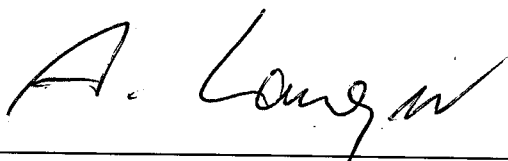


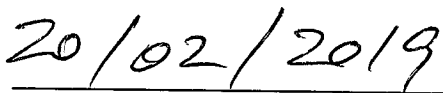
CASE REPORT FORM
APPROVAL SIGNATURE PAGE

Study Title: Guidelines Oriented Approach to Lipid lowering Quality
Enhancement Research Initiative (GOAL QuERI) International

The signature below constitutes the approval of the **case report form version dated February 20, 2019** reflecting data to be collected in accordance with the GOAL INTERNATIONAL study protocol version dated January 28, 2019.



Anatoly Langer, MD, MSc, FRCPC, FACC
Chair, Canadian Heart Research Centre



Date (Day/Month/Year)

Visit 1 page 1

eCRF Portal - Add New Patient

PATIENT ELIGIBILITY

Patient Number: XXXX

Patient's Initials:

Inclusion Criteria: ALL of the criteria must be present

1. Please confirm ☐ Adults \geq 18 years old
2. Please confirm ☐ High risk for cardiovascular morbidity and mortality defined as clinical atherosclerotic cardiovascular disease (CVD) and/or familial hypercholesterolemia
3. Please confirm ☐ Receiving current optimal (maximal or maximal tolerated) statin therapy for at least 3 months prior to enrolment
4. Please confirm ☐ LDL-C above currently recommended target by the Canadian Cardiovascular Society measured while on maximal tolerated statin therapy (\pm other lipid modifying therapies).
5. Please confirm ☐ Desire and ability to execute the consent to participate

Exclusion Criteria: None of the criteria present

1. Current treatment with PCSK9 inhibitor
2. Current participation in investigational study
3. Prior participation in GOAL program

☐ This patient does NOT have any of the above Exclusion Criteria

Visit Date: (yyyy/mm/dd)

Visit 1 page 2

eCRF Portal - Add New Patient

DEMOGRAPHICS AND HISTORY

Patient Number: XXXX

Gender:

- ☐ Male
☐ Female

Age: (years)

Ethnicity: *Select one from the drop down menu*

Drop down list: Aboriginal Canadian (First Nations / Metis / Inuit), Arabic / North African, Black, Caucasian / White, Hispanic, East / South-East Asian, Multi-Racial, South Asian, Other

Smoking History: *Select one from the drop down menu*

Drop down list: Never Smoked, Past Smoker, Current Smoker

Medication Insurance Coverage:

Drop down list: Private, Public

If Private:

- ☐ Employer
☐ Self pay
☐ Other

CO-MORBIDITIES

Select Yes/No for each of the following

Yes No

Coronary Artery Disease	<input type="radio"/>	<input checked="" type="radio"/>
Cerebrovascular Disease	<input type="radio"/>	<input type="radio"/>
Abdominal Aortic Aneurism	<input type="radio"/>	<input type="radio"/>
Peripheral Arterial Disease	<input type="radio"/>	<input type="radio"/>
Diabetes Mellitus	<input type="radio"/>	<input type="radio"/>
Treated Hypertension	<input type="radio"/>	<input type="radio"/>
Chronic Kidney Disease	<input type="radio"/>	<input type="radio"/>
Microvascular Disease (retinopathy, neuropathy)	<input type="radio"/>	<input type="radio"/>
Familial Hypercholesterolemia	<input type="radio"/>	<input type="radio"/>
Premature Family History or CV disease (1 ^o relative – 55 yo/male, 65 yo/female)	<input type="radio"/>	<input type="radio"/>
Atrial Fibrillation	<input type="radio"/>	<input type="radio"/>
Congestive Heart Failure	<input type="radio"/>	<input checked="" type="radio"/>
Cancer	<input type="radio"/>	<input type="radio"/>
Liver Disease	<input type="radio"/>	<input type="radio"/>

(Note: The following sub-comorbidities will be displayed if Yes to Coronary artery disease, Cerebrovascular disease, Diabetes mellitus, microvascular disease, and familial hypercholesterolemia.)

History of Coronary Artery Disease (CAD)

Check ALL that Apply (*at least ONE must be checked*)

Myocardial Infarction or Acute Coronary Syndrome ☐

Coronary artery bypass surgery ☐

Percutaneous coronary intervention ☐

Angiographic disease (>50% stenosis with stable angina) ☐

History of Cerebrovascular Disease (CeVD)

Check ALL that Apply (*at least ONE must be checked*)


Cerebrovascular Accident ☐

Transient ischemic attack ☐

Carotid Surgery ☐

2DM Duration

Select one from the drop down menu

Please Select 

Microvascular Disease

Check ALL that Apply (*at least ONE must be checked*)

Microalbuminuria ☐

eGFR < 60 mL/min ☐

Neuropathy ☐

Retinopathy ☐

Familial Hypercholesterolemia LDL-C > 5mmol/L prior to lipid lowering therapy and one of:

Check ALL that Apply (*at least ONE must be checked*)

Typical physical findings (stigmata) such as tendon xanthomata, xanthelasma, and corneal arcus ☐

Personal history of premature cardiovascular disease ☐

Family history of premature cardiovascular disease or of marked hyperlipidemia ☐

Visit 1 page 3

eCRF Portal - Add New Patient

MEDICATION AND PHYSICAL ASSESSMENT**Patient Number: XXXX**

CURRENT MEDICATION (OTHER THAN LIPID MODIFYING THERAPY)	Yes	No
Select Yes/No for each of the following		
ASA	<input type="radio"/>	<input type="radio"/>
Other Antiplatelet Agent (Clopidogrel, Prasugrel, Ticagrelor)	<input type="radio"/>	<input type="radio"/>
ACE-Inhibitor	<input type="radio"/>	<input type="radio"/>
Angiotensin Receptor Blocker (ARB)	<input type="radio"/>	<input type="radio"/>
Beta-Blocker	<input type="radio"/>	<input type="radio"/>
Calcium Channel Blocker	<input type="radio"/>	<input type="radio"/>
Diuretic	<input type="radio"/>	<input type="radio"/>
Warfarin	<input type="radio"/>	<input type="radio"/>
Direct Oral Anticoagulation Agent	<input type="radio"/>	<input type="radio"/>
Valsartan/Succubitril	<input type="radio"/>	<input type="radio"/>
Spironolactone/Eplerenon	<input type="radio"/>	<input type="radio"/>

(Note: If Diabetic Mellitus=Yes on page 2, then display Antihyperglycemic medications)

ANTIHYPERGLYCEMIC MEDICATION		
Select Yes/No for each of the following	Yes	No
a-Glucosidase Inhibitor	<input type="radio"/>	<input type="radio"/>
DPP-4 Inhibitor	<input type="radio"/>	<input type="radio"/>
GLP-1 Receptor Agonist	<input type="radio"/>	<input type="radio"/>
Insulin	<input type="radio"/>	<input type="radio"/>
Meglitinide	<input type="radio"/>	<input type="radio"/>
Metformin	<input type="radio"/>	<input type="radio"/>
Metformin/DPP-4 Fixed Dose Combination	<input type="radio"/>	<input type="radio"/>
SGLT2 Inhibitor	<input type="radio"/>	<input type="radio"/>
Sulfonylurea	<input type="radio"/>	<input type="radio"/>
Thiazolidinedione	<input type="radio"/>	<input type="radio"/>

CURRENT LDL LOWERING THERAPY:

Select Yes/No for each of the following

Yes No

Statin

☐☐

Bile Acid Sequestrant

☐☐

Ezetimibe

☐☐

Fibrate

☐☐

Niacin

☐☐

Please confirm that this patient is on maximal tolerated statin dose which may include no statin therapy in case of complete intolerance

☐ Yes☐ No**PHYSICAL ASSESSMENT**

Blood Pressure

Systolic mmHgDiastolic mmHgHeart Rate bpmWeight ☐ kg ☐ lbsHeight ☐ cm ☐ in

Iliac Waist Circumference

If the Iliac Waist Circumference is Not Available, check the N/A box ☐ cm ☐ in ☐ N/A

Visit 1 page 4

eCRF Portal - Add New Patient

LIPID PROFILE AND MANAGEMENT

Patient Number: XXXX

Record values exactly as they appear in the lab report. Include decimal places where applicable

Most Recent Lab Date: (yyyy/mm/dd)

Total Cholesterol:

mmol/L

LDL-C:

mmol/L

HDL-C:

mmol/L

Non HDL-C:

mmol/L

Triglycerides:

mmol/L

Apo-B:

If Apo-B is Not Available, check the N/A box

☒ g/L ☐ mg/dL ☐ N/A

Current Statin Therapy:

Please Select	
---------------	--

Drop down list: Atorvastatin, Fluvastatin, Lovastatin, Pravastatin, Rosuvastatin, Simvastatin, No statin

Statin dosage will display depend on the chosen statin

In light of the LDL-C and/or non-HDL-C level will you add one or more of the following lipid lowering therapies?
Select Yes/No for each of the following

	Yes	No
PCSK9i (evolocumab)	<input type="radio"/>	<input type="radio"/>
PCSK9i (alirocumab)	<input type="radio"/>	<input type="radio"/>
Bile Acid Sequestrant	<input type="radio"/>	<input type="radio"/>
Fibrate	<input type="radio"/>	<input type="radio"/>
Ezetimibe	<input type="radio"/>	<input type="radio"/>
Niacin	<input type="radio"/>	<input type="radio"/>

(Note: If Ezetimibe = No, display reasons why not (only one reason is allowed))

Please select the most applicable reason for not providing the Ezetimibe prescription to this patient at this visit:
Select only one

- Patient Refusal ☐
- Patient intolerant ☐
- Not Needed ☐
- Co-morbidities ☐
- Cost ☐
- Patient is on PCSK9i ☐
- Patient will return for Rx/Will provide Rx at next patient visit. ☐

Please note that ezetimibe is recommended to achieve lower LDL.

(Note: If PCSK9i = No, display reasons why not (only one reason is allowed))

Please select the most applicable reason for not providing the PCSK9i prescription to this patient at this visit:
Select only one

- Patient Refusal ☐
- Patient intolerant ☐
- Not Needed ☐
- Co-morbidities ☐
- Cost ☐
- Patient will return for Rx/Will provide Rx at next patient visit. ☐

Please note that PCSK9i is recommended to achieve lower LDL.

Visit 1 signoff page

eCRF Portal - Add New Patient

This e-CRF is COMPLETE

Patient Number: XXXX

You have successfully completed the e-CRF for this patient. You can either Submit or Review / Modify the e-CRF

Please note that Visit 2 for this subject may be completed

If you click the "SUBMIT e-CRF" button, the data entered for this patient will be considered final and no modifications to any of the data fields can be made.

If you click the "REVIEW e-CRF" button, you will be able to review all previous pages of this e-CRF and make any applicable modifications if warranted. Once you have reviewed / modified the e-CRF to your satisfaction, you will be able to submit the final.

Visit 2 page 1

eCRF Portal

Patient Number: XXXX

Is the Patient Lost to Follow-up?

☐ Yes ☐ No

If YES, please select

Please Select 

Drop down list if Yes is selected:

Patient died

Patient is lost to follow-up (moved, no longer being followed-up by physician)

Patient withdrew consent

Physician took patient out

Since Last Visit has the Patient Experienced the Following
Select Yes/No for each of the following

Yes No

Acute Coronary Syndrome

☐ ☐

Cerebro-Vascular Accident/Transient Ischemic Attack

☐ ☐

Coronary Artery Bypass Grafting

☐ ☐

Percutaneous Coronary Intervention

☐ ☐

Hospitalization for cardiovascular diagnosis

☐ ☐

Visit Date: (yyyy/mm/dd)

Visit 2 page 2

eCRF Portal

MEDICATION AND PHYSICAL ASSESSMENT

Patient Number: xxxx

PHYSICAL ASSESSMENT

Blood Pressure

Systolic mmHg

Diastolic

mmHg

Heart Rate

bpm

Weight

☐ kg ☒ lbs

Height

☐ cm ☒ in

Iliac Waist Circumference

If the Iliac Waist Circumference is Not Available, check the N/A box

☐ cm ☒ in ☐ N/A

CURRENT LDL LOWERING THERAPY:		
Select Yes/No for each of the following	Yes	No
Statin	<input checked="" type="radio"/>	<input type="radio"/>
PCSK9i	<input checked="" type="radio"/>	<input type="radio"/>
Bile Acid Sequestrant	<input checked="" type="radio"/>	<input type="radio"/>
Ezetimibe	<input checked="" type="radio"/>	<input type="radio"/>
Fibrate	<input checked="" type="radio"/>	<input type="radio"/>
Niacin	<input checked="" type="radio"/>	<input type="radio"/>

Visit 2 page 3

eCRF Portal

LIPID PROFILE AND MANAGEMENT

Patient Number: XXXX

Record values exactly as they appear in the lab report. Include decimal places where applicable

Most Recent Lab Date: (yyyy/mm/dd)

Total Cholesterol:

mmol/L

LDL-C:

mmol/L

HDL-C:

mmol/L

Non HDL-C:

mmol/L

Triglycerides:

mmol/L

Apo-B:

If Apo-B is Not Available, check the N/A box

☒ g/L ☐ mg/dL ☐ N/A

Current Statin Therapy:

Please Select

Drop down list: Atorvastatin, Fluvastatin, Lovastatin, Pravastatin, Rosuvastatin, Simvastatin, No statin

Statin dosage will display depend on the chosen statin

In light of the LDL-C and/or non-HDL-C level will you add one or more of the following lipid lowering therapies?
Select Yes/No for each of the following

	Yes	No
PCSK9i (evolocumab)	<input type="radio"/>	<input type="radio"/>
PCSK9i (alirocumab)	<input type="radio"/>	<input type="radio"/>
Bile Acid Sequestrant	<input type="radio"/>	<input type="radio"/>
Fibrate	<input type="radio"/>	<input type="radio"/>
Ezetimibe	<input type="radio"/>	<input type="radio"/>
Niacin	<input type="radio"/>	<input type="radio"/>

(Note: If Ezetimibe = No, display reasons why not (only one reason is allowed))

Please select the most applicable reason for not providing the Ezetimibe prescription to this patient at this visit:
Select only one

Patient Refusal



Patient intolerant



Not Needed



Co-morbidities



Cost



Patient is on PCSK9i



Patient will return for Rx/Will provide Rx at next patient visit.



Please note that ezetimibe is recommended to achieve lower LDL.

(Note: If PCSK9i = No, display reasons why not (only one reason is allowed))

Please select the most applicable reason for not providing the PCSK9i prescription to this patient at this visit:
Select only one

Patient Refusal



Patient intolerant



Not Needed



Co-morbidities



Cost



Patient will return for Rx/Will provide Rx at next patient visit.



Please note that PCSK9i is recommended to achieve lower LDL.

Visit 2 signoff page

This e-CRF is COMPLETE

Patient Number: xxxx

You have successfully completed the e-CRF for this patient. You can either Submit or Review / Modify the e-CRF

Please note that Visit 3 for this subject may be completed

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(Note: Visits 3 and 4 have the same display as Visit 2)