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

TABLE OF CONTENTS
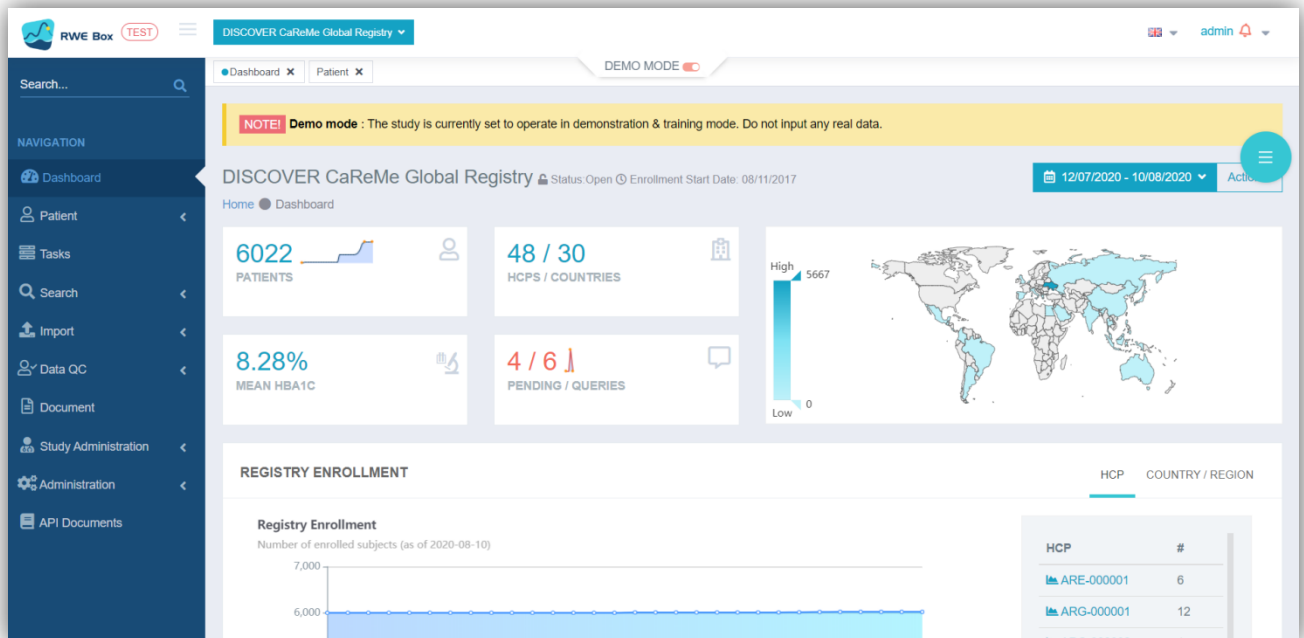
1   GENERAL EDC SYSTEM INFORMATION

1.1 LOGIN & NAVIGATION

1.11 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.

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

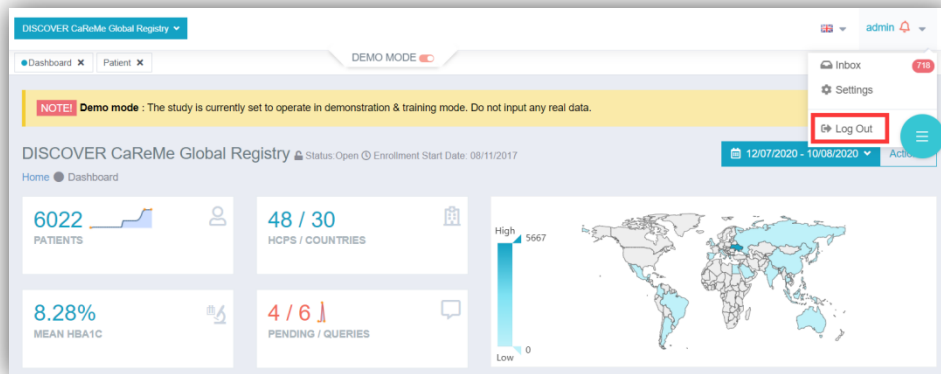## 1.12 Login failure

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

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.
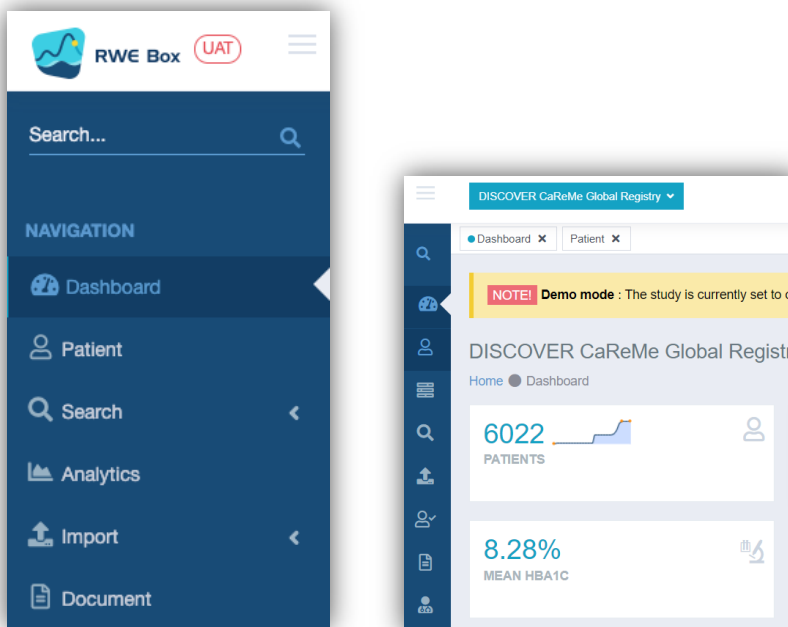
1.2 CHANGE USER SETTINGS

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.)

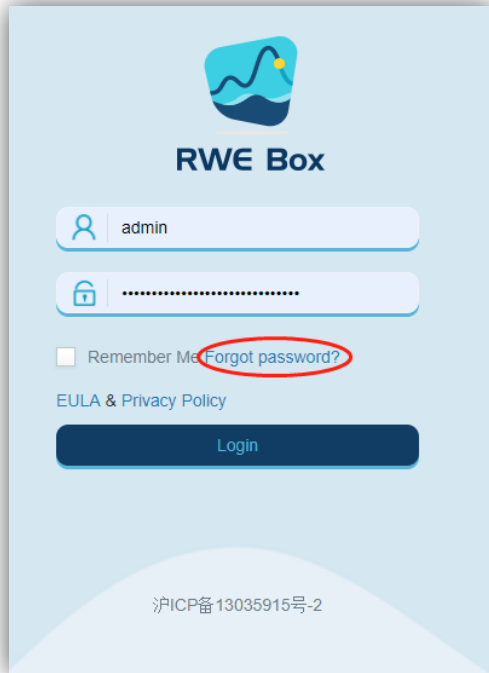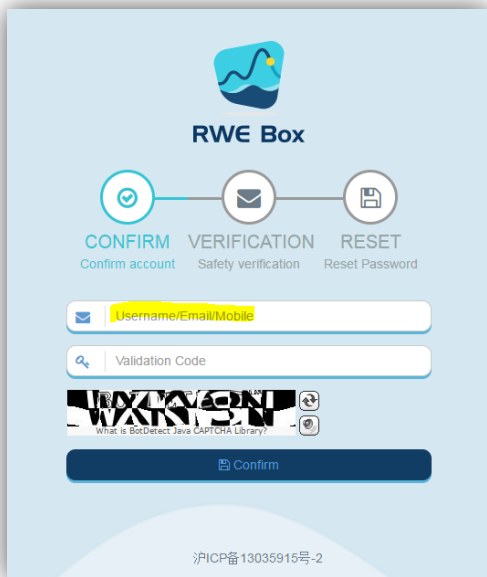Also, the user can select the "Forgot password?" button on the login page to recover their password.
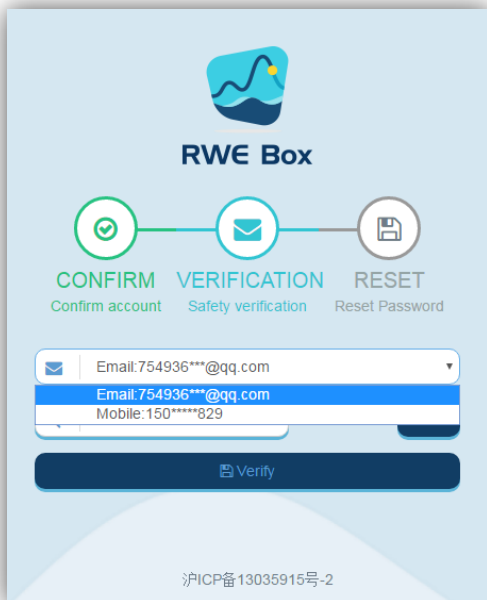
After clicking the "Forgot password?" button, the users can verify their identities by entering their "username/email address" which they provided during the registration process. Type "Username" or "Email" then enter the "Validation Code" found underneath the text field on the login page.

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 user can choose to receive the verification code by email.

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.)

Dear User yafei-HCP:

Hello! Thank you for using RWE Box services! Your verification code is:

239594　(In order to protect your account, please submit your verification code and complete varification within an hour.)

RWE Box team
2019-07-17 10:00:38
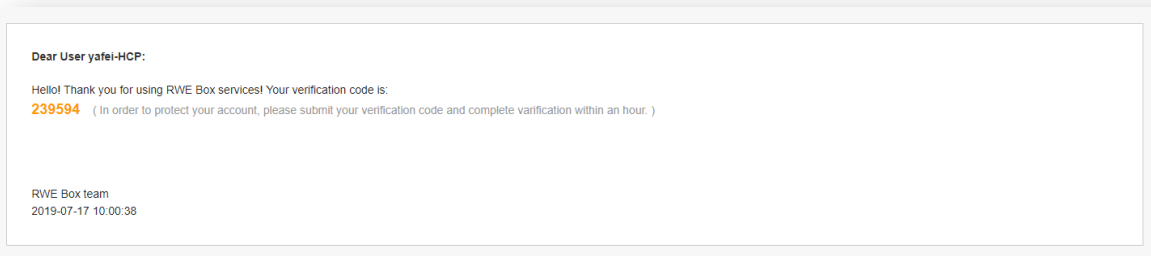
The user can change their password by typing the received code into the text field on the verification page. The new password must be at least 8 characters long, cannot match username, must contain an uppercase character and at least one number, and it is case sensitive.

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.

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

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.
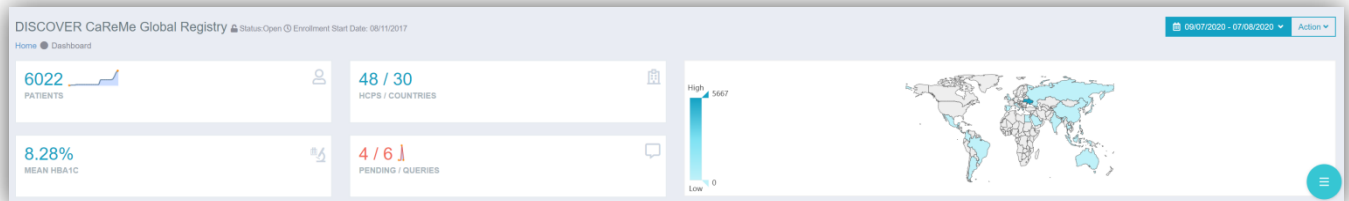
Users can also change the dashboard date range on the top of the study dashboard page.
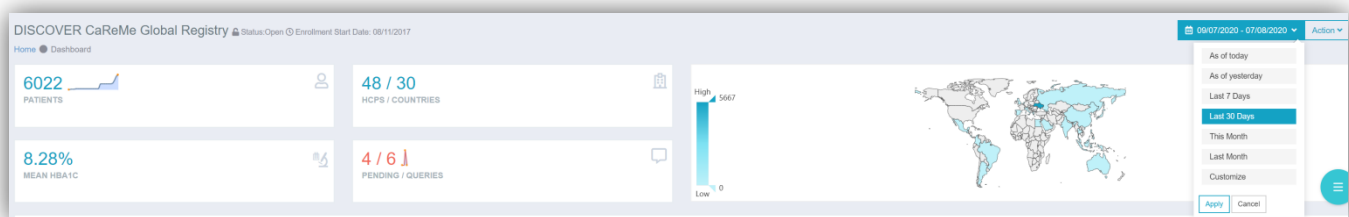
1.31 Recruitment overview by site

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.
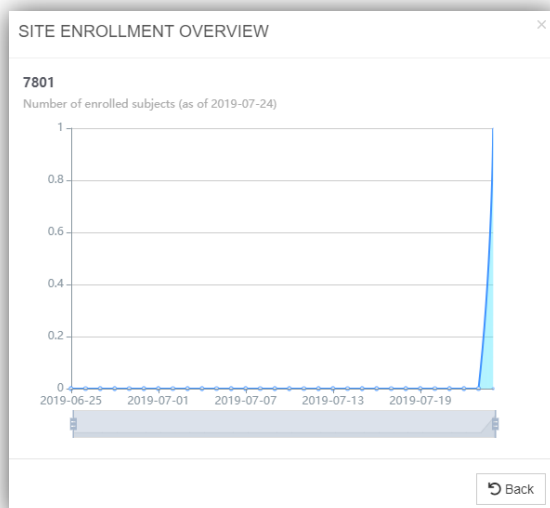
1.4 PATIENTS

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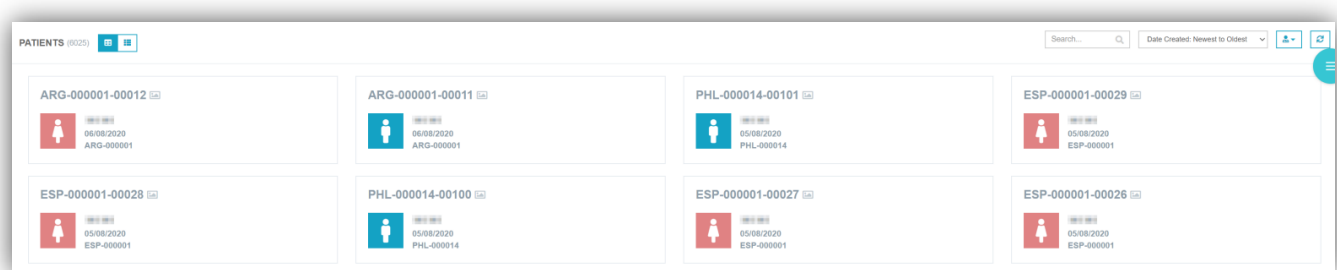
In the Card format, each patient is represented by a card. By default the cards are sorted according to the date added, where the most recently added cards are displayed first. To sort the cards, select the "Sort By" option in the dropdown list.

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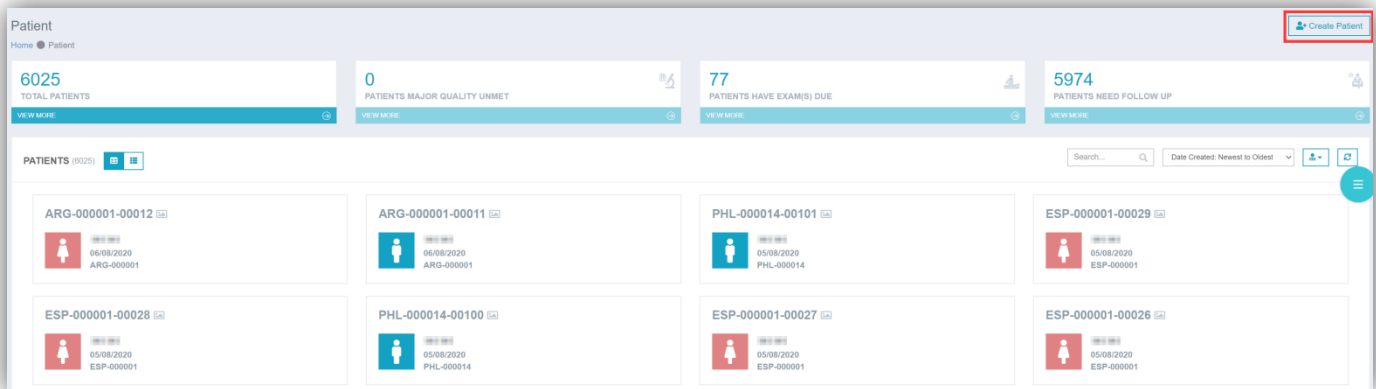
The end user shall fill out all of the mandatory fields before saving the patient info. Once the information is saved, an enrollment number will be generated automatically. Next, the user will be directed to the patient dashboard of this new patient.

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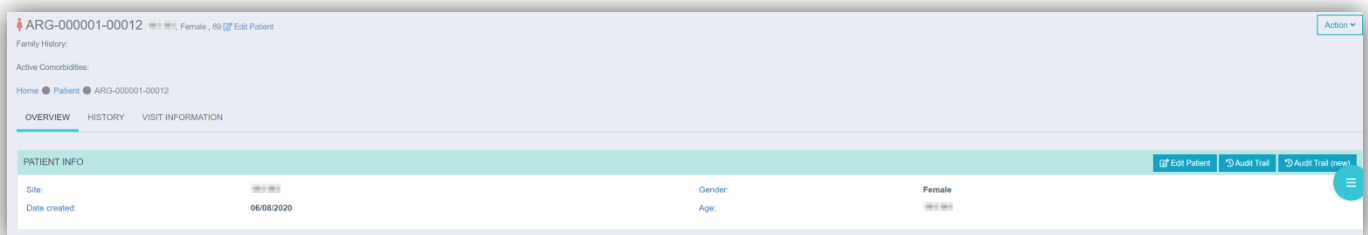
They summary component under the overview tab has a few mini-tabs: latest view tab displays patient's HbA1c, BMI, DBP, SBP and weight measurement. Active comorbidities tab displays the patient's top 10 comorbidities. Current treatment tab lists the patient's active medications. Quality metrics tab shows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

patient's important vital signs and lab tests and compares the results to normal testing ranges. By clicking the "history" tab, the uses 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.
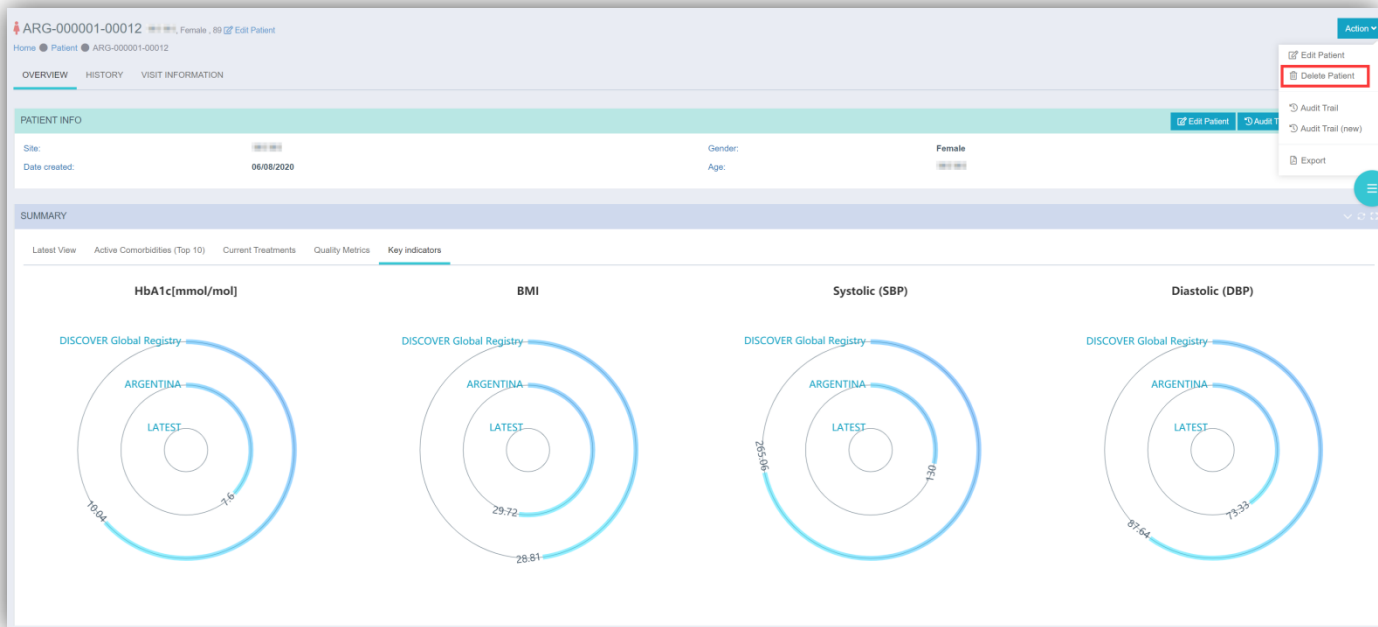
1.46 Audit trail

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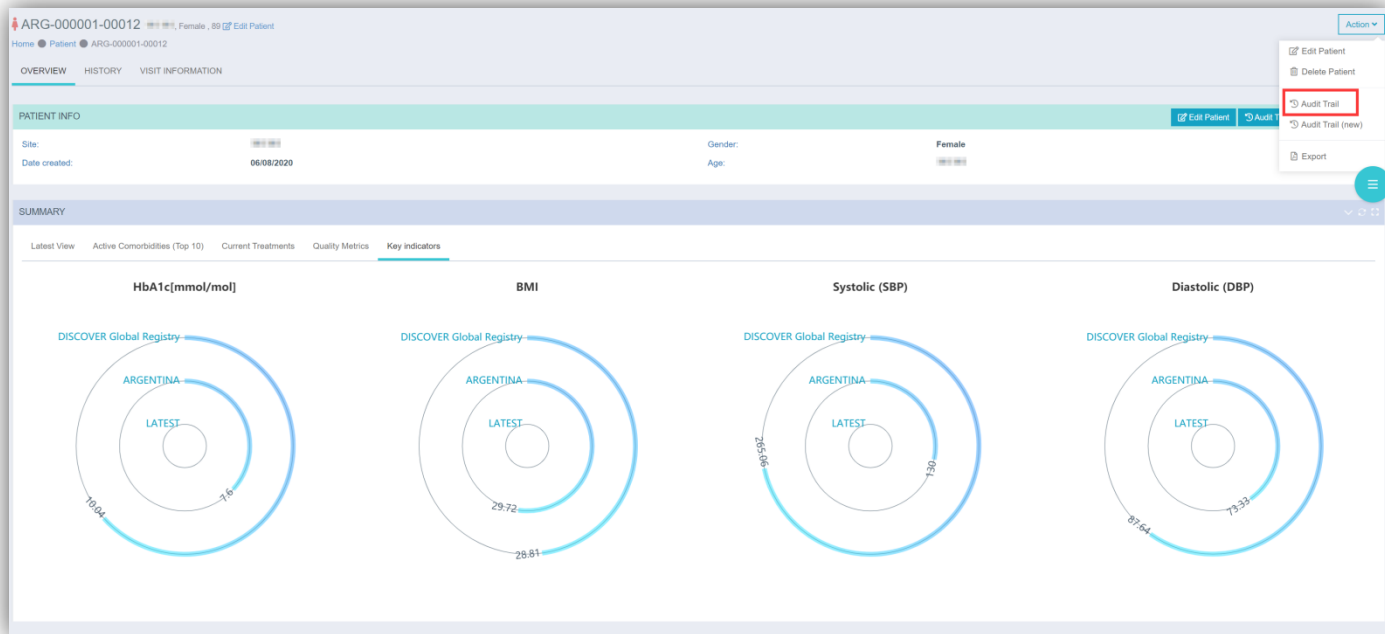
1.5 VISIT AND FORMS

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.

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.

1.52 Edit form

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

`

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.

2 DETAILED ECRF COMPLETION GUIDELINES

2.1 DEMOGRAPHICS

2.11 Basic Info

Name Initials *	s
Family Name Initials *	s
Age *	89
Gender	○ Male ● Female
Date of Enrollment *	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

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

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		○ Kilograms ○ Pounds		☐ Not measured
Height		○ Centimeters ○ Inches		☐ Not measured
Body Mass Index		kg/m²		
Seated Blood Pressure at rest				
Systolic (SBP)		mmHg		☐ Not measured
Diastolic (DBP)		mmHg		☐ Not measured
Pulse rate at rest				
Beats per minute				☐ 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:

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

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	○ Yes ○ 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	yyyy ⌄ mm ⌄	○ Yes
○ YES	dd ⌄	○ No
● NO		
○ Unknown		
Major hypoglycemic events	If Yes, Total number of episodes:	○ Yes
○ Yes	[ ]	○ No
○ No		
○ Unknown		

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 ◯ Yes ◯ No ◯ Unknown	If Yes, Total number of episodes: [ ]	◯ Yes ◯ 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

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	
	____ hours	
	Adequacy	
	____ Kt/V	
Anemia ◯ YES ◯ NO ◯ Unknown	Definition of Anemia: Man: Hemoglobin (Hb) level of < 12.0 g/dL Woman: Hemoglobin (Hb) level of < 13.0 g/dL	yyyy ⌄ mm ⌄ dd ⌄
Hyperkalaemia ◯ YES ◯ NO ◯ Unknown	Definition of hyperkalaemia: K+ > 5.0 mmol/L	yyyy ⌄ mm ⌄ dd ⌄
Renal transplant ◯ YES ◯ NO ◯ Unknown	Type ◯ Living donor ◯ Paired kidney ◯ Deceased donor	yyyy ⌄ mm ⌄ 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

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".

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.

Diastolic Dysfunction:
- ○ YES
- ○ NO
- ○ Unknown

Valvular Disease
- ○ YES
- ○ NO
- ○ Unknown

If Yes, (multiple choices)
- ☐ AS (Aortic Stenosis)
- ☐ AR (Aortic Regurgitation) AR (Aortic Regurgitation)
- ☐ MS (Mitral Stenosis) MS (Mitral Stenosis)
- ☐ MR (Mitral Regurgitation) MR (Mitral Regurgitation)
- ☐ Unknown

Evidence of pulmonary hypertension:
- ○ YES
- ○ NO
- ○ Unknown

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.

✓ **Any new event since the last visit or within the last 12 months**

HF hospitalization	If Yes, number of hospitalizations:
○ YES ○ NO ○ Unknown	⌄

Emergency/Unplanned HF ER/outpatient visit	If Yes, number of ER visits:
○ YES ○ NO ○ Unknown	⌄

HF Treatment

Implantable cardioverter Defibrillator(ICD)	Date
○ YES ○ NO ○ Unknown	yyyy ⌄ | mm ⌄ | dd ⌄

Cardiac resynchronization Therapy(CRT)	Date
○ YES ○ NO ○ Unknown	yyyy ⌄ | mm ⌄ | dd ⌄

Dual chamber pacemaker	Date
○ YES ○ NO ○ Unknown	yyyy ⌄ | mm ⌄ | 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		○ % ○ mmol/L	☐ Not measured
Fasting plasma glucose		○ mmol/L ○ mg/dL	☐ Not measured
Postprandial plasma glucose		○ mmol/L ○ mg/dL	☐ Not measured

☑ **Lipid Profile**

Total cholesterol		○ mg/dL ○ mmol/L	☐ Not measured
HDL		○ mg/dL ○ mmol/L	☐ Not measured
LDL		○ mg/dL ○ mmol/L	☐ Not measured
Triglycerides		○ mg/dL ○ mmol/L	☐ Not measured

☑ Renal function

Serum creatinine (Serum CR)		○ mg/dL ○ µmol/L	☐ Not measured
eGFR ○ CKD-EPI ○ MDRD ○ Cockcroft Gault		mL/min/1.73 m^2	
Urine albumin/creatinine Ratio		○ mg/mmol ○ mg/g	☐ Not measured
Serum albumin		○ g/dL ○ g/L	☐ Not measured
24-hour albumin		○ mcg/min ○ mcg/mg	☐ Not measured
Protein in urine		○ mg/dL ○ µmol/L	☐ Not measured
Urine protein/creatinine ratio		○ mg/mmol ○ mg/g	☐ Not measured
24-hour urine protein		○ g/24 hours	☐ Not measured

☑ Electrolyte

Potassium (K)		○ mmol/L or mEq/L ○ mg/dL	☐ Not measured

☑ Blood Test

Hemoglobin (Hb)		○ mg/dL ○ mg/L ◉ g/dL	☐ 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)

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)		◯ IU/L ◯ μmol/L*s

✔ Renal function tests

	Value	Unit
Urine albumin (spot urine collection)		◯ mg/L ◯ μg/g
Urine albumin (spot urine collection)	◯ + ◯ ++ ◯ +++	
Blood urea nitrogen (BUN)		◯ mmol/L ◯ mg/dL
Uric acid		◯ mg/dL ◯ μmol/L

✔ Electrolyte

	Value	Unit
Sodium (Na)		◯ mmol/L or mEq/L ◯ mg/dL
Calcium (Ca)		◯ mmol/L or mEq/L ◯ mg/dL
Chloride (Cl)		◯ mmol/L or mEq/L ◯ mg/dL
Magnesium (Mg)		◯ mmol/L or mEq/L ◯ mg/dL
Serum Phosphorus (P)		◯ mmol/L or mEq/L ◯ mg/dL

Blood tests

	Value	Unit
White blood cell (WBC)		x10E3/µL
Red blood cell (RBC)		x10E3/µL
C-reactive protein		mg/dL
Hematocrit		%
Platelets (PLT)		x10E3/µL

Need to record target setting

	Value	Unit
Hb1Ac		○ % ○ mmol/L
Fasting Plasma Glucose		○ mmol/L ○ 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? ( ) Yes ( ) No (✓) Unknown

Disease	History	Relationship
Type 2 diabetes	( ) Yes ( ) No	[⌄]
Hypertension	( ) Yes ( ) No	[⌄]
Dyslipidemia	( ) Yes ( ) No	[⌄]
Metabolic syndrome	( ) Yes ( ) No	[⌄]

* 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
☐ Angina ☑ Unknown	Please indicate last known CCS Class ○ 1 ○ 2 ○ 3 ○ 4 ○ Unknown	yyyy ⌄ mm ⌄ dd ⌄		○ Yes ○ No
☐ Transient Ischemic Attack(TIA) ☐ Unknown	○ Single ○ Multiple ○ Unknown	yyyy ⌄ mm ⌄ dd ⌄		○ Yes ○ No
☐ Carotid stenting ☐ Unknown		yyyy ⌄ mm ⌄ dd ⌄		○ Yes ○ 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".

Name	Details	Diagnosis Date	Duration	Ongoing
☐ Carotid endarterectomy ☐ Unknown		yyyy ▾ mm ▾ dd ▾		○ Yes ○ No
☐ Peripheral arterial diseases(PAD) ☐ Unknown		yyyy ▾ mm ▾ dd ▾		⦿ Yes ○ No
☐ Venous thromboembolism (deep vein thrombosis/Pulmonary embolism) ☐ Unknown		yyyy ▾ mm ▾ dd ▾		○ Yes ○ No
☐ Atrial fibrillation / flutter ☐ Unknown		yyyy ▾ mm ▾ dd ▾		○ Yes ○ No
☐ Ventricular Arrhythmia ☐ Unknown		yyyy ▾ mm ▾ dd ▾		○ Yes ○ No
☐ Pacemaker implanted ☐ Unknown		yyyy ▾ mm ▾ dd ▾		○ Yes ○ No
☐ Defibrillator (ICD) ☐ Unknown		yyyy ▾ mm ▾ dd ▾		▾
☐ Severe Valve disease ☐ Unknown	Type: ○ Aortic ○ Mitral ○ Pulmonic ○ Tricuspid ○ Unknown	yyyy ▾ mm ▾ dd ▾		○ Yes ○ No

☐ None of the above

Previous history of microvascular pathologies and procedures

Name	Details	Diagnosis Date	Duration (years)	Ongoing
☐ Albuminuria ☐ Unknown	Please indicate year of last diagnosis [ ] Please indicate urine albumin value [ ] ○ mg/g ○ mg/L ○ μg/min	yyyy ▾ mm ▾ dd ▾		○ Yes ○ No
☐ Symptomatic peripheral neuropathy		yyyy ▾ mm ▾ dd ▾		○ Yes ○ 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".

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".

☐ Depression ☐ Unknown		yyyy ⌄ mm ⌄ dd ⌄		◯ Yes ◯ No
☐ Dementia ☐ Unknown		yyyy ⌄ mm ⌄ dd ⌄		◯ Yes ◯ No
☐ Infection in the last 12 months ☐ Unknown	☐ Urinary tract infection ☐ Genital infection ☐ Pneumonia ☐ Cellulitis ☐ Septicemia ☐ Pyelonephritis ☐ Arthritis (infection of the joints) ☐ Other serious infections	yyyy ⌄ mm ⌄ dd ⌄		◯ Yes ◯ No
☐ Cancer ☐ Unknown	Please indicate primary site of cancer(s) ☐ Bladder ☐ Brain ☐ Breast ☐ Colorectal ☐ Endometrial ☐ Kidney ☐ Leukemia ☐ Liver ☐ Lungs ☐ Lymphoma ☐ Pancreatic ☐ Prostate ☐ Other, please specify ☐ Unknown	yyyy ⌄ mm ⌄ dd ⌄		◯ Yes ◯ No
☐ Hepatic insufficiency ☐ Unknown	Please indicate Child-Pugh Class ◯ A ◯ B ◯ C ◯ Unknown	yyyy ⌄ mm ⌄ dd ⌄		◯ Yes ◯ No

Condition		Type	Date		Notes
☐ Chronic pancreatitis		○ Single ○ Recurrent ○ Unknown	yyyy / mm / dd		○ Yes ○ No
☐ Unknown					
☐ Acute pancreatitis		○ Single ○ Recurrent ○ Unknown	yyyy / mm / dd		○ Yes ○ No
☐ Unknown					
☐ Tuberculosis			yyyy / mm / dd		○ Yes ○ No
☐ Unknown					
☐ HIV			yyyy / mm / dd		○ Yes ○ No
☐ Unknown					
☐ Bariatric surgery			yyyy / mm / dd		
☐ Unknown					
☐ Gastric balloon			yyyy / mm / dd		
☐ Unknown					

Condition		Type	Date		Notes
☐ Sleep apnea		Treated with CPAP ○ Yes ○ No ○ Unknown	yyyy / mm / dd		○ Yes ○ No
☐ Unknown					
☐ Bone fractures in the last 12 months			yyyy / mm / dd		
☐ Unknown					
☐ Hip or knee replacement			yyyy / mm / dd		
☐ Unknown					
☐ Thyroid disease		○ Hyperthyroidism ○ Hypothyroidism ○ N/A	yyyy / mm / dd		○ Yes ○ No
☐ Unknown					
☐ 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/hosp admission:
Reproductive history/menstrual history for female patients	
Menstruation	
☐ Regular	
☐ Menopause	Year of Menopause ____ OR At the age of ____ Years
☐ Hysterectomy	At the age of ____ Years
Reproductive History	
G: No. of Gravida	
P: No. of Parity	
A: No. of Abortions	
L: No. of Live Births	

Allergies	
List of drugs with known allergies	☐ Balsam of Peru
	☐ Tetracycline
	☐ Dilantin
	☐ Tegretol (carbamazepine)
	☐ Penicillin
	☐ Cephalosporins
	☐ Sulfonamide
	☐ Non-steroidal anti-inflammatories (cromolyn sodium, nedocromil sodium, etc.)
	☐ Intravenous contrast dye
	☐ 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)

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)

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

☐ Outpatient Percutaneous coronary intervention (PCI)	○ YES ○ NO ○ Unknown If yes, ○ PCI - With stent/s ○ PCI - Without stent/s
☐ Outpatient Peripheral arterial disease (PAD)-related procedures	
☐ Outpatient cardiac testing (for example, imaging techniques, nuclear stress test, etc.)	
☐ Outpatient neurologic tests (e.g., electrophysiological tests, etc.)	
☐ Eye surgery	
☐ Others	
☐ 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
☐ ⌄	☐ ⌄	☐	☐ ⌄	☐	☐ (dd/mm/yyyy)	☐ (dd/mm/yyyy)	○ Yes ○ No

Unit
○ mg
○ IU
○ Other unit
☐

Frequency ☐ ⌄

Details of insulin therapy

Short acting insulin	○ Basal ○ Bolus
Long acting insulin	○ Basal ○ Bolus
Short acting insulin	☐
Long acting insulin	☐
Intermediate insulin	☐
FDCs of insulin	☐

TREATMENTS

Line of treatment	Therapy type	Product	Route of administration	Dose/duration	Start date	End date	Ongoing
☐ ⌄	☐ ⌄	☐	☐ ⌄	☐	☐ (dd/mm/yyyy)	☐ (dd/mm/yyyy)	○ Yes ○ No

Unit
○ mg
○ IU
○ Other unit
☐

Frequency ☐ ⌄

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)

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.

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".

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".

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	
[ ]	[ ] Day(s)	[—]

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@genomseqcare.com

4 APPENDIX

4.1 eGFR calculations

CKD Epi

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

$\kappa = 0.7$ if female
$\kappa = 0.9$ if male

$\alpha = -0.329$ if female
$\alpha = -0.411$ if male

min = The minimum of Scr/κ or 1
max = The maximum of Scr/κ or 1

Scr = serum creatinine (mg/dL)

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

Cockcroft Gault:

Creatinine Clearance Value = $(140-age)(weight\ kg) / (72 \times S_{cr})$ in mL/min
Scr = serum creatinine (mg/dL), Multiply by .85 if female