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:

<table>
<thead>
<tr>
<th>Department</th>
<th>Printed Name</th>
<th>Signature</th>
<th>Date</th>
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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.
## HISTORY OF CHANGES TO TEMPLATE

<table>
<thead>
<tr>
<th>Version</th>
<th>Date Revised</th>
<th>Revised By</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1</td>
<td>08/01/2020</td>
<td>GenomSeqCare</td>
<td>Create</td>
</tr>
<tr>
<td>0.2</td>
<td>08/31/2020</td>
<td>GenomSeqCare</td>
<td>Update screenshots</td>
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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.

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.)
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.

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.
2.1 DEMOGRAPHICS

2.11 Basic Info

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

<table>
<thead>
<tr>
<th>Field</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled in study</td>
<td>Patients enrolling into TakeCaReMe study, TKCoMe Wave 1 must be selected.</td>
</tr>
<tr>
<td>Marriage</td>
<td>Select one option only from: “Single”, “Married”, “Divorced”, “Widowed”, and “Widowed”.</td>
</tr>
<tr>
<td>Self-reported Ethnicity</td>
<td>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.</td>
</tr>
<tr>
<td>Education Level</td>
<td>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)”.</td>
</tr>
</tbody>
</table>
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**

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

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
- [X] NO
- [ ] Unknown

**Major hypoglycemic events**
- [ ] Yes
- [ ] No
- [ ] Unknown

If Yes, Total number of episodes:
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.

<table>
<thead>
<tr>
<th>Anemia</th>
<th>Definition of Anemia:</th>
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<tbody>
<tr>
<td><img src="#" alt="Yes/No/Unknown options" /></td>
<td>Man: Hemoglobin (Hb) level of &lt; 12.0 g/dL</td>
</tr>
<tr>
<td><img src="#" alt="Yes/No/Unknown options" /></td>
<td>Woman: Hemoglobin (Hb) level of &lt; 13.0 g/dL</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hyperkalaemia</th>
<th>Definition of hyperkalaemia:</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="#" alt="Yes/No/Unknown options" /></td>
<td>K+ &gt; 5.0 mmol/L</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renal transplant</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="#" alt="Yes/No/Unknown options" /></td>
<td>Living donor</td>
</tr>
<tr>
<td><img src="#" alt="Yes/No/Unknown options" /></td>
<td>Paired kidney</td>
</tr>
<tr>
<td><img src="#" alt="Yes/No/Unknown options" /></td>
<td>Deceased donor</td>
</tr>
</tbody>
</table>

**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.
**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: 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

**Glucose**

- HbA1c
- Fasting plasma glucose
- Postprandial plasma glucose

**Lipid Profile**

- Total cholesterol
- HDL
- LDL
- Triglycerides
### Renal Function

<table>
<thead>
<tr>
<th>Test</th>
<th>Unit Options</th>
<th>Measured Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum creatinine (Serum CR)</td>
<td>mg/dL, μmol/L</td>
<td>Not measured</td>
</tr>
<tr>
<td>eGFR</td>
<td>mL/min/1.73 m²</td>
<td>Not measured</td>
</tr>
<tr>
<td>Urine albumin/creatinine Ratio</td>
<td>mg/mmol, mg/g</td>
<td>Not measured</td>
</tr>
<tr>
<td>Serum albumin</td>
<td>g/dL, g/L</td>
<td>Not measured</td>
</tr>
<tr>
<td>24-hour albumin</td>
<td>mcg/min, mcg/mg</td>
<td>Not measured</td>
</tr>
<tr>
<td>Protein in urine</td>
<td>mg/dL, μmol/L</td>
<td>Not measured</td>
</tr>
<tr>
<td>Urine protein/creatinine ratio</td>
<td>mg/mmol, mg/g</td>
<td>Not measured</td>
</tr>
<tr>
<td>24-hour urine protein</td>
<td>g/24 hours</td>
<td>Not measured</td>
</tr>
</tbody>
</table>

### Electrolyte

<table>
<thead>
<tr>
<th>Test</th>
<th>Unit Options</th>
<th>Measured Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potassium (K)</td>
<td>mmol/L or mEq/L, mg/dL</td>
<td>Not measured</td>
</tr>
</tbody>
</table>

### Blood Test

<table>
<thead>
<tr>
<th>Test</th>
<th>Unit Options</th>
<th>Measured Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin (Hb)</td>
<td>mg/dL, mg/L, g/dL</td>
<td>Not measured</td>
</tr>
</tbody>
</table>
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)

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**

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gamma glutamyl transpeptidase (γ-GT, GGT)</td>
<td></td>
<td>IU/L, μmol/L/s</td>
</tr>
</tbody>
</table>

**Renal function tests**

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine albumin (spot urine collection)</td>
<td></td>
<td>mg/L, μg/g</td>
</tr>
<tr>
<td>Urine albumin (spot urine collection)</td>
<td>+++</td>
<td></td>
</tr>
<tr>
<td>Blood urea nitrogen (BUN)</td>
<td></td>
<td>mmol/L, mg/dL</td>
</tr>
<tr>
<td>Uric acid</td>
<td></td>
<td>mg/dL, μmol/L</td>
</tr>
</tbody>
</table>

**Electrolyte**

<table>
<thead>
<tr>
<th>Test</th>
<th>Value</th>
<th>Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium (Na)</td>
<td></td>
<td>mmol/L or mEq/L, mg/dL</td>
</tr>
<tr>
<td>Calcium (Ca)</td>
<td></td>
<td>mmol/L or mEq/L, mg/dL</td>
</tr>
<tr>
<td>Chloride (Cl)</td>
<td></td>
<td>mmol/L or mEq/L, mg/dL</td>
</tr>
<tr>
<td>Magnesium (Mg)</td>
<td></td>
<td>mmol/L or mEq/L, mg/dL</td>
</tr>
<tr>
<td>Serum Phosphorus (P)</td>
<td></td>
<td>mmol/L or mEq/L, mg/dL</td>
</tr>
</tbody>
</table>
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)

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”.

<table>
<thead>
<tr>
<th>Disease</th>
<th>History</th>
<th>Relationship</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 diabetes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metabolic syndrome</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Relationship: First degree (e.g. parent, sibling or child); Second degree (e.g. grandparent, aunt/uncle or niece/nephew).
## 2.7 MEDICAL HISTORY (This form should only be filled once at the first visit)

### 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”.

<table>
<thead>
<tr>
<th>Name</th>
<th>Details</th>
<th>Diagnosis Date</th>
<th>Duration (years)</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angina</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transient Ischemic Attack (TIA)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carotid stenting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Previous history of microvascular pathologies and procedures

<table>
<thead>
<tr>
<th>Name</th>
<th>Details</th>
<th>Diagnosis Date</th>
<th>Duration (years)</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Albuminuria</strong></td>
<td>Please indicate year of last diagnosis</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
</tr>
<tr>
<td>Unknown</td>
<td>Please indicate urine albumin value</td>
<td>mm</td>
<td>mg/L, µg/min</td>
<td></td>
</tr>
<tr>
<td><strong>Symptomatic peripheral neuropathy</strong></td>
<td></td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
</tr>
</tbody>
</table>
**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”**.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Yes/No Date Format</th>
<th>Yes/No Date Format</th>
<th>Yes/No Date Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dementia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection in the last 12 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genital infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Septicemia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyelonephritis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthritis (infection of the joints)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other serious infections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatic Insufficiency</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please indicate primary site of cancer(s):
- Bladder
- Brain
- Breast
- Colorectal
- Endometrial
- Kidney
- Leukemia
- Liver
- Lungs
- Lymphoma
- Pancreatic
- Prostate
- Other, please specify

Please indicate Child-Pugh Class:
- A
- B
- C
- Unknown
<table>
<thead>
<tr>
<th>Condition</th>
<th>Single</th>
<th>Recurrent</th>
<th>Unknown</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pancreatitis</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Acute pancreatitis</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>HIV</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Bariatric surgery</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Gastric balloon</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sleep apnea</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Bone fractures in the last 12 months</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hip or knee replacement</td>
<td>yyyy</td>
<td>mm</td>
<td>dd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Thyroid disease</td>
<td>Hyperthyroidism</td>
<td>mm</td>
<td>dd</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>N/A</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>None of the above</td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
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)
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”.

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2.10 TREATMENTS (Additional medications not recorded in Core Metrics)

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”.

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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)

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.
### CONTACT INFORMATION

#### 3.1 Contact List

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Phone</th>
<th>E-Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>RWE Box Help Desk</td>
<td>Technical Support available 24 hours/day, 7 days/week</td>
<td>NA</td>
<td><a href="mailto:discover_global_registry_support@genomseqcare.com">discover_global_registry_support@genomseqcare.com</a></td>
</tr>
</tbody>
</table>
4  APPENDIX

4.1  eGFR calculations

CKD Epi

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

\[a = 0.7 \text{ if female} \]
\[a = 0.9 \text{ if male} \]
\[\alpha = -0.329 \text{ if female} \]
\[\alpha = -0.411 \text{ if male} \]
\[\min = \text{The minimum of Scr/k or 1} \]
\[\max = \text{The maximum of Scr/k or 1} \]

Scr = serum creatinine (mg/dL)

MDRD:  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 = \frac{(140-g{} \text{ age})(\text{weight kg})}{(72 \times \text{Scr})} \text{ in mL/min}

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