x Q3

Clearance Cp Measured: L/hr

Clearance(pop): L/hr

To calculate Vd based on patient's factor(s)

Factor Vd:
Note: Adult = 0.5 Premature = 0.7

Vd (pop): L

Note: Q =		Phenobarbitone	1.3
Smoking History	1.6	Phenytoin	1.6
Cystic Fibrosis	1.5	Rifampicin	1.3
Severe COPD	0.8	Erythromycin	0.75
Acute Pulmonary Oedema	0.5	Ciprofloxacin	0.7
Hepatic Cirrhosis	0.5	Cimetidine	0.6
Acute Pulmonary Edema	0.5	Propranolol	0.6
Acute Viral Illness	0.5	Influenza Vaccine	0.5
Chronic Heart Failure	0.4	Elderly > 70 y.o	0.8
None	1		

To calculate Ke and t1/2 based on CI

CI: L/hr

Ke: hr-1

t1/2: hour

To calculate Loading Dose (LD) if NO Theophylline given within 24 hours

LD: mg

To calculate Loading Dose (LD) based on Cp desired and Vd

Cp desired: mcg/ml
Note: mcg/ml = mg/L

Vd: L

LD: mg

To calculate Withhold Therapy Period (T) if level is SUPRA-therapeutic based on Cp desired and Ke

Cp Desired: mcg/ml

T: hour

To calculate Ke and t1/2 based on CI

CI: L/hr

Ke: hr-1

t1/2: hour

To calculate C_{ss} level based on current dose and CI

CI: L/hr

Note: mcg/ml = mg/L

C_{ss}: mcg/ml

To calculate Loading Dose (LD) if Theophylline given within 24 hours

LD: mg

To calculate Incremental Loading Dose (ILD) if level is SUB-therapeutic based on Cp desired and Vd

Cp Desired: mcg/ml
Note: mcg/ml = mg/L

Vd: L

ILD: mg

To calculate infusion rate (Ko) based on Cp desired and CI

Cp desired: mcg/ml
Note: mcg/ml = mg/L

Clearance: L/hr

Infusion rate (Ko): mg/hr

To convert IV Aminophylline to Oral

CI: L/hr

Note: mcg/ml = mg/L

Cp Desired: mcg/ml

Dose: mg/day

Notes	<ul style="list-style-type: none"> This pop up screen appears upon clicking on “calculator” hyperlink at the Reporting screen. Click on ‘Close’ button to close the screen and go back to the reporting screen. Field with yellow colour is an auto calculated field based on formula has been set. There are to tab/option can be select: <ul style="list-style-type: none"> Theophylline Oral Theophylline IV
Cross References	None

3.5.3.13.2 Application Business Rules

No.	Name	Description
3.	Activate Calculator	Tick on the checkbox to activate the calculator and display the result in Pharmacokinetic Profile field
4.	Pharmacokinetics Profile result	Result format to be displayed in ‘Pharmacokinetics Profile’ field as below: <ol style="list-style-type: none"> Clearance Cp Measured : 0 L/hr Clearance(pop) : 0 L/hr Vd (pop) : 0 L



No.	Name	Description
		4) Ke : 0 hr-1 5) t _{1/2} : 0 hour 6) Cpss : 0 mcg/ml 7) LD : 0 mg/day 8) ILD : 0 mg/day 9) New Dose : 0 mg/day 10) Ko(IV) : 0 mg/hr

3.5.3.13.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	Body Weight 1	A drop down field to indicate the patient body weight based on the below: 1) Actual (Default value) 2) Adjusted 3) Ideal	Yes	Drop Down
2.	Body Weight 2	Display patient body weight based on selected body weight 1: 1) Actual Body Weight: Directly take the patient actual body weight as entered in patient banner 2) Ideal Body Weight: i. Male= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 50$ ii. Female= $\{[(\text{Height}(\text{cm}) - 150)/30] \times 12 \times 2.3\} + 45.5$ 3) Adjusted Body Weight: $\text{Ideal Body Weight} + [0.4 \times (\text{Actual Body Weight} - \text{Ideal Body Weight})]$	Yes	Auto calculated
3.	Dose	Free text (user key in)	No	Free Text
4.	T (Interval)	Free text (user key in)	No	Free Text
5.	S	Free text (user key in)	No	Free Text
6.	Cp measured	Free text (user key in)	No	Free Text
7.	Factor Q	Free text (user key in)	No	Free Text
8.	Factor Vd	Free text (user key in)	No	Free Text
9.	Clearance Cp measured	$\text{Factor Q (4)} * (\text{S (2B)} * \text{F} * (\text{Dose (2)} / \text{T (2A)}) / \text{Cp measured (3)})$	Yes	Auto calculated
10.	Clearance (pop)	$\text{Factor Q (4)} * 0.04 * \text{Body Weight (1)}$	Yes	Auto calculated
11.	Vd (pop)	$\text{Factor Vd (5)} * 0.5 * \text{Body weight (1)}$	Yes	Auto



				calculated
12.	Cl	Free text (user key in)	No	Free Text
13.	Ke	$Cl (9) / Vd (8)$	Yes	Auto calculated
14.	$t_{1/2}$	$0.693 / Ke (10)$	Yes	Auto calculated
15.	Cl	Free text (user key in)	No	Free Text
16.	Cpss	$((S(2B)(F) (Dose (2)/T (2A)) / Cl (12)$	Yes	Auto calculated
17.	Cp desired	Free text (user key in)	No	Free Text
18.	Loading Dose	$(Vd (8)) (Cp desired (14)) /((S(2B))(F))$	Yes	Auto calculated
19.	Cpdesired	Free text (user key in)	No	Free Text
20.	Vd	Free text (user key in)	No	Free Text
21.	ILD	$(Vd(18)(Cp desired (17)-Cp measured(3))) / (S(2B)(F))$	Yes	Auto calculated
22.	Cp desired	Free text (user key in)	No	Free Text
23.	Cl	Free text (user key in)	No	Free Text
24.	New interval, T	Free text (user key in)	No	Free Text
25.	New Maintenance Dose	$(Clearance (21)*Cp desired (20)*T (22))/ (S(2B)*F)$	Yes	Auto calculated
26.	Cp	Free text (user key in)	No	Others
27.	Cl	Free text (user key in)	No	Others
28.	Ko	$Cp (24 * Clearance (25))$	Yes	Auto calculated
29.	F	1	No	Others

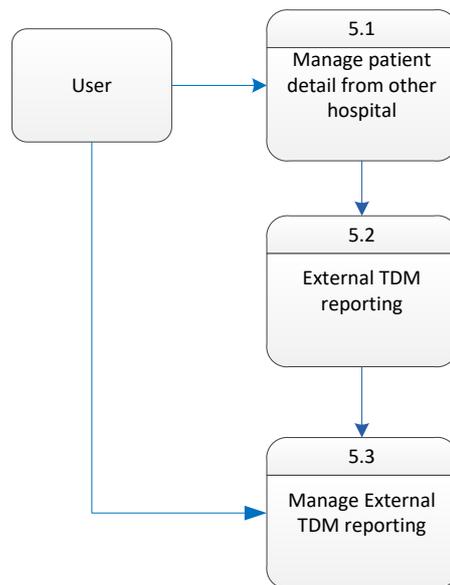


3.6 TDM External Resulting

3.6.1 Purpose

This module shall be used by Pharmacist to record external TDM result reporting for clinical pharmacokinetics services or therapeutic drug monitoring (TDM) services. External TDM can be via online and offline record.

3.6.2 Screen Navigation Diagram





3.6.3 Detail Functionality and Screen

3.6.3.1 External TDM Result Reporting Listing Screen

3.6.3.1.1 Screen Design

ID	EXTDM.SD1
Description	External TDM Resulting Listing page
Diagram	
Notes	<ul style="list-style-type: none"> Click on the 'Search' button to list down the results based on the criteria entered. Click on the 'Close' button to cancel task and return to home page. Click on "Register Patient" button to register patient. Screen for registration will appear. Refer to Screen Name – External TDM Registration.
Cross References	None

3.6.3.1.2 Application Business Rules

No.	Name	Description
1.	Search Transaction	If the External TDM record received via online services record will auto display with Online = Yes
2.	View search result in listing page	Columns in search result listing are displayed based on: <ol style="list-style-type: none"> External TDM No External Facility Others Facility External MRN Patient Name Received Date/Time Status Online



3.6.3.1.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	External TDM No	An enterable lookup field which will display list of external TDM no in popup screen.	No	Searching Field
2.	External Facility	External Facility to be selected from the dropdown combo box with values populated from External Facility Master .	No	Drop Down
3.	External MRN	A free text field to enter the text with capacity maximum of 20 characters	No	Free Text
4.	Patient Name	A free text field to enter the text with capacity maximum of 100 characters	No	Free Text
5.	Received Date From	Received Date From to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
6.	Received Date To	Received Date To to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
7.	Status	A drop down combo box with value as below: 1) Recorded 2) Resulted 3) Rejected	No	Drop Down
8.	Other Facility	A free text field with maximum 100 characters	No	Free Text



3.6.3.2 External TDM Registration

3.6.3.2.1 Screen Design

ID	EXTDM.SD2
Description	External TDM Registration
Diagram	
Notes	<ul style="list-style-type: none"> Click on 'Add' button to register new patient Click on the 'Cancel' button to go back to the main page. Click on the 'Save' button to save the record, will generate External TDM No.
Cross References	None

3.6.3.2.2 Application Business Rules

No.	Name	Description
1.	Search Patient	<ul style="list-style-type: none"> If the patient is already registered before, user can click on the "search button"  at the External MRN field to search for the registered patient and information about the registered patient will appear as below: <ul style="list-style-type: none"> External MRN Patient Name External Facility External TDM No
2.	Manage Sample	<ul style="list-style-type: none"> Click on "Manage Sample" system will open screen for TDM resulting. Refer to screen 8.26 Screen Name – External TDM Resulting. After save system will generate External TDM No. <ul style="list-style-type: none"> Format no will be: (EXTDMXXXXXXXX) <p>EXTDM and followed by 8 running number.</p>

3.6.3.2.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	External MRN	A free text field to enter the text with capacity maximum of 20 characters	Yes	Text Field
2.	Patient Name	A free text field to enter the text with capacity maximum of 100 characters	Yes	Text Field



3.	External Facility	External Facility to be selected from the dropdown combo box with values populated from External Facility Master list	No	Drop Down
4.	Patient ID Number	Free text with maximum 20 characters field	Yes	Free text
5.	Other Facility	Free text with maximum 100 characters field	No	Free text
6.	ID Type	Drop Down field with value as below: 1) Birth Certificate 2) Driving License 3) Father IC 4) Military Card Number 5) Mother IC 6) Mykad 7) Mykid 8) Old IC 9) Others 10) Passport 11) Pension Card 12) Police Card Number 13) Work Permit	Yes	Drop Down
7.	Date of Birth	Date of Birth to be entered in dd/mm/yyyy format. Calendar selection to be provided	Yes	Calendar
8.	Gender	Drop Down field with value as below: 1) Female 2) Male 3) Unknown	Yes	Drop Down



3.6.3.3 External TDM Resulting

3.6.3.3.1 Screen Design

ID	EXTDM.SD3
Description	External TDM Resulting
Diagram	
Notes	<ul style="list-style-type: none"> User may add multiple drugs by click on the TDM Drug and click on 'Add' button. Click on the 'Save' button to save the record. Click on the 'Close' button to return to the listing page. Click on the 'Confirm' button to confirm the record and the record no longer can be edited. Click on 'Print' button to print the External TDM resulting record
Cross References	None

3.6.3.3.2 Application Business Rules

No.	Name	Description
1.	Delete Record	<ul style="list-style-type: none"> Online offline record can be deleted Click on the 'Delete' check box to delete the drug. Alert message will prompted as below: "Are you sure to Cancel the record?" Y – Yes , N – No <ul style="list-style-type: none"> Yes – delete the record from screen No – Keep the record in the screen No cancellation can be done after "confirm' the record.

3.6.3.3.3 Input Validation Rules

No.	Name	Description	Mandatory	Type
-----	------	-------------	-----------	------



1.	External TDM No	System auto generated after save record in 'External TDM Registration'	Yes	Auto generated
Patient Details				
2.	External MRN	This field will captured entered value from External MRN field	Yes	Auto generated
3.	Patient Name	This field will captured entered value from Patient Name field	Yes	Auto generated
4.	External Facility	This field will captured selected value from External Facility master list	Yes	Auto generated
Delivery Detail				
5.	Sample Sent By	A free text field to enter the text with capacity maximum of 100 characters	No	Text Field
6.	Sample Sent Date/Time	Sample Sent Date/Time to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
7.	Sample Received By	A free text field to enter the text with capacity maximum of 100 characters	No	Text Field
8.	Sample Received Date/Time	Sample Received Date/Time to be entered in dd/mm/yyyy format. Calendar selection to be provided	No	Calendar
Drug Details				
9.	TDM Drug	An enterable lookup field which will display list of TDM Drug in popup screen.	Yes	Searching Field
10.	Sampling Type	A drop down combo box with values as below: 1) Pre 2) Post 3) Random	Yes	Drop Down
Resulting				
11.	TDM Drug	This field will capture selected value from TDM drug field in Drug Details.	Yes	Auto captured
12.	Sampling Type	This field will capture selected value from Sampling Type Master	Yes	Auto captured
13.	Result Value	A free text field to enter the text with capacity maximum of 10 characters. Value to set with 3 decimal points.	Yes	Text Field
14.	Uom	A drop down combo box with values populated from UOM Master	No	Drop Down
15.	Prepared By	This field will be auto captured login person ID.	Yes	Auto captured
16.	Remarks	A free text field to enter the text with capacity maximum of 1000 characters	No	Text Field
17.	Delete	Check box provided. Tick – Yes, delete the record Untick – No, keep the record.	No	Check Box



18.	Toxic	Check box provided. Tick – Yes, Toxic Untick – No, Non Toxic	No	Check Box
19.	Reject	Check box provided. Tick – Yes, Rejected Untick – No, Non rejected	No	Check Box
20.	Status	Status will be display based on the transaction with below value: 1) Recorded 2) Rejected 3) Resulted	Yes	Auto captured



3.7 TDM Guideline (Master Setup)

3.7.1.1 TDM Guideline Listing Screen (Master Setup)

3.7.1.1.1 Screen Design

ID	TDMGL.SD1
Description	TDM Guideline listing Screen (Master Setup)
Diagram	
Notes	<ul style="list-style-type: none"> Click on the 'Add' button to add new drug guideline. Click on the 'Search' button to list the record based on the search criteria inserted. <ul style="list-style-type: none"> Search criteria is provided based on 'TDM Drug' and 'Remarks'
Cross References	None

3.7.1.1.2 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	TDM Drug	An enterable lookup field which will display list of TDM Drugs in popup screen. TDM Drugs is capture from drugs with TDM checked in Drug master list.	No	Searching Field
2.	Remarks	A free text field to enter the text with capacity maximum of 100 characters.	No	Text Field

3.7.1.2 TDM Guideline Screen (Master Setup)

3.7.1.2.1 Screen Design

ID	TDMGL.SD2
Description	TDM Guideline Screen (Master Setup)
Diagram – Add Drug	



Sampling Type	After/Before	Default time	Lab Order	Therapeutic Range	UOM	Updated On
Random	AFTER	30	Amikacin random	TROUGH : < 10 mcg / ml ; < 5 mcg/ ml (children) PEAK : 20 – 30 mcg /ml	mcg/ml	03/11/2013
Pre	BEFORE	30	Amikacin PRE	TROUGH : < 10 mcg / ml ; < 5 mcg/ ml (children)	mcg/ml	03/11/2013
Post	AFTER	30	Amikacin POST	PEAK : 20 – 30 mcg /ml	mcg/ml	03/11/2013
POST1	AFTER	1	Amikacin POST		mcg/ml	05/05/2015
POST2	AFTER	6	Amikacin POST		mcg/ml	05/05/2015

Click on “Add” button will pop up screen as below diagram.

Diagram – Add Sample

Notes	<ul style="list-style-type: none"> Click on the ‘Close’ button to go back to the main page. Click on the ‘Add’ button to add sample. Click on the ‘Save’ to save the record and refresh data.
Cross References	None

3.7.1.2.2 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	TDM Drug	An enterable lookup field which will display list of TDM Drugs in popup screen. TDM Drugs is capture from drugs with TDM checked in Drug master list.	Yes	Searching Field
2.	Calculator	This field will provide dual listbox function. User may select multiple calculators for one drug. Value contains as below:	No	List box



		Code	Description		
		TDMC1	Gentamicin Pre & Post		
		TDMC2	Gentamicin Post1 & Post6		
		TDMC3	Amikacin Pre & Post		
		TDMC4	Amikacin Post1 & Post6		
		TDMC5	Vancomycin		
		TDMC6	Phenytoin		
		TDMC7	Valproic Acid		
		TDMC8	Carbamazepine		
		TDMC9	Phenobarbitone		
		TDMC10	Digoxin		
		TDMC11	Theophylline		
		TDMC12	Cyclosporin		
		TDMC13	Tacrolimus		
		TDMC14	Sirolimus		
		TDMC15	Methotrexate		
		TDMC16	Salicylate		
		TDMC17	Paracetamol		
3.	Time to reach steady state	A free text field to enter the text with capacity maximum of 2000 characters.		No	Text field
4.	Remarks	A free text field to enter the text with capacity maximum of 2000 characters.		No	Text field
5.	Total Cost of Analysis (RM)	A free text field to enter the text with capacity maximum of 5 characters. *Pending data set from MOH.		No	Text field
TDM Guideline Details					
6.	Sampling type	A drop down combo box with values populated from 'Sampling Type' ph_ref_code The value contains as below: 1) Pre 2) Post 3) Random		No	Drop Down
7.	Lab Order	An enterable lookup field which will display list of 'TDM Lab order' ph_ref_code, in popup screen. The value contains as below:		No	Drop Down
		Code	Description		
		TDMS1	Gentamicin PRE		
		TDMS2	Gentamicin POST		
		TDMS3	Gentamicin random		
		TDMS4	Gentamicin post 1 hour		
		TDMS5	Gentamicin post 2 hours		
		TDMS6	Gentamicin post 6 hour		



		TDMS7	Amikacin PRE		
		TDMS8	Amikacin POST		
		TDMS9	Amikacin random		
		TDMS10	Amikacin post 1 hour		
		TDMS11	Amikacin post 2 hours		
		TDMS12	Amikacin post 6 hour		
		TDMS13	Vanvomycin PRE		
		TDMS14	Vancomycin POST		
		TDMS15	Vancomycin random		
		TDMS16	Phenytoin PRE		
		TDMS17	Phenytoin Random		
		TDMS18	Valproic Acid PRE		
		TDMS19	Valproic Acid Random		
		TDMS20	Carbamazepine PRE		
		TDMS21	Carbamazepine Random		
		TDMS22	Phenobarbitone PRE		
		TDMS23	Phenobarbitone Random		
		TDMS24	Digoxin PRE		
		TDMS25	Digoxin Random		
		TDMS26	Aminophylline PRE		
		TDMS27	Aminophylline Random		
		TDMS28	Cyclosporin PRE		
		TDMS29	Cyclosporin post 2 hour		
		TDMS30	Tacrolimus PRE		
		TDMS31	Sirolimus PRE		
		TDMS32	Methotrexate Random		
		TDMS33	Salicylate Random		
		TDMS34	Paracetamol Random		
8.	Default time	A free text field to enter number with capacity maximum of 5 characters		No	Text Field
9.	Default time type	A drop down combo box with values populated from 'Default Time' ph_ref_code. The value contains as below: 1) Hour(s) 2) Minute(s)		No	Drop Down
10.	After/Before	A drop down combo box with values populated from 'After_Before' ph_ref_code. The value contains as below: 1) After 2) Before		No	Drop Down
11.	UOM	A drop down combo box with values populated from 'tdm_uom' ph_ref_code. The value		No	Drop Down



		contains as below: 1) mcg/ml 2) ng/ml 3) mmol/L 4) mg/dL		
12.	Therapeutic Range	A free text field to enter the text with capacity maximum of 1000 characters.	No	Text Field
13.	Updated On	This field will capture updated date and time of the guideline.	No	Others



3.7.1.3 TDM Guideline Screen (TDM Order Screen)

3.7.1.3.1 Screen Design

ID	TDMGL.SD3
Description	TDM Guideline Screen (TDM Order Screen)
<p>Diagram</p> <p style="text-align: center;"><i>SD3.TDM Guideline Screen</i></p>	
Notes	<ul style="list-style-type: none"> This screen will be display upon clicks on TDM Guideline hyperlink in TDM Order screen and the screen is for viewing purpose only. <ul style="list-style-type: none"> 'TDM Drug' will be the key of searching. Click on search and will display the drug and sample details. Click on the 'Close' button to close and go back to the previous screen. Field in this screen will be captured from TDM Guideline Master depends on the selection of TDM Drug.
Cross References	None

3.7.1.3.2 Input Validation Rules

No.	Name	Description	Mandatory	Type
1.	TDM Drug	An enterable lookup field which will display list of TDM Drugs in popup screen. TDM Drugs is capture from drugs with TDM checked in Drug master list.	No	Auto display
2.	Calculator	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display



3.	Time to reach steady state	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
4.	Remarks	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
5.	Total Cost of Analysis (RM)	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
TDM Guideline Details				
1.	Sampling type	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
2.	Lab Order	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
3.	Default time	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
4.	Default time type	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
5.	After/Before	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
6.	UOM	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
7.	Therapeutic Range	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display
8.	Updated On	This field will display value entered in TDM Guideline Master based on the selected TDM Drug.	No	Auto display



4 References

Document	Description/ Expansion
PhIS_CPS_URS_TDM_v1.3	
PhIS_CPS_SDD_TDM_v1.2	

5 Acronyms

Item	Description
LN	Log no
EXP	Exponent
TDM	Therapeutic Drug Monitoring
SDD	System Design Documents
URS	User Requirement Study

6 Appendix