

eCRF COMPLETION GUIDELINES

Protocol ID: D1690R00044

Study Title: Discover CaReMe Global Registry: real world data on patient management and quality of care

Protocol Version 2.0, July 10th, 2020

Signatures designate the following:			
Signatories or designees have reviewed the eCRF Completion Guidelines and verify the content is sufficient to ensure data entry quality and satisfies study team expectations.			
Department	Printed Name	Signature	Date

HISTORY OF CHANGES TO TEMPLATE

Version	Date Revised	Revised By	Description of Change
0.1	08/01/2020	GenomSeqCare	Create
0.2	08/31/2020	GenomSeqCare	Update screenshots

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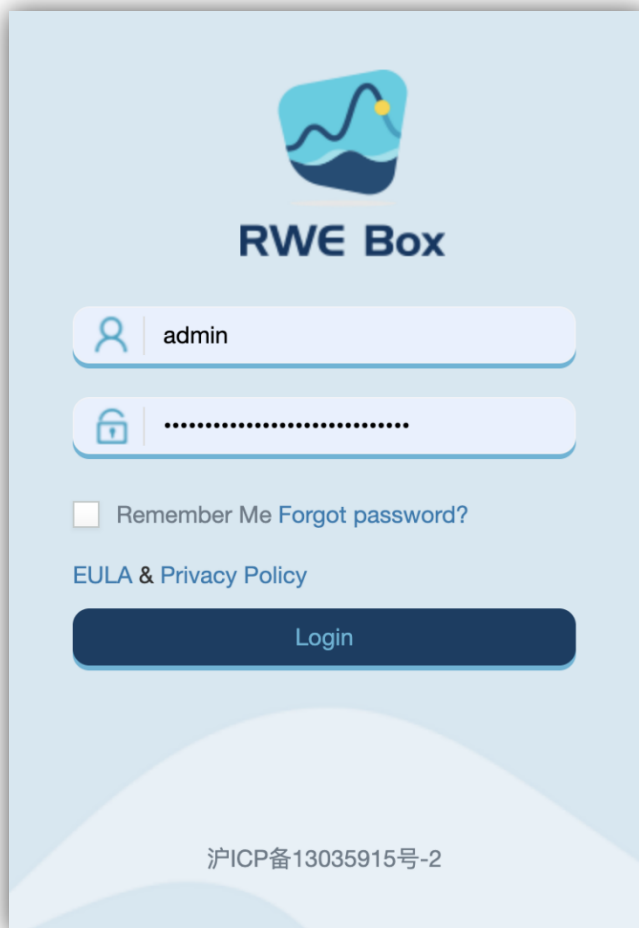
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1 GENERAL EDC SYSTEM INFORMATION

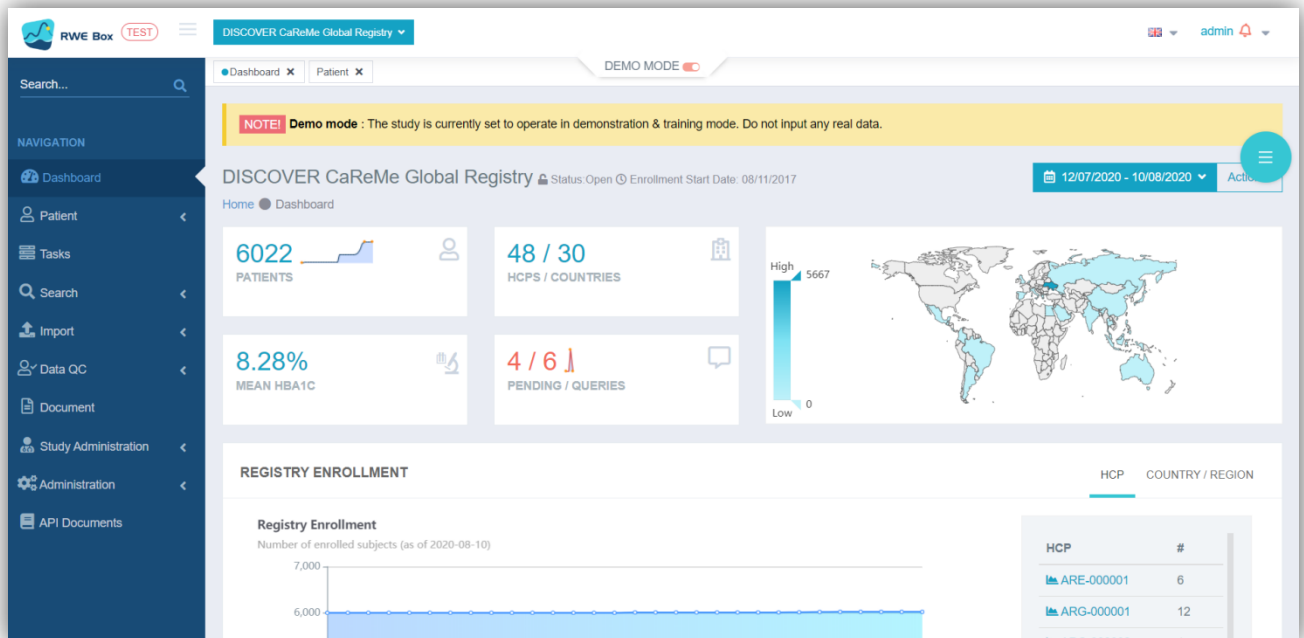
1.1 LOGIN & NAVIGATION

1.1.1 Login

After users complete the training session with GenomSeqCare RWE Box instructors, they will request access to the RWE Box production database by emailing dedicated study data manager from GenomSeqCare. The users will receive their login credentials through email. On the login page, users will input their user name & password to log into the system. If necessary, users can click “Remember Me” in order to make subsequent sign in attempts easier. After a user enters the username & password and clicks the “Login” button, the system will validate the username & password.

The image shows a login page for 'RWE Box'. At the top center is a logo consisting of a blue square with a white wave-like shape inside, and a yellow dot. Below the logo is the text 'RWE Box' in a bold, dark blue font. Underneath the logo and text are two input fields. The first field has a user icon on the left and the text 'admin' inside. The second field has a lock icon on the left and a series of dots inside, representing a password. Below these fields is a checkbox labeled 'Remember Me' followed by a link 'Forgot password?'. Below that is a link 'EULA & Privacy Policy'. At the bottom of the form is a dark blue button with the text 'Login' in white. At the very bottom of the page, there is a small text string '沪ICP备13035915号-2'.

If the log in is successful, the study dashboard page will appear next.



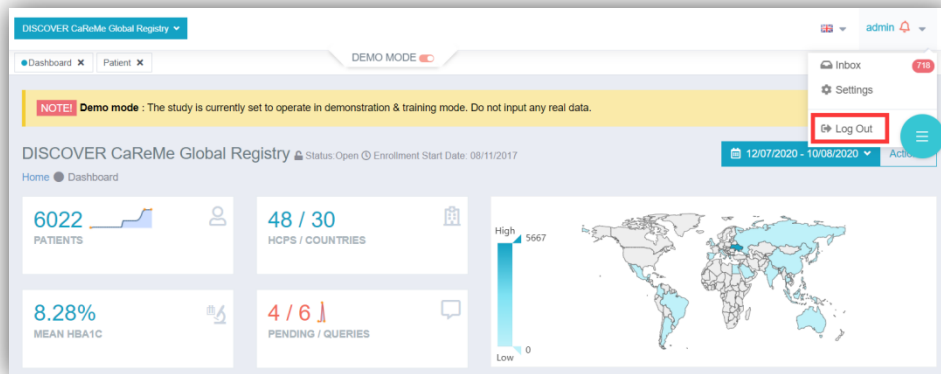
1.12 Login failure

If the username and password are not matched, the screen will display the reason for the log in failure.

The screenshot shows the RWE Box login page. At the top is the RWE Box logo. Below it, a red message box states: 'Login failed, invalid credentials.' The login form includes a username field, a password field with a toggle for visibility, a 'Remember Me' checkbox, and a 'Forgot password?' link. Below the form is a link to 'EULA & Privacy Policy' and a 'Login' button. At the bottom, the text '沪ICP备13035915号-2' is displayed.

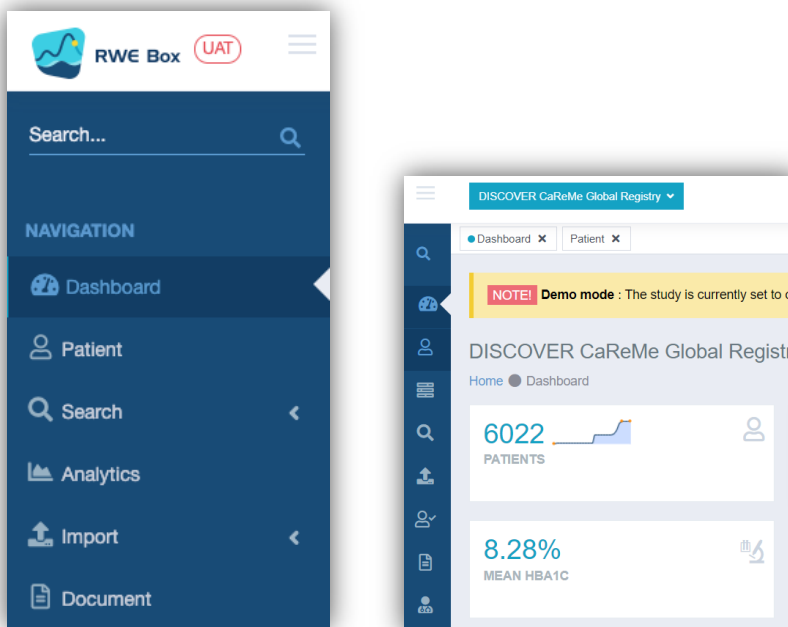
1.13 Logout

The logout link is located on the top right of the main page under the current user account. It allows an end user to log out of the system and it will take an end user to the login page after logging out.



1.14 Navigation bar

The navigation bar is on the left side of the main page. After the user clicks the menu option in the navigation bar, the corresponding pages will appear. When the user clicks the three-line icon at the top left of the main page, the navigation bar will toggle downward.

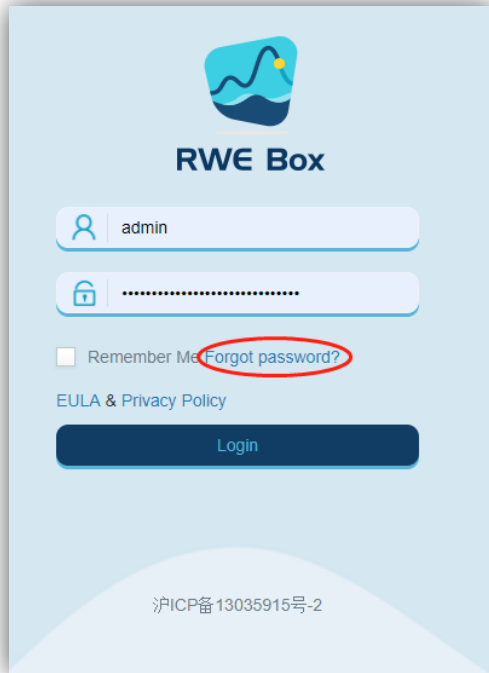


1.2 CHANGE USER SETTINGS

1.21 Change Password

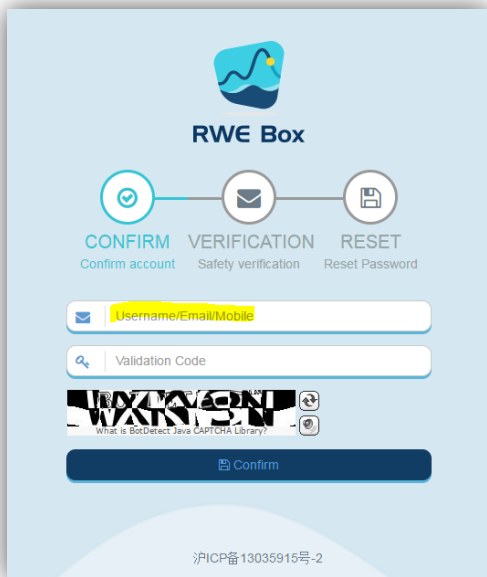
Users can change the settings by navigating to the “Settings” option after logging in. (Please refer to “1.22 Change user settings” for details.)

Also, the user can select the “Forgot password?” button on the login page to recover their password.

The image shows the login page for 'RWE Box'. At the top is a logo with a blue square containing a white line graph and a yellow circle. Below the logo is the text 'RWE Box'. There are two input fields: the first has a user icon and the text 'admin'; the second has a lock icon and a masked password '.....'. Below these fields is a checkbox labeled 'Remember Me' and a link 'Forgot password?' which is circled in red. Below the checkbox is a link 'EULA & Privacy Policy'. At the bottom is a dark blue 'Login' button. At the very bottom of the page is the text '沪ICP备13035915号-2'.

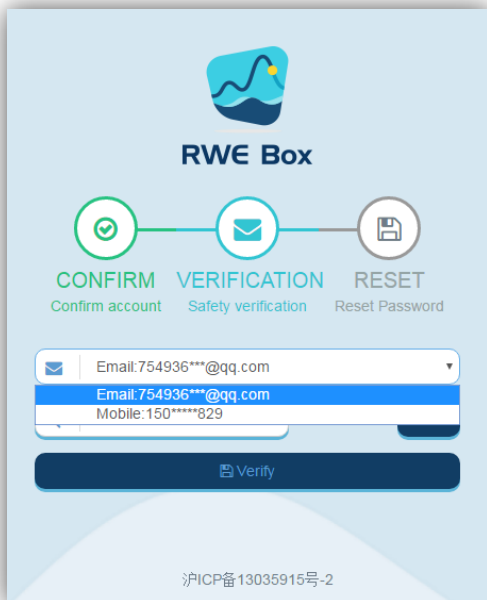
After clicking the “Forgot password?” button, the users can verify their identities by entering their “username/email address” which they provided during the registration process. Type “Username” or “Email” then enter the “Validation Code” found underneath the text field on the login page.

If the user hasn’t registered an email address, the “Forgot password” function will be unavailable. In this case the user must contact the system administrator at discover_global_registry_support@genomseqcare.com to register an email in order to change the password.



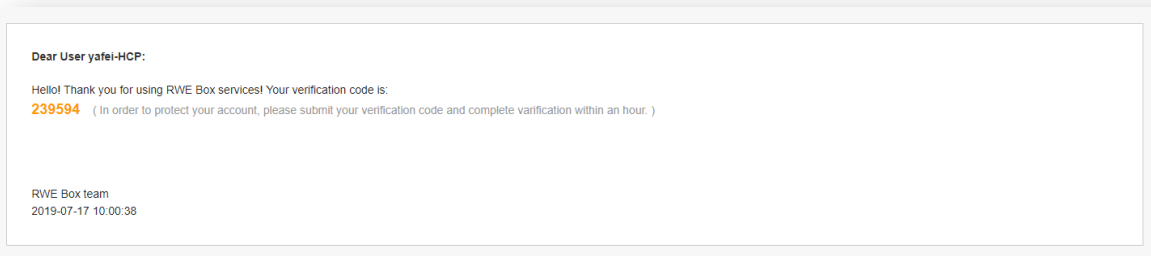
The image shows the 'CONFIRM' step of the RWE Box registration process. At the top is the RWE Box logo. Below it is a progress bar with three icons: a checkmark (CONFIRM), an envelope (VERIFICATION), and a floppy disk (RESET). The 'CONFIRM' step is highlighted. Below the progress bar are two input fields: 'Username/Email/Mobile' and 'Validation Code'. The 'Validation Code' field is currently empty. Below the input fields is a CAPTCHA image showing the word 'WATSON' in a stylized font. At the bottom is a blue button labeled 'Confirm'. The footer contains the text '沪ICP备13035915号-2'.

The user can choose to receive the verification code by email.



The image shows the 'VERIFICATION' step of the RWE Box registration process. The progress bar now highlights the 'VERIFICATION' step (envelope icon). Below the progress bar is a dropdown menu for selecting the verification method. The dropdown is open, showing three options: 'Email: 754936***@qq.com', 'Email: 754936***@qq.com', and 'Mobile: 150*****829'. Below the dropdown is a blue button labeled 'Verify'. The footer contains the text '沪ICP备13035915号-2'.

After clicking the “Verify” button, the user will receive a verification code by email or SMS. (It is important that the user checks their junk mail as the verification code email may be delivered either there or to an RSS email folder.)

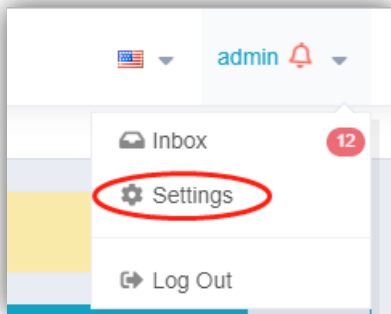


The user can change their password by typing the received code into the text field on the verification page. The new password must be at least 8 characters long, cannot match username, must contain an uppercase character and at least one number, and it is case sensitive.

A mobile application interface for RWE Box. At the top is the RWE Box logo. Below it is a progress bar with three steps: "CONFIRM" (Confirm account), "VERIFICATION" (Safety verification), and "RESET" (Reset Password). The "RESET" step is currently active. Below the progress bar are two input fields: "New Password" and "Confirm Password", each with a magnifying glass icon on the left. A blue "Save" button is positioned below the input fields. At the bottom of the screen is the text "沪ICP备13035915号-2".

1.22 Change user settings

The user can change their account profile after logging into the system. Click the drop-down menu under the username and choose the "Settings" option to navigate to the settings page. The user can change their names (Given/Middle/Family Name), Gender, and email address on the "Profile Info" page.



PROFILE ACCOUNT

Profile Info | Change Password | Locale Settings | Danger Zone

Username
admin


Given *
Super

Middle

Family Name *
User

Gender *
☒ Male ☐ Female

Mobile Number



Email *
104653859@qq.com

The user can change his/her recent password on the “Change Password” page.

PROFILE ACCOUNT

Profile Info | Change Password | Locale Settings

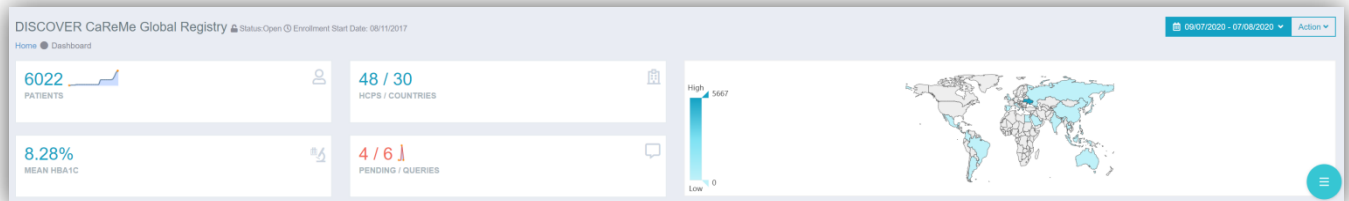
Old Password *

New Password *

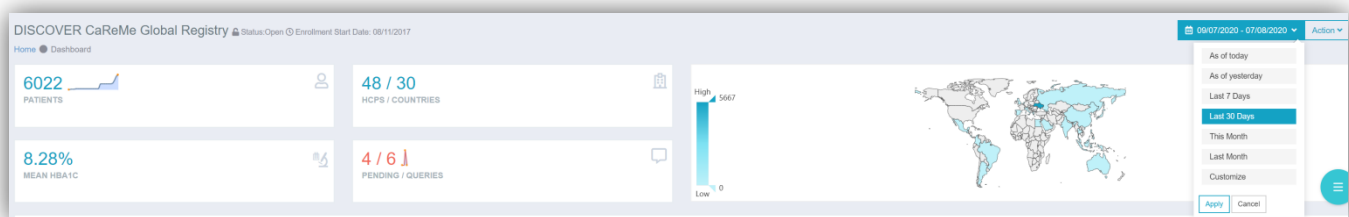
Confirm New Password *

1.3 STUDY DASHBOARD

The study dashboard page shows a summary of the current study, including a recruitment overview by site and detailed study information. A site user (Investigator or study coordinator) can only see the relevant data from his/her site.

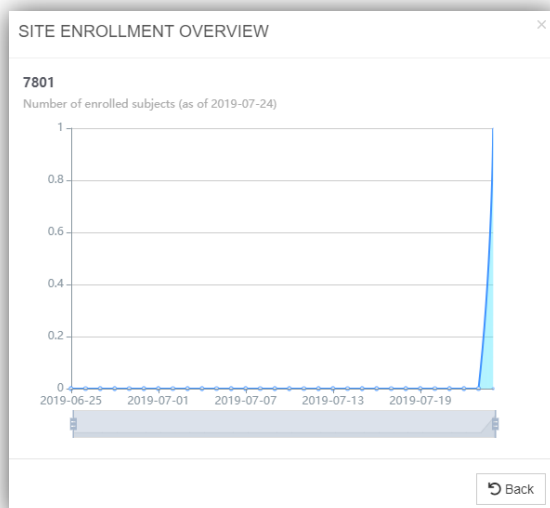


Users can also change the dashboard date range on the top of the study dashboard page.



1.31 Recruitment overview by site

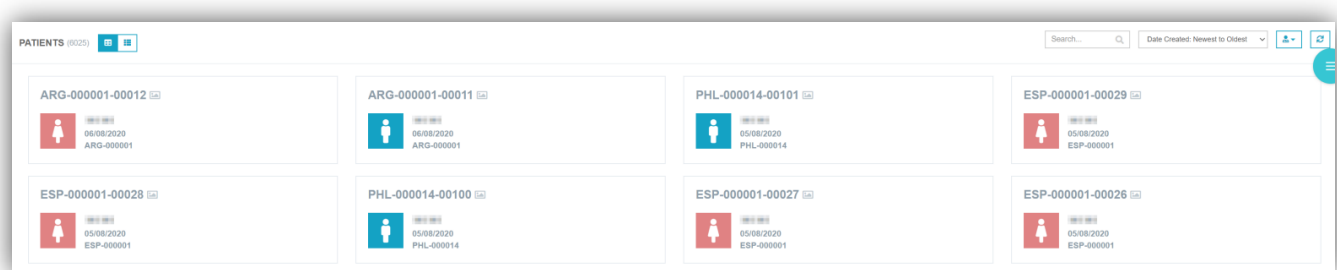
When you enter the dashboard page, the “Site” tab is selected by default, and it will show the recruitment overview chart. The overview provides basic data regarding the number of patients enrolled or recruited at a user’s site.



1.4 PATIENTS

1.41 Patient list

The patient list page shows recruited patients along with their individual enrollment number, dates of recruitment and their corresponding site names. The end user can view this information in either a Card or a Table format.



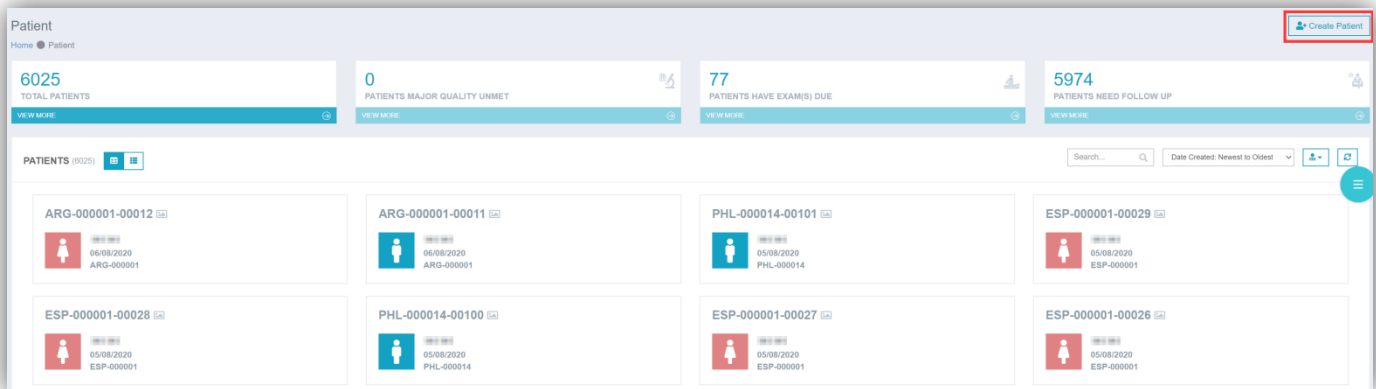
In the Card format, each patient is represented by a card. By default the cards are sorted according to the date added, where the most recently added cards are displayed first. To sort the cards, select the "Sort By" option in the dropdown list.

On the top right corner of each patient card, you can find a blue icon indicating that the patient data has been verified or a red icon indicating that the patient data has open queries. A card without an icon indicates that data QC has not been completed on the patient data.

Identifier ID	Gender	Name Initials	Location	Date of Birth	APP	Date of Enrollment
780101			7801	01/01/1990		07/24/2019
780102			7801	01/01/1990		07/24/2019
780103			7801	01/01/1980		07/24/2019
780104			7801	01/01/1990		07/24/2019
780105			7801	01/01/1976		07/24/2019
780106			7801	01/01/1991		07/24/2019
780107			7801	01/01/1992		07/24/2019
780108			7801	01/01/1971		07/24/2019

1.42 Create patient profile

After a user clicks the “Create Patient” button at the top of the patient list, it will go to the “Create Patient” page.

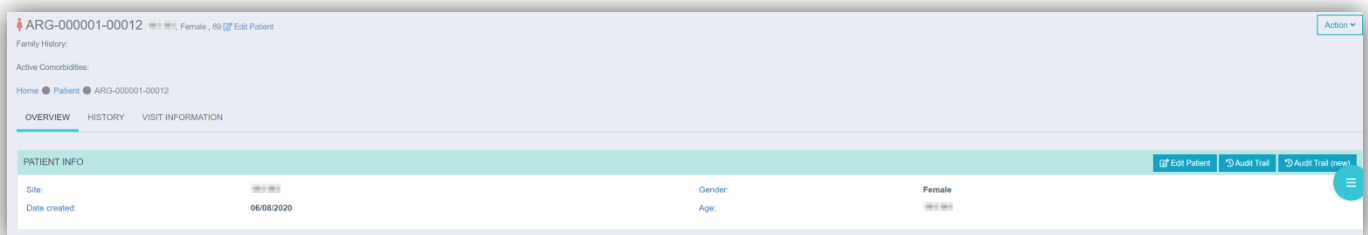


The end user shall fill out all of the mandatory fields before saving the patient info. Once the information is saved, an enrollment number will be generated automatically. Next, the user will be directed to the patient dashboard of this new patient.

The 'Create Patient' form is shown. It has tabs for 'Basic Info' and 'More Info'. The 'Basic Info' tab is active, showing fields for: 'Identifier ID' (with a dropdown for 'Automatic patient identifier'), 'Identifier Type' (with a dropdown for 'DISCOVER identifier'), 'Location' (with a dropdown for 'PHL-000014'), 'Name Initials', 'Family Name Initials', 'Age', 'Gender' (with radio buttons for 'Male' and 'Female'), and 'Date of Enrollment' (with a date picker set to '07/08/2020'). There are '+ Add' and '- Delete' buttons for the identifier, location, and date fields. At the bottom right, there are 'Cancel' and 'Save' buttons.

1.43 Patient dashboard

On the patient dashboard, a patient's gender and enrollment number are displayed on the top left hand corner of the page. There are three tabs. The first one is "OVERVIEW", the second one is "HISTORY", and the third one is "VISIT INFORMATION". The patient info component under the overview tab displays the basic demographic data of the current patient



They summary component under the overview tab has a few mini-tabs: latest view tab displays patient's HbA1c, BMI, DBP, SBP and weight measurement. Active comorbidities tab displays the patient's top 10 comorbidities. Current treatment tab lists the patient's active medications. Quality metrics tab shows the

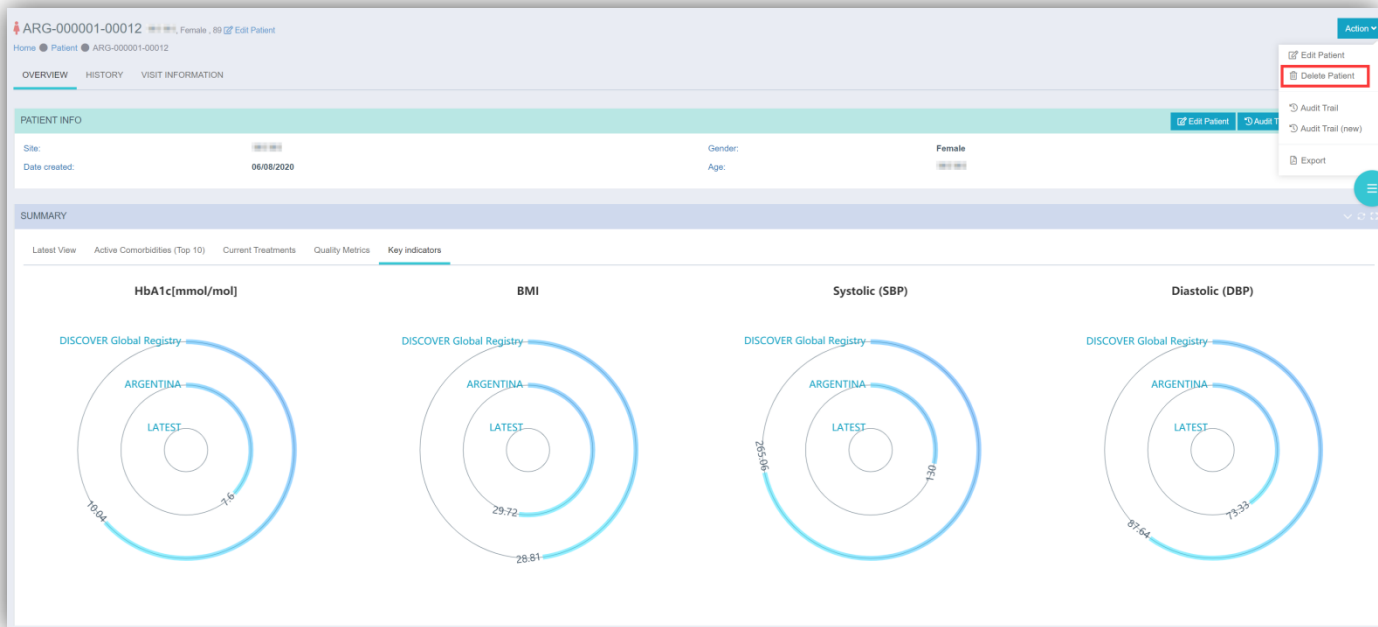
patient's important vital signs and lab tests and compares the results to normal testing ranges. By clicking the “history” tab, the user will be able to see the longitudinal changes of HbA1c, LDL and SBP by visits. By clicking the “visit information” tab, the user will be able to see the complete history of a patient's clinical visits. The right side displays a form under a specific visit.

1.44 Edit patient profile

By clicking “Edit Patient” at the top right corner of the patient info page, the user will be sent to the “Edit Patient” page where the user can alter patient information.

1.45 Delete patient profile

The “Delete Patient” menu appears after clicking the “Action” button. When a user clicks the “Delete Patient” menu, the delete confirmation window will pop up. Users are asked to input the reason for the action and then press “delete”, or press “cancel” to discontinue deletion. After deleting the patient, the enrollment number will not be reassigned.

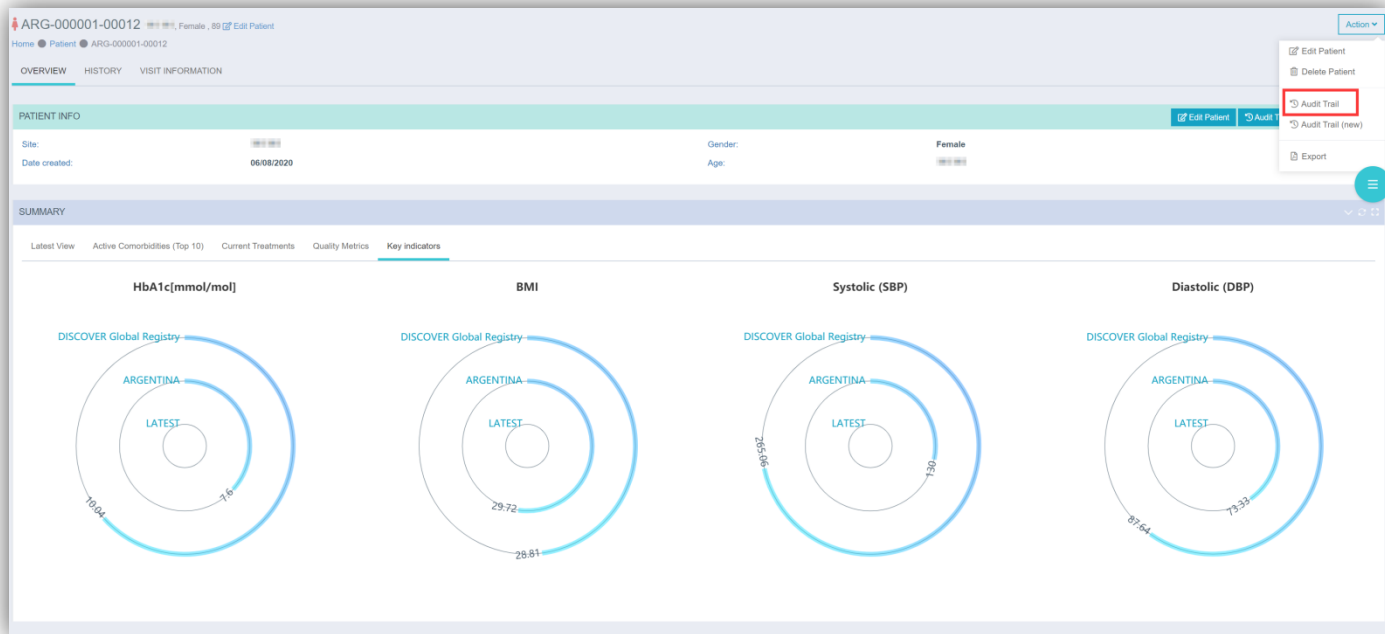


DELETE CONFIRMATION

Delete Reason *

1.46 Audit trail

Click "Audit trail" under "Actions" to view any changes or actions made to the patient information.



1.5 VISIT AND FORMS

Under each visit, a user can find a list of the forms that are required to be filled in. To enter data on a form, the visit first needs to be initiated by clicking “Start Visit”.

1.51 Routine visit

The Routine visit needs to be initiated before data can be entered. By clicking “Start Visit”, a default visit dialog will pop up. A user can click “Save” to confirm.

DISCOVER Gateway: Global Registry

Patient: ARG-000001-00012

NOTE: Demo mode: The study is currently set to operate in demonstration & training mode. Do not input any data.

ARG-000001-00012: Female, 89

Home Patient ARG-000001-00012

OVERVIEW HISTORY VISIT INFORMATION

VISIT

Search

COMMON VISIT

06/08/2020 - 06/08/2020

CORE METRICS

LIFESTYLE

TREATMENT

FORMS

+ Create Form Edit Form Delete Form More Legend

General Query Entry Lock Hard Lock

Core Metrics

Info! This core metrics form is essential for accurate reporting of quality of care. Please complete as fully as possible.

GENERAL DIABETES CKD HEART FAILURE MEDICATIONS LAB TESTS

[] HISTORY

Family History of CVD

[] YES

[] NO

[] Unknown

Smoking

Usage

[] Non-smoker

[] Ex-smoker

[] Current smoker

If "Ex-smoker" or "Current smoker", specify below:

____ pack-years

Number of cigarettes per day: ____

Definitions:

Non-smoker: Patients who have never smoked more than 20 grams of tobacco in their lifetime.

Ex-smoker: Patients who stopped smoking >=365 days ago.

Current smoker: Patients who smoke 1 or more tobacco products

[] PHYSICAL MEASUREMENTS

A list of forms to be completed for a Routine visit will be displayed under it. Same as described before, a user can click a form and enter data.

ARG-000001-00012: Female, 89

Home Patient ARG-000001-00012

OVERVIEW HISTORY VISIT INFORMATION

VISIT

Search

COMMON VISIT

07/08/2020

CORE METRICS

06/08/2020 - 06/08/2020

CORE METRICS

LIFESTYLE

TREATMENT

FORMS

+ Create Form Edit Form Delete Form More Legend

General Query Entry Lock Hard Lock

Core Metrics

Info! This core metrics form is essential for accurate reporting of quality of care. Please complete as fully as possible.

GENERAL DIABETES CKD HEART FAILURE MEDICATIONS LAB TESTS

[] HISTORY

Family History of CVD

[] YES

[] NO

[] Unknown

Smoking

Usage

[] Non-smoker

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If "Ex-smoker" or "Current smoker", specify below:

____ pack-years

Number of cigarettes per day: ____

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Non-smoker: Patients who have never smoked more than 20 grams of tobacco in their lifetime.

Ex-smoker: Patients who stopped smoking >=365 days ago.

Current smoker: Patients who smoke 1 or more tobacco products

[] PHYSICAL MEASUREMENTS

1.52 Edit form

By clicking the “Edit Form” button, users can edit whichever form they have chosen to review.

The screenshot shows the 'FORMS' interface. At the top right, there are buttons: '+ Create Form', 'Edit Form' (highlighted with a red box), 'Delete Form', 'More', '? Legend', and a refresh icon. Below these are tabs for 'CORE METRICS', 'LIFESTYLE', and 'TREATMENT'. Under 'CORE METRICS', there are sub-tabs: 'General Query', 'Entry Lock', and 'Hard Lock'. A blue bar contains the text: 'Info! This core metrics form is essential for accurate reporting of quality of care. Please complete as fully as possible.' Below this are tabs for 'GENERAL', 'DIABETES', 'CKD', 'HEART FAILURE', 'MEDICATIONS', and 'LAB TESTS'. The 'GENERAL' tab is active, showing a 'HISTORY' section with fields for 'Family History of CVD' (YES, NO, Unknown) and 'Smoking' (Usage, Non-smoker, Ex-smoker, Current smoker). It also includes definitions for Non-smoker, Ex-smoker, and Current smoker. At the bottom, there is a 'PHYSICAL MEASUREMENTS' section.

The screenshot shows the 'FORMS' interface. At the top right, there are buttons: 'Cancel', 'Save' (highlighted with a red box), '? Legend', and a refresh icon. Below these are tabs for 'CORE METRICS', 'LIFESTYLE', and 'TREATMENT'. Under 'CORE METRICS', there are sub-tabs: 'General Query', 'Entry Lock', and 'Hard Lock'. A blue bar contains the text: 'Info! This core metrics form is essential for accurate reporting of quality of care. Please complete as fully as possible.' Below this are tabs for 'GENERAL', 'DIABETES', 'CKD', 'HEART FAILURE', 'MEDICATIONS', and 'LAB TESTS'. The 'GENERAL' tab is active, showing a 'HISTORY' section with fields for 'Family History of CVD' (YES, NO, Unknown) and 'Smoking' (Usage, Non-smoker, Ex-smoker, Current smoker). It also includes definitions for Non-smoker, Ex-smoker, and Current smoker. At the bottom, there is a 'PHYSICAL MEASUREMENTS' section. A blue bar at the very bottom contains the text 'Save'.

A user can click “Full Screen” to maximize the form when entering data. This feature can be useful when a form is crowded with many columns in a table.

This screenshot shows the 'VISIT INFORMATION' tab for patient ARG-000001-00012. On the left, a 'VISIT' sidebar lists visits for 07/08/2020 and 08/08/2020 - 09/08/2020, with the latter selected. The main area displays the 'CORE METRICS' form under the 'FORMS' section. The form includes tabs for CORE METRICS, LIFESTYLE, and TREATMENT, and sub-tabs for GENERAL, DIABETES, CKD, HEART FAILURE, MEDICATIONS, and LAB TESTS. The 'GENERAL' sub-tab is active, showing checkboxes for HISTORY, PHYSICAL MEASUREMENTS, COMORBIDITY, and PATIENT SURVIVAL STATUS. A 'Save' button is at the bottom. A red box highlights the 'Full Screen' icon in the top right corner.

This screenshot shows the 'CORE METRICS' form in full-screen mode. The interface is maximized, and the 'Full Screen' icon in the top right corner is now a red 'X' inside a square. The form content is the same as in the previous screenshot, but the sidebar and other UI elements are hidden to provide more space for data entry.

2 DETAILED ECRF COMPLETION GUIDELINES

2.1 DEMOGRAPHICS

2.11 Basic Info

Name Initials *	<input type="text" value="s"/>
Family Name Initials *	<input type="text" value="s"/>
Age *	<input type="text" value="89"/>
Gender	<input type="radio"/> Male <input checked="" type="radio"/> Female
Date of Enrollment *	<input type="text" value="06/08/2020"/>

- 1) **Initials:** Please fill in the name initials or family name initials of the subject's name.
- 2) **Age:** Please fill in the age of the user when signing the informed consent form.
- 3) **Gender:** Select one option only from: "Male", "Female".
- 4) **Date of Enrollment:** Enter complete date in DD/MM/YYYY format.

2.12 More Info

Enrolled in study	<div><div></div><div>TKCoMe Wave 1</div></div>
Marriage	
Self-reported Ethnicity	
Education Level	
Main Working Status	
Health Insurance Coverage	
Notes	
Present Role in the Family	
Financial Resources	
Family Lifecycle Status	

Family Structure	
Patient discontinued in study?	
Discontinuation reason	

5) **Enrolled in study:** Patients enrolling into TakeCaReMe study, TKCoMe Wave 1 must be selected.

6) **Marriage:** Select one option only from: “Single”, “Married”, “Divorced”, “Widowed”, and “Widowed”.

7) **Self-reported Ethnicity:** Select one option only from: “Caucasian”, “Black”, “Mixed (e.g. brown, mulato, others)”, “Native American”, “Asian”, “Hispanic”, “Arabic”, “Others”.

If selecting “Asian”, select one option from “Chinese”, “East Asian”, “South Asian”, “Other Asian”. If select “Others”, complete the other ethnicity field.

8) **Education Level:** Select one option only from: “No formal education”, “Primary (1-6 years of education)”, “Secondary (7-13 years of education)”, “University / Higher Education (greater than 13 years of education)”.

- 9) **Main Working Status:** Select one option only from: "Employed", "Self-Employed", "Disabled", "Not working", "Retired". If select "Employed", need to select one option from "Full-time", "Part-time".
- 10) **Health Insurance Coverage:** Select one option only from: "Private", "Public/government", "Mixed", "Widowed", and "No insurance".
- 11) **Present Role in the Family:** Select one option only from: "Decision Maker", "Financial provider", "Breadwinner (sole financial provider)" and "Caregiver".
- 12) **Financial Resources:** Select one option only from: "Employed with salary", "Self-employed", "Allowance", "Remittance", "Insurance", "Pension" and "Overseas Filipino Worker (OFW)".
- 13) **Family Lifecycle Status:** Select one option only from: "Unattached young adult", "Newly married couple", "Family with young children", "Family with adolescents", "Family with adolescents", "Launching family" and "Family in later years".
- 14) **Family Structure:** Select one option only from: "Nuclear" and "Extended".
- 15) **Patient discontinued in study?:** Select "Yes" or "No".
- 16) **Discontinuation reason:** If Yes is selected for the "Patient discontinued in study?", select one option only from: "Withdrawal of consent", "Patient could not be contacted (lost to follow-up)" and "other".

2.2 CORE METRICS

2.21 General

The screenshot shows a web form titled "CORE METRICS". Below the title is a light blue banner with the text: "Info! This core metrics form is essential for accurate reporting of quality of care. Please complete as fully as possible." Below the banner is a horizontal menu with tabs: "GENERAL", "DIABETES", "CKD", "HEART FAILURE", "MEDICATIONS", and "LAB TESTS". The "GENERAL" tab is selected and highlighted with a blue underline. Below the tabs is a section titled "HISTORY" with a blue checkmark icon. This section contains two main areas: "Family History of CVD" and "Smoking Usage". The "Family History of CVD" area has three radio button options: "YES", "NO", and "Unknown". The "Smoking Usage" area has three radio button options: "Non-smoker", "Ex-smoker", and "Current smoker". Below these options is a "Definitions:" section with three lines of text: "Non-smoker: Patients who have never smoked more than 20 grams of tobacco in their lifetime.", "Ex-smoker: Patients who stopped smoking >=365 days ago.", and "Current smoker: Patients who smoke 1 or more tobacco products".

CORE METRICS

Info! This core metrics form is essential for accurate reporting of quality of care. Please complete as fully as possible.

GENERAL DIABETES CKD HEART FAILURE MEDICATIONS LAB TESTS

☒ HISTORY

Family History of CVD

☐ YES

☐ NO

☐ Unknown

Smoking Usage

☐ Non-smoker

☐ Ex-smoker

☐ Current smoker

Definitions:

Non-smoker: Patients who have never smoked more than 20 grams of tobacco in their lifetime.

Ex-smoker: Patients who stopped smoking >=365 days ago.

Current smoker: Patients who smoke 1 or more tobacco products

HISTORY

- 1) **Family History of CVD:** Select one option only from: "Yes", "No" and "Unknown".
- 2) **Smoking Usage:** Select one option only from: "Non-smoker", "Ex-smoker", and "Current smoker". If a user chooses "Current smoker" or "Ex-smoker", specify the number of pack-years and number of cigarettes per day.
 - 1 pack per day for 10 years = 10 pack-years
 - ½ pack per day for 15 years = 7.5 pack-years

✓ PHYSICAL MEASUREMENTS			
Weight	<input type="text"/>	<input type="radio"/> Kilograms <input type="radio"/> Pounds	<input type="checkbox"/> Not measured
Height	<input type="text"/>	<input type="radio"/> Centimeters <input type="radio"/> Inches	<input type="checkbox"/> Not measured
Body Mass Index	<input type="text"/>	kg/m ²	
Seated Blood Pressure at rest			
Systolic (SBP)	<input type="text"/>	mmHg	<input type="checkbox"/> Not measured
Diastolic (DBP)	<input type="text"/>	mmHg	<input type="checkbox"/> Not measured
Pulse rate at rest			
Beats per minute	<input type="text"/>		<input type="checkbox"/> Not measured

PHYSICAL MEASUREMENTS

For all PHYSICAL MEASUREMENTS:

- If the test is not done, the “Not measured” option should be selected. No value should be entered to any field.
- If the test result is available, enter the value of the result. Note the result should be within the plausible range of each parameter.
- If the value of the test result has been entered, the user should select the unit of the value.

1) Height : Enter a measured value obtained during vital sign test, select the unit.

2) Weight: Enter a measured value obtained during vital sign test, select the unit.

3) Body Mass Index: BMI is automatically derived from weight and height.

4) Systolic (SBP): Enter a measured value obtained during vital sign test, using mmHg as the unit.

5) Diastolic (DBP): Enter a measured value obtained during vital sign test, using mmHg as the unit.

6) Pulse rate at rest: Enter a measured value obtained during vital sign test.

7) Beats per minute: Enter a measured value obtained during vital sign test, using beats per minute as the unit.

COMORBIDITY		
Hypertension <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Diagnosis date yyyy mm dd	
Dyslipidemia <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Diagnosis date yyyy mm dd	
Myocardial infarction (MI) <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	<input type="radio"/> Single <input type="radio"/> Multiple <input type="radio"/> Unknown	Diagnosis date yyyy mm dd
Stroke <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	<input type="radio"/> Haemorrhagic <input type="radio"/> Ischemic <input type="radio"/> Unknown	Diagnosis date yyyy mm dd
Coronary Artery Disease <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	yyyy mm dd	
Coronary revascularization (including PCI, thrombolytic therapy and CABG) <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	<input type="radio"/> PCI - With stent/s <input type="radio"/> PCI - Without stent/s <input type="radio"/> PCI - Unknown <input type="radio"/> Thrombolysis <input type="radio"/> CABG <input type="radio"/> Unknown	Year of Procedure yyyy mm dd

COMORBIDITY:

- 1) For all COMORBIDITY:** Select “Yes”, “No”, or “Unknown”. If the choice is “No” or “Unknown”, please do not fill in the details. If the choice is “Yes”, please complete the details.
- 2) Diagnosis date:** Select year, month and day. If the date is unknown, please leave the field blank.

PATIENT SURVIVAL STATUS	
Is patient dead?	Date of death
<input type="radio"/> Yes <input type="radio"/> No	<input type="text"/> (dd/mm/yyyy)
Cause of death	<input type="checkbox"/> CV related <ul style="list-style-type: none"> <input type="checkbox"/> Heart disease <input type="checkbox"/> Stroke/TIA <input type="checkbox"/> Other <input type="checkbox"/> Renal related <input type="checkbox"/> Others <ul style="list-style-type: none"> <input type="checkbox"/> Cancer <input type="checkbox"/> COPD <input type="checkbox"/> Infection <input type="checkbox"/> Diarrheal diseases <input type="checkbox"/> Accident/trauma <input type="checkbox"/> Other <input type="text"/> <input type="checkbox"/> Unknown

PATIENT SURVIVAL STATUS

1) Is patient dead? This field is required. Select “Yes” or “No”.

- If the choice is “Yes”, specify the date of death; Enter the complete date in DD/MM/YYYY format.
- If the choice is “No”, date of death should be blank.

2) Cause of death: This field is required.

- If the answer to “Is patient dead?” is “Yes”, select one option only for cause of death. If “Other” is selected, please specify the cause of death in text.
- If the answer to “Is patient dead” is “No”, cause of death should be blank.

2.22 Diabetes

GENERAL	DIABETES	CKD	HEART FAILURE	MEDICATIONS	LAB TESTS
---------	----------	-----	---------------	-------------	-----------

☒ **Type II Diabetes (Fill once at first visit)**

	Date of diagnosis	Ongoing?
Type II DM	yyyy ▼ mm ▼ dd ▼	<input type="radio"/> Yes <input type="radio"/> No

Type II Diabetes (Fill once at first visit)

- 1) **Date of diagnosis:** Select year, month and day. If the date is unknown, please leave the field blank.
- 2) **Ongoing:** Select "Yes" or "NO".

☒ Any new events/diagnosis/procedures since last visit (Details, Date of Diagnosis (mm-dd-yyyy), Ongoing?)

Macrovascular pathologies and procedures

☐ Heart failure (HF)

☐ Foot Exam

Microvascular pathologies and procedures

☐ Eye Exam

☐ Chronic kidney disease

Others

Diabetic ketoacidosis

☐ YES
☒ NO
☐ Unknown

yyyy mm
dd

☐ Yes
☐ No

Major hypoglycemic events

☐ Yes
☐ No
☐ Unknown

If Yes, Total number of
episodes:

☐ Yes
☐ No

Major hypoglycaemic events are defined as those requiring external/3rd party help, e.g. going to the doctor or other healthcare professional, needing a caregiver, needing a family member, emergency room visit or hospitalization		
Minor hypoglycemic events <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	If Yes, Total number of episodes: <input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
Note: More events and procedures can be filled in the Diagnosis and Procedures forms.		

Any new events/diagnosis/procedures since last visit (Details, Date of Diagnosis (mm-dd-yyyy), Ongoing?): If the option is clicked, the content should not be empty.

1) Macrovascular pathologies and procedures: Select from "Heart failure (HF)", "Foot Exam", "Eye Exam", "Chronic kidney disease", and complete the details. If "Heart failure" or "CKD" is selected, a dialog will pop up and remind users: "Please complete the Heart Failure section" or "Please complete the CKD section"

2) Date of Diagnosis: Select year, month and day. If the date is unknown, please leave the field blank.

3) Ongoing: Select "Yes" or "No".

2.23 Chronic Kidney Disease

GENERAL	DIABETES	CKD	HEART FAILURE	MEDICATIONS	LAB TESTS
---------	----------	-----	---------------	-------------	-----------

Heart Failure

☐ Yes

☐ No

☒ Etiology of CKD (Fill once at first visit)

Name	Date of first Diagnosis
<input type="radio"/> Diabetic Kidney Disease	yyyy <input type="text"/> mm <input type="text"/> dd <input type="text"/>
<input type="radio"/> Hypertensive kidney disease	
<input type="radio"/> IgA glomerulonephritis	
<input type="radio"/> Polycystic kidney diseases	
<input type="radio"/> Lupus nephritis	
<input type="radio"/> Tubulointerstitial diseases	
<input type="radio"/> Vascular diseases	
<input type="radio"/> Alport syndrome	
<input type="radio"/> Other, please specify <input type="text"/>	

Heart Failure: Select “Yes” or “NO”. If Yes, a dialog will pop up and remind users: “Please complete the Heart Failure section”.

1) Etiology of CKD (Fill once at first visit): If the option is clicked, please complete the details.

Name: Select one option from “Diabetic Kidney Disease”, “Hypertensive kidney disease”, “IgA glomerulonephritis”, “Polycystic kidney diseases”, “Lupus nephritis”, “Tubulointerstitial diseases”, “Vascular diseases”, “Alport syndrome”, “Other, please specify”. If the choice is “Other, please specify”, please specify.

Date of first Diagnosis: Select year, month and day.

	Duration <input type="text"/> hours Adequacy <input type="text"/> Kt/V	
Anemia <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Definition of Anemia: Man: Hemoglobin (Hb) level of < 12.0 g/dL Woman: Hemoglobin (Hb) level of < 13.0 g/dL	<input type="text" value="yyyy"/> <input type="text" value="mm"/> <input type="text" value="dd"/>
Hyperkalaemia <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Definition of hyperkalaemia: K+ > 5.0 mmol/L	<input type="text" value="yyyy"/> <input type="text" value="mm"/> <input type="text" value="dd"/>
Renal transplant <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Type <input type="radio"/> Living donor <input type="radio"/> Paired kidney <input type="radio"/> Deceased donor	<input type="text" value="yyyy"/> <input type="text" value="mm"/> <input type="text" value="dd"/>

3) Clinical Outcome: If the option is clicked, please complete the details.

Name: for all clinical outcomes (“Dialysis,” Anemia,” Hyperkalaemia,” Renal transplant”), select “Yes”, “No”, or “Unknown”.

- If the choice is “No” or “Unknown”, please do not fill in the details.
- If the choice is “Yes”, please complete the details.

Date of Dx/Initiation: Select year, month and day. If the date is unknown, please leave the field blank.

2.24 Heart Failure

GENERAL	DIABETES	CKD	HEART FAILURE	MEDICATIONS	LAB TESTS
---------	----------	-----	---------------	-------------	-----------

Type II Diabetes

☐ Yes
☐ No

Chronic kidney disease

☐ Yes
☐ No

☒ Etiology (Fill once at first visit)

Type	Date of First Diagnosis	Ongoing?
<input type="radio"/> Ischaemic <input type="radio"/> Non-ischaemic <input type="radio"/> Valvular <input type="radio"/> Other,specify <input type="text"/>	<input type="text" value="yyyy"/> <input type="text" value="mm"/> <input type="text" value="dd"/>	<input type="radio"/> Yes <input type="radio"/> No

Type II Diabetes: Select “Yes” or “NO”. If Yes, a dialog will pop up and remind users: “Please complete the Diabetes section”.

Chronic kidney disease: Select “Yes” or “NO”. If Yes, a dialog will pop up: “Please complete the CKD section”.

Etiology (Fill once at first visit):

- 1) **Type:** Select only one option from “Ischaemic”, “Non-ischaemic”, “Valvular”, “Other, specify”, complete the other field if “Other, specify” is selected.
- 2) **Date of First Diagnosis:** Select year, month and day.
- 3) **Ongoing? :** Select “Yes” or “NO”.

<input checked="" type="checkbox"/> Classification	
Please indicate last known NYHA Class <input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV <input type="radio"/> Unknown	<div> <div>yyyy</div> <div>mm</div> <div>dd</div> </div>

Classification: If the option is selected, please fill in the details.

- 1) **Please indicate last known NYHA class:** Select one option only from “I”, “II”, “III”, “IV”, “Unknown”.
- 2) **Date of First Diagnosis:** Select year, month and day. If the date is unknown, please leave the field empty.

<input checked="" type="checkbox"/> Examinations	
ECG <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	<div> <div>Sinus rhythm</div> <div> <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown </div> <div>If No, Atrial fibrillation</div> <div> <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown </div> </div>
2D Echo (Modality) <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	<div> <div> <div>LVEF(%)</div> <div> <div>yyyy</div> <div>mm</div> <div>dd</div> </div> </div> <div> <div>LVH:</div> <div> <input type="radio"/> Present <input type="radio"/> Absent <input type="radio"/> Unknown </div> <div> <div>LA enlargement:</div> <div> <input type="radio"/> Present <input type="radio"/> Absent <input type="radio"/> Unknown </div> </div> </div> </div>

		<p>Diastolic Dysfunction:</p> <p><input type="radio"/> YES</p> <p><input type="radio"/> NO</p> <p><input type="radio"/> Unknown</p> <p>Valvular Disease</p> <p><input type="radio"/> YES</p> <p><input type="radio"/> NO</p> <p><input type="radio"/> Unknown</p> <p>If Yes, (multiple choices)</p> <p><input type="checkbox"/> AS (Aortic Stenosis)</p> <p><input type="checkbox"/> AR (Aortic Regurgitation) AR (Aortic Regurgitation)</p> <p><input type="checkbox"/> MS (Mitral Stenosis) MS (Mitral Stenosis)</p> <p><input type="checkbox"/> MR (Mitral Regurgitation) MR (Mitral Regurgitation)</p> <p><input type="checkbox"/> Unknown</p> <p>Evidence of pulmonary hypertension:</p> <p><input type="radio"/> YES</p> <p><input type="radio"/> NO</p> <p><input type="radio"/> Unknown</p>	
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Examinations: If the option is selected, please fill in details.

for all examinations ("ECG", "Echo (Modality)"), select "Yes", "No", or "Unknown".

- If the choice is "No" or "Unknown", please do not fill in the details.
- If the choice is "Yes", please complete the details.

1) ECG:

- Sinus rhythm: Select from "Yes", "No", or "Unknown".
- If No, Atrial fibrillation: "Yes", "No", or "Unknown".
- Date: Select year, month and day. If the date is unknown, please leave the field empty.

2) Echo (Modality):

- LV EF (%): Fill in the value.
- LVH: Select from "Present", "Absent", or "Unknown".
- LA enlargement: Select from "Present", "Absent", or "Unknown".
- Diastolic Dysfunction: Select from "Yes", "No", or "Unknown".
- Valvular Disease: Select from "Yes", "No", or "Unknown".
- If Yes, (multiple choices): If "Yes" is selected, select related valvular diseases.

- Evidence of pulmonary hypertension: Select from “Yes”, “No”, or “Unknown”.
- Date: Select year, month and day. If the date is unknown, please leave the field empty.

<input checked="" type="checkbox"/> Any new event since the last visit or within the last 12 months	
HF hospitalization <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If Yes, number of hospitalizations: <input type="text"/>
Emergency/Unplanned HF ER/outpatient visit <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	If Yes, number of ER visits: <input type="text"/>
HF Treatment	
Implantable cardioverter Defibrillator(ICD) <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Date <input type="text"/> yyyy <input type="text"/> mm <input type="text"/> dd

Cardiac resynchronization Therapy(CRT) <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Date <input type="text"/> yyyy <input type="text"/> mm <input type="text"/> dd
Dual chamber pacemaker <input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown	Date <input type="text"/> yyyy <input type="text"/> mm <input type="text"/> dd

Any new event since the last visit or within the last 12 months: If the option is selected, please fill in the details

For all new event (“HF hospitalization”, “Latest HF hospitalization (Appear only if HF hospitalization is YES)”, “Emergency/Unplanned HF ER/outpatient visit”, “Latest HF ER visit (Appear only if Emergency/Unplanned HF ER/outpatient visit is YES)”, “Implantable cardioverter Defibrillator

(ICD)”, “Cardiac resynchronization Therapy (CRT)”, “Dual chamber pacemaker”.), select “Yes”, “No”, or “Unknown”.

- If the choice is “No” or “Unknown”, please do not fill in the details.
- If the choice is “Yes”, please complete the details.

Date: Select year, month and day. If the date is unknown, please leave the field blank.

2.25 Medications

Repeat medications from last visit?: If the option is clicked, medications from last visit will be copied. Multiple medications can be entered by clicking the “+” button.

1) Example: Details should include:

- Line of treatment: Select one option only for line of treatment at the visit: 1 = First line, 2 = Second line, 3 = Third line, 4 = >Third line.
- Therapy type: Select one option only from: “antidiabetic”, “antilipidemic”, “antihypertensive”, “antiplatelet”, “anticoagulant”, “antianemic”, “antihyperkalemia”, “thrombolytics”, “antiHF therapy”, “acid blocker” and “immunosuppressant”.
- Agent: Please fill in the drug name. Enter the first 2 or more characters of the drug name. Then select one choice from the list provided by the system.
- Route of administration: Select one option only for the route of administration of Diuretics: 1 = Oral, 2 = IV, 3 = Topical, 4 = Inhaled, 5 = Other.
- Dose/duration: Please fill in the daily dose of the agent, using mg or IU as the unit or specify the unit used in text.
- Frequency: Select one option only from:
 - QH - Every hour
 - QD - Daily; Per day
 - BID - BD; Twice per day
 - TID - Three times per day
 - QID - Four times per day
 - QOD - Every other day

- QM - Every month
- PRN - As needed
- Q2H - Every two hours
- Q4H - Every four hours
- Start date: Enter complete date in DD/MM/YYYY format.
- End date: Enter complete date in DD/MM/YYYY format.
- Ongoing: select one option only from: "Yes" and "NO".

2.26 Lab Tests

GENERAL
DIABETES
CKD
HEART FAILURE
MEDICATIONS
LAB TESTS

☒
Glucose

HbA1c	<input type="text"/>	<input type="radio"/> % <input type="radio"/> mmol/L	<input type="checkbox"/> Not measured
Fasting plasma glucose	<input type="text"/>	<input type="radio"/> mmol/L <input type="radio"/> mg/dL	<input type="checkbox"/> Not measured
Postprandial plasma glucose	<input type="text"/>	<input type="radio"/> mmol/L <input type="radio"/> mg/dL	<input type="checkbox"/> Not measured

☒
Lipid Profile

Total cholesterol	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> mmol/L	<input type="checkbox"/> Not measured
HDL	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> mmol/L	<input type="checkbox"/> Not measured
LDL	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> mmol/L	<input type="checkbox"/> Not measured
Triglycerides	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> mmol/L	<input type="checkbox"/> Not measured

☒ Renal function

Serum creatinine (Serum CR)	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> μmol/L	<input type="checkbox"/> Not measured
eGFR <input type="radio"/> CKD-EPI <input type="radio"/> MDRD <input type="radio"/> Cockcroft Gault	<input type="text"/>	mL/min/1.73 m ²	
Urine albumin/creatinine Ratio	<input type="text"/>	<input type="radio"/> mg/mmol <input type="radio"/> mg/g	<input type="checkbox"/> Not measured
Serum albumin	<input type="text"/>	<input type="radio"/> g/dL <input type="radio"/> g/L	<input type="checkbox"/> Not measured
24-hour albumin	<input type="text"/>	<input type="radio"/> mcg/min <input type="radio"/> mcg/mg	<input type="checkbox"/> Not measured
Protein in urine	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> μmol/L	<input type="checkbox"/> Not measured
Urine protein/creatinine ratio	<input type="text"/>	<input type="radio"/> mg/mmol <input type="radio"/> mg/g	<input type="checkbox"/> Not measured
24-hour urine protein	<input type="text"/>	<input type="radio"/> g/24 hours	<input type="checkbox"/> Not measured

☒ Electrolyte

Potassium (K)	<input type="text"/>	<input type="radio"/> mmol/L or mEq/L <input type="radio"/> mg/dL	<input type="checkbox"/> Not measured
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☒ Blood Test

Hemoglobin (Hb)	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> mg/L <input checked="" type="radio"/> g/dL	<input type="checkbox"/> Not measured
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<input checked="" type="checkbox"/> Liver Function			
Alanine transaminase (ALT)	<input type="text"/>	<input type="radio"/> IU/L <input type="radio"/> $\mu\text{mol/L}\cdot\text{s}$	<input type="checkbox"/> Not measured
Aspartate transaminase (AST)	<input type="text"/>	<input type="radio"/> IU/L <input type="radio"/> $\mu\text{mol/L}\cdot\text{s}$	<input type="checkbox"/> Not measured

<input checked="" type="checkbox"/> Biomarker			
Pro-N-terminal-Brain natriuretic peptide (NT-proBNP)	<input type="text"/>	<input checked="" type="radio"/> pg/mL <input type="radio"/> pmol/L <input type="radio"/> ng/L	<input type="checkbox"/> Not measured
BNP	<input type="text"/>	<input checked="" type="radio"/> pg/mL <input type="radio"/> pmol/L <input type="radio"/> ng/L	<input type="checkbox"/> Not measured
Troponin I	<input type="text"/>	<input type="radio"/> ng/mL <input type="radio"/> pmol/L	<input type="checkbox"/> Not measured
Troponin T	<input type="text"/>	<input type="radio"/> ng/mL <input type="radio"/> pmol/L	<input type="checkbox"/> Not measured

1) For all laboratory tests:

- If the test is not done, the “Not measured” option should be selected. No value should be entered to any field.
- If the test result is available, enter the value of the result. Note the result should be within the plausible range of each parameter.
- If the value of the test result has been entered, the user should select the unit of the value.

2) For Mandatory tests: Laboratory tests labelled by a red asterisk (*) are required (e.g., HbA1c and Serum creatinine). The user must either enter the test result or select the “Not measured” option.

2.3 LIFESTYLE (Optional)

LIFESTYLE

Alcohol Drinking

Usage

☐ Lifetime abstainer
☐ Former drinker
☐ Social drinker
☐ Heavy drinker

If "Former drinker or Drinker", specify below:

years of drinking

Glasses per day

Substance use classified as prohibited drugs ☐ YES ☐ NO ☐ Unknown

If yes, date of last use

1) **Alcohol Drinking:** Select one option only from: "Lifetime abstainer", "Former drinker", "Social drinker", and "Heavy drinker". If a user chooses "Former drinker", "Social drinker" or "Heavy drinker", specify the number of years drinking and fill in the "Glasses per day" field.

Definitions:

- **Lifetime abstainers:** Patients who have never drunk.
- **Former drinker:** Patients who stopped drinking ≥ 365 days ago. Consider a "drink" to be a can or bottle of beer, a glass of wine, a wine cooler, or one cocktail or a shot of hard liquor (like scotch, gin, or vodka)
- **Social drinker:** Patients who drink alcohol chiefly on social occasions and only in moderate quantities.
- **Heavy drinker:** women who consume 8 or more drinks per week. And for men, 15 or more drinks a week.

2) **Substance use classified as prohibited drugs:** Select "Yes", "No" or "Unknown".

3) **Date of last use:** If substance use is "Yes", select year, month and day. If the date is unknown, please leave the field blank.

2.4 PHYSICAL MEASUREMENTS (Optional)

PHYSICAL MEASUREMENTS

Waist circumference

☐ Centimeters ☐ Inches

Save

1) **Waist circumference:** Enter a measured value obtained during vital sign test, select the appropriate unit.

2.5 LAB TESTS (Optional)

LAB TESTS

☒ Liver function tests

	Value	Unit
Gamma glutamyl transpeptidase (r-GT, GGT)	<input type="text"/>	<input type="radio"/> IU/L <input type="radio"/> $\mu\text{mol/L}\cdot\text{s}$

☒ Renal function tests

	Value	Unit
Urine albumin (spot urine collection)	<input type="text"/>	<input type="radio"/> mg/L <input type="radio"/> $\mu\text{g/g}$
Urine albumin (spot urine collection)	<input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	
Blood urea nitrogen (BUN)	<input type="text"/>	<input type="radio"/> mmol/L <input type="radio"/> mg/dL
Uric acid	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> $\mu\text{mol/L}$

☒ Electrolyte

	Value	Unit
Sodium (Na)	<input type="text"/>	<input type="radio"/> mmol/L or mEq/L <input type="radio"/> mg/dL
Calcium (Ca)	<input type="text"/>	<input type="radio"/> mmol/L or mEq/L <input type="radio"/> mg/dL
Chloride (Cl)	<input type="text"/>	<input type="radio"/> mmol/L or mEq/L <input type="radio"/> mg/dL
Magnesium (Mg)	<input type="text"/>	<input type="radio"/> mmol/L or mEq/L <input type="radio"/> mg/dL
Serum Phosphorus (P)	<input type="text"/>	<input type="radio"/> mmol/L or mEq/L <input type="radio"/> mg/dL

☒ Blood tests

	Value	Unit
White blood cell (WBC)	<input type="text"/>	x10E3/ μ L
Red blood cell (RBC)	<input type="text"/>	x10E3/ μ L
C-reactive protein	<input type="text"/>	mg/dL
Hematocrit	<input type="text"/>	%
Platelets (PLT)	<input type="text"/>	x10E3/ μ L

☒ Need to record target setting

	Value	Unit
Hb1Ac	<input type="text"/>	<input type="radio"/> % <input type="radio"/> mmol/L
Fasting Plasma Glucose	<input type="text"/>	<input type="radio"/> mmol/L <input type="radio"/> mg/dL

1) For all additional lab tests not captured in the Core Metrics:

- If the test is not done, no value should be entered to any field.
- If the test result is available, enter the value of the result. Note the result should be within the plausible range of each parameter.
- If the value of the test result has been entered, the user should select the unit of the value.

2) Need to record target setting: HbA1c and Fasting plasma glucose target attainment can be specified.

2.6 FAMILY MEDICAL HISTORY (This form should only be filled once at the first visit)

FAMILY MEDICAL HISTORY		
Any Relevant Family Medical History? <input type="radio"/> Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown		
Disease	History	Relationship
Type 2 diabetes	<input type="radio"/> Yes <input type="radio"/> No	<input type="text" value="v"/>
Hypertension	<input type="radio"/> Yes <input type="radio"/> No	<input type="text" value="v"/>
Dyslipidemia	<input type="radio"/> Yes <input type="radio"/> No	<input type="text" value="v"/>
Metabolic syndrome	<input type="radio"/> Yes <input type="radio"/> No	<input type="text" value="v"/>
* Relationship: First degree (e.g. parent, sibling or child); Second degree (e.g. grandparent, aunt/uncle or niece/nephew).		

Any Relevant Family Medical History?: Select “Yes”, “No”, “Unknown”.

1) Type 2 diabetes: If the patient has a family history of Type 2 diabetes, select “Yes” and complete the relationship. If not, please select “NO”.

2) Hypertension: If the patient has a family history of Hypertension, select “Yes” and complete the relationship. If not, please select “NO”.

3) Dyslipidemia: If the patient has a family history of Dyslipidemia, select “Yes” and complete the relationship. If not, please select “NO”.

4) Metabolic syndrome: If the patient has a family history of Metabolic syndrome, select “Yes” and complete the relationship. If not, please select “NO”.

2.7 MEDICAL HISTORY (This form should only be filled once at the first visit)

MEDICAL HISTORY				
Previous history of macrovascular pathologies and procedures				
Name	Details	Diagnosis Date	Duration (years)	Ongoing
<input type="checkbox"/> Angina <input checked="" type="checkbox"/> Unknown	Please indicate last known CCS Class <input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> Unknown	yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Transient Ischemic Attack(TIA) <input type="checkbox"/> Unknown	<input type="radio"/> Single <input type="radio"/> Multiple <input type="radio"/> Unknown	yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Carotid stenting <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No

Previous history of macrovascular pathologies and procedures

Name: Click the option to indicate that there is a macrovascular pathology or a procedure.

- If “Unknown” is selected, please do not fill in the details.
- If the option is clicked, you should complete the details.

Angina example:

- If the answer to “Angina” is “Yes”, details should include:
 - CCS class: Select one option only from: “1”, “2”, “3”, “4” and “Unknown”.
 - Diagnosis Date: Select the year, month, day in different list.
 - Duration: It is auto-calculated by the system.
 - Ongoing: Select “Yes” or “No”.

<input type="checkbox"/> Carotid endarterectomy <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Peripheral arterial diseases(PAD) <input type="checkbox"/> Unknown		yyyy mm dd		<input checked="" type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Venous thromboembolism (deep vein thrombosis/Pulmonary embolism) <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Atrial fibrillation / flutter <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Ventricular Arrhythmia <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Pacemaker implanted <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Defibrillator (ICD) <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No

<input type="checkbox"/> Severe Valve disease <input type="checkbox"/> Unknown	Type: <input type="radio"/> Aortic <input type="radio"/> Mitral <input type="radio"/> Pulmonic <input type="radio"/> Tricuspid <input type="radio"/> Unknown	yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> None of the above				
Previous history of microvascular pathologies and procedures				
Name	Details	Diagnosis Date	Duration (years)	Ongoing
<input type="checkbox"/> Albuminuria <input type="checkbox"/> Unknown	Please indicate year of last diagnosis <input type="text"/> Please indicate urine albumin value <input type="text"/> <input type="radio"/> mg/g <input type="radio"/> mg/L <input type="radio"/> µg/min	yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Symptomatic peripheral neuropathy <input type="checkbox"/> Unknown		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No

Previous history of microvascular pathologies and procedures

Name: Click the option to indicate that there is a microvascular pathology or a procedure.

- If “Unknown” is selected, please do not fill in the details.
- If the option is clicked, you should complete the details.

Albuminuria example:

- If the answer to “Albuminuria” is “Yes”, details should include:
 - Details: Fill in the year of last diagnosis and urine albumin value, select corresponding unit.
 - Diagnosis Date: Select the year, month and day.
 - Duration: It is auto-calculated by the system.
 - Ongoing: Select “Yes” or “No”.

<input type="checkbox"/> Autonomic neuropathy		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Unknown				
<input type="checkbox"/> Erectile dysfunction		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Unknown				
<input type="checkbox"/> None of the above				
Previous history of other pathologies				
Name	Details	Diagnosis Date	Duration (years)	Ongoing
<input type="checkbox"/> Gout		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Unknown				
<input type="checkbox"/> Hyperuricemia		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Unknown				
<input type="checkbox"/> COPD/Bronchitis		yyyy mm dd		<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Unknown				

Previous history of other pathologies

Name: Click the option to indicate other pathologies.

- If “Unknown” is selected, please do not fill in the details.
- If the option is clicked, you should complete the details.

Gout example:

- If the answer to “Gout” is “Yes”, details should include:
 - Diagnosis Date: Select the year, month and day.
 - Duration: It is auto-calculated by the system.

- Ongoing: Select “Yes” or “No”.

<input type="checkbox"/> Depression <input type="checkbox"/> Unknown		yyyy <input type="text"/> mm <input type="text"/> dd <input type="text"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Dementia <input type="checkbox"/> Unknown		yyyy <input type="text"/> mm <input type="text"/> dd <input type="text"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Infection in the last 12 months <input type="checkbox"/> Unknown	<input type="checkbox"/> Urinary tract infection <input type="checkbox"/> Genital infection <input type="checkbox"/> Pneumonia <input type="checkbox"/> Cellulitis <input type="checkbox"/> Septicemia <input type="checkbox"/> Pyelonephritis <input type="checkbox"/> Arthritis (infection of the joints) <input type="checkbox"/> Other serious infections	yyyy <input type="text"/> mm <input type="text"/> dd <input type="text"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No

<input type="checkbox"/> Cancer <input type="checkbox"/> Unknown	Please indicate primary site of cancer(s) <input type="checkbox"/> Bladder <input type="checkbox"/> Brain <input type="checkbox"/> Breast <input type="checkbox"/> Colorectal <input type="checkbox"/> Endometrial <input type="checkbox"/> Kidney <input type="checkbox"/> Leukemia <input type="checkbox"/> Liver <input type="checkbox"/> Lungs <input type="checkbox"/> Lymphoma <input type="checkbox"/> Pancreatic <input type="checkbox"/> Prostate <input type="checkbox"/> Other, please specify <input type="checkbox"/> Unknown	yyyy <input type="text"/> mm <input type="text"/> dd <input type="text"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Hepatic insufficiency <input type="checkbox"/> Unknown	Please indicate Child-Pugh Class <input type="radio"/> A <input type="radio"/> B <input type="radio"/> C <input type="radio"/> Unknown	yyyy <input type="text"/> mm <input type="text"/> dd <input type="text"/>	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No

<input type="checkbox"/> Chronic pancreatitis <input type="checkbox"/> Unknown	<input type="radio"/> Single <input type="radio"/> Recurrent <input type="radio"/> Unknown	yyyy ▾ mm ▾ dd ▾	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Acute pancreatitis <input type="checkbox"/> Unknown	<input type="radio"/> Single <input type="radio"/> Recurrent <input type="radio"/> Unknown	yyyy ▾ mm ▾ dd ▾	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Tuberculosis <input type="checkbox"/> Unknown		yyyy ▾ mm ▾ dd ▾	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> HIV <input type="checkbox"/> Unknown		yyyy ▾ mm ▾ dd ▾	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Bariatric surgery <input type="checkbox"/> Unknown		yyyy ▾ mm ▾ dd ▾	<input type="text"/>	
<input type="checkbox"/> Gastric balloon <input type="checkbox"/> Unknown		yyyy ▾ mm ▾ dd ▾	<input type="text"/>	

<input type="checkbox"/> Sleep apnea <input type="checkbox"/> Unknown	Treated with CPAP <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown	yyyy ▾ mm ▾ dd ▾	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> Bone fractures in the last 12 months <input type="checkbox"/> Unknown		yyyy ▾ mm ▾ dd ▾	<input type="text"/>	
<input type="checkbox"/> Hip or knee replacement <input type="checkbox"/> Unknown		yyyy ▾ mm ▾ dd ▾	<input type="text"/>	
<input type="checkbox"/> Thyroid disease <input type="checkbox"/> Unknown	<input type="radio"/> Hyperthyroidism <input type="radio"/> Hypothyroidism <input type="radio"/> N/A	yyyy ▾ mm ▾ dd ▾	<input type="text"/>	<input type="radio"/> Yes <input type="radio"/> No
<input type="checkbox"/> None of the above				

Major hypoglycaemic events	
Did the patient experience any major hypoglycaemic events in the last 12 months (Major hypoglycaemic events are defined as those requiring external/3rd party help, e.g. going to the doctor or the healthcare professional, needing a caregiver, needing a family member, emergency room visit or hospitalization.)	Number of these episodes requiring emergency room visit/hospital admission: <input type="text"/>
Reproductive history/menstrual history for female patients	
Menstruation	
<input type="checkbox"/> Regular	
<input type="checkbox"/> Menopause	Year of Menopause <input type="text"/> OR At the age of <input type="text"/> Years
<input type="checkbox"/> Hysterectomy	At the age of <input type="text"/> Years
Reproductive History	
G: No. of Gravida	<input type="text"/>
P: No. of Parity	<input type="text"/>
A: No. of Abortions	<input type="text"/>
L: No. of Live Births	<input type="text"/>

Allergies	
List of drugs with known allergies	<input type="checkbox"/> Balsam of Peru <input type="checkbox"/> Tetracycline <input type="checkbox"/> Dilantin <input type="checkbox"/> Tegretol (carbamazepine) <input type="checkbox"/> Penicillin <input type="checkbox"/> Cephalosporins <input type="checkbox"/> Sulfonamide <input type="checkbox"/> Non-steroidal anti-inflammatories (cromolyn sodium, nedocromil sodium, etc.) <input type="checkbox"/> Intravenous contrast dye <input type="checkbox"/> Local anesthetics

1) Major hypoglycemic events

Number of these episodes requiring emergency room visit/hospital admission: Fill in the number if the value is available.

2) Menstruation: Fill in the details if available.

3) Reproductive History: Fill in the details if available.

4) Allergies: Multiple choices, one or more options can be selected according to the actual situation.

2.8 DIAGNOSIS (Diagnosis in this visit)

DIAGNOSIS

Diagnosis date

2020

3

dd

+

Name	Details	
<div><div></div><div>Please enter 2 or more characters</div></div>	<div></div>	<div>-</div>

Save

- 1) **Diagnosis date:** Please select the year, month and day.
- 2) **Name:** Please fill in the diagnosis name. Enter the first 2 or more characters of the diagnosis name. Then select one choice from the list provided by the system. Multiple diagnosis can be entered.
- 3) **Details:** Complete the details for a diagnosis if it is available.

2.9 PROCEDURE (Other procedures done in this visit not recorded in Core Metrics)

PROCEDURES

<input type="checkbox"/> Diagnostic cath with PCI	<input type="checkbox"/> Bare metal
	<input type="checkbox"/> Drug eluting
<input type="checkbox"/> Diagnostic cath without PCI	
<input type="checkbox"/> Carotid stenting	
<input type="checkbox"/> Carotid endarterectomy	
<input type="checkbox"/> Pacemaker implanted	
<input type="checkbox"/> Defibrillator (ICD)	
<input type="checkbox"/> Vascular surgical repair	
<input type="checkbox"/> Peripheral angiography	
<input type="checkbox"/> Peripheral vascular intervention	

<input type="checkbox"/> Electrophysiologic (EP) study	
<input type="checkbox"/> Retinal laser photocoagulation	
<input type="checkbox"/> Bariatric surgery	
<input type="checkbox"/> Gastric balloon	
<input type="checkbox"/> Hip or knee replacement	
<input type="checkbox"/> Stress test	
<input type="checkbox"/> CT Scan	
<input type="checkbox"/> ABI	
<input type="checkbox"/> Routine tests (for example, cardiac monitor, fingerstick glucose, blood and urine analyses, etc.)	

<input type="checkbox"/> Outpatient Percutaneous coronary intervention (PCI)	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown If yes, <input type="radio"/> PCI - With stent/s <input type="radio"/> PCI - Without stent/s
<input type="checkbox"/> Outpatient Peripheral arterial disease (PAD)-related procedures	
<input type="checkbox"/> Outpatient cardiac testing (for example, imaging techniques, nuclear stress test, etc.)	
<input type="checkbox"/> Outpatient neurologic tests (e.g., electrophysiological tests, etc.)	
<input type="checkbox"/> Eye surgery	
<input type="checkbox"/> Others	
<input type="checkbox"/> None of the above	

Procedure: For all procedures (“Diagnostic cath with PCI”, “Diagnostic cath without PCI”, and “Carotid stenting”, click the option to indicate that there is a record.

- If the choice is not clicked, please do not fill in the details.
- If the option is clicked, please complete the details.

- 1) **Diagnostic cath with PCI:** If the option is selected, please select an option from “Bare metal”, “Drug eluting”.
- 2) **Outpatient percutaneous coronary intervention (PCI):** If the option is clicked, please select one option from “Yes”, “No” and “Unknown”. If the choice is “Yes”, select an option from “PCI - With stent/s”, “PCI - Without stent/s”.

2.10 TREATMENTS (Additional medications not recorded in Core Metrics)

TREATMENTS

☐ Repeat medications from last visit?

+

Line of treatment	Therapy type	Agent	Route of administration	Dose/duration	Start date	End date	Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> Unit <input type="radio"/> mg <input type="radio"/> IU <input type="radio"/> Other unit <input type="text"/> Frequency <input type="text"/>	<input type="text"/> (dd/mm/yyyy)	<input type="text"/> (dd/mm/yyyy)	<input type="radio"/> Yes <input type="radio"/> No

Details of insulin therapy

Short acting insulin	<input type="radio"/> Basal <input type="radio"/> Bolus
Long acting insulin	<input type="radio"/> Basal <input type="radio"/> Bolus
Short acting insulin	<input type="text"/>
Long acting insulin	<input type="text"/>
Intermediate insulin	<input type="text"/>
FDCs of insulin	<input type="text"/>

TREATMENTS

+

Line of treatment	Therapy type	Product	Route of administration	Dose/duration	Start date	End date	Ongoing
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> Unit <input type="radio"/> mg <input type="radio"/> IU <input type="radio"/> Other unit <input type="text"/> Frequency <input type="text"/>	<input type="text"/> (dd/mm/yyyy)	<input type="text"/> (dd/mm/yyyy)	<input type="radio"/> Yes <input type="radio"/> No

1) Repeat additional medications from last visit?: If the option is clicked, medications from last visit will be populated in the table. Multiple medications can be entered by clicking the “+” button.

2) Example: Details should include:

- Line of treatment: Select one option only for line of treatment at the visit: 1 = First line, 2 = Second line, 3 = Third line, 4 = >Third line, 5=others.

- Therapy type: Select one option only from: "Antidepressant", "NSAIDs", "Thyroid replacement drug", and "Other".
- Agent: Please fill in the drug name. Enter the first 2 or more characters of the drug name. Then select one choice from the list provided by the system.
- Route of administration: Select one option only for the route of administration of Diuretics: 1 = Oral, 2 = IV, 3 = Topical, 4 = Inhaled, 5 = Other.
- Dose/duration: Please fill in the daily dose of the product, using mg or IU as the unit or specify the unit used in text.
- Frequency: Select one option only from:
 - QH - Every hour
 - QD - Daily; Per day
 - BID - BD; Twice per day
 - TID - Three times per day
 - QID - Four times per day
 - QOD - Every other day
 - QM - Every month
 - PRN - As needed
 - Q2H - Every two hours
 - Q4H - Every four hours
- Start date: Enter complete date in DD/MM/YYYY format.
- End date: Enter complete date in DD/MM/YYYY format.
- Ongoing: select one option only from: "Yes" and "NO".

3) Details of insulin therapy: Complete the details of insulin therapy

- "Short acting insulin", "Long acting insulin": select an option from "Basal" or "Bolus".
- "Short acting insulin", "Long acting insulin", "Intermediate insulin", "FDCs of insulin": Enter the agent(s).

2.11 LIFE WITH DISEASE (Optional)

REMOTE MONITORING

Does the patient use glucose monitoring equipment?

☐ YES ☐ NO ☐ Unknown

If Yes, Frequency of glucose monitoring:

Times per week

Times per month

Test Strips consumption: per month

☐ Continuous Glucose Monitoring

1) **Does the patient use glucose monitoring equipment?:** Select “Yes”, “No” or “Unknown”.

- If the choice is “Yes”, specify the “Frequency of glucose monitoring” and “Test Strips consumption”, and complete the “Continuous Glucose Monitoring” field.
- If the choice is “No” or “Unknown”, leave the field blank.

EDUCATION

Please indicated Whether patient has received education about diabetes treatment and management.	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown If Yes: <input type="radio"/> Individual education <input type="radio"/> Group education <input type="radio"/> Belongs to a diabetes patients association
HCP checked patient knowledge of type 2 diabetes	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown
HCP clarified misconceptions about type 2 diabetes with the patient	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> Unknown
Patient awareness of type 2 diabetes support resources	<input type="radio"/> Existing type 2 diabetes program <input type="radio"/> Health Center <input type="radio"/> None

2) **Please indicated Whether patient has received education about diabetes treatment and management.:** Select “Yes”, “No”, or “Unknown”.

- If the choice is “Yes”, select one option only from: “Individual education”, “Group education”, “Belongs to a diabetes patients association”.
- If the choice is “No” or “Unknown”, no choice can be selected.

3) **HCP checked patient knowledge of type 2 diabetes:** Select “Yes”, “No”, or “Unknown”.

4) **HCP clarified misconceptions about type 2 diabetes with the patient:** Select “Yes”, “No”, or “Unknown”.

5) **Patient awareness of type 2 diabetes support resources:** Select one option only from: “Existing type 2 diabetes program”, “Health Center”, “None”.

Physical Activity	
Frequency (weekly)	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> >=5
Intensity	<input type="radio"/> Light (able to talk or sing during exercise) <input type="radio"/> Moderate (able to talk but not sing during exercise) <input type="radio"/> Vigorous/hard (difficulty talking during exercise)
Length of each session of physical activity	<input type="radio"/> <=1 hr <input type="radio"/> >1 hr

6) **Frequency (weekly):** Select one option from “1”, “2”, “3”, “4”, “>=5”.

7) **Intensity:** Select one option only from: “Light (able to talk or sing during exercise)”, “Moderate (able to talk but not sing during exercise)”, “Vigorous/hard (difficulty talking during exercise)”.

8) **Length of each session of physical activity:** Select one option only from: “<=1 hr”, “>1 hr”.

Diet

Nutritional advice provided by HCP	<input type="radio"/> Pinanggang pinoy <input type="radio"/> Calorie counting <input type="radio"/> Low salt, low fat type 2 diabetes diet <input type="radio"/> Refer to a nutritionist <input type="radio"/> None
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9) **Nutritional advice provided by HCP:** Select one option only from: “Pinanggang pinoy”, “Calorie counting”, “Low salt, low fat type 2 diabetes diet”, “Refer to a nutritionist”, “None”.

2.12 USE OF HEALTHCARE RESOURCE (Optional)

USE of HEALTHCARE RESOURCES

☐ YES ☐ NO ☐ Unknown

Number of hospitalization/ER since last visit

+

Reason for hospitalization/ER	Length of stay	
<div></div>	<div>Day(s)</div>	<div>-</div>

Save

- 1) **USE OF HEALTHCARE RESOURCES:** For all types of healthcare resource utilization (“Hospitalization” and “Emergency department visit”), select “Yes”, “No”, or “Unknown”. If the choice is “No” or “Unknown”, please do not fill in the details. If the choice is “Yes”, please complete the details. For Hospitalization and Emergency department visit, multiple occurrences can be entered by clicking the “+” button.
- 2) **Number of hospitalization/ER since last visit:** If the choice is “Yes”, please fill in the number.
- 3) **Reason for hospitalization/ER:** If the choice is “Yes”, please fill in the reason.
- 4) **Length of stay:** If the choice is “Yes”, please fill in the length of stay.

3 CONTACT INFORMATION

3.1 Contact List

Name	Role	Phone	E-Mail
RWE Box Help Desk	Technical Support available 24 hours/day, 7 days/week	NA	discover_global_registry_support@genomseq care.com

4 APPENDIX

4.1 eGFR calculations

CKD Epi

$$\text{GFR} = 141 \times \min(\text{Scr}/\kappa, 1)^{\alpha} \times \max(\text{Scr}/\kappa, 1)^{-1.209} \times 0.993^{\text{Age}} \times 1.018[\text{if female}] \times 1.159[\text{if black}]$$

$$\kappa = 0.7 \text{ if female}$$

$$\kappa = 0.9 \text{ if male}$$

$$\alpha = -0.329 \text{ if female}$$

$$\alpha = -0.411 \text{ if male}$$

min = The minimum of Scr/ κ or 1

max = The maximum of Scr/ κ or 1

Scr = serum creatinine (mg/dL)

MDRD: $\text{GFR} = 186 \times (\text{Creatinine}/88.4)^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.210 \text{ if black})$

Cockcroft Gault:

Creatinine Clearance Value = $(140 - \text{age})(\text{weight kg}) / (72 \times S_{cr})$ in mL/min

Scr = serum creatinine (mg/dL), Multiply by .85 if female