CHOLESTABETES

CHOLESTerol lowering in type 2 diABETES QuERI

You are invited to participate in an observational Quality Enhancement Research Initiative

Register: www.CHOLESTABETES.ca **Enter Your Unique Registration ID:**

Dear

On behalf of the Canadian Heart Research Centre (CHRC: www.chrc.net), we are pleased to invite you to participate in the **CHOLEST**erol lowering in type 2 di**ABETES Q**uality **E**nhancement **R**esearch **I**nitiative **(CHOLESTABETES QuERI).**

The CHRC is a not-for-profit, academic research organization and will be responsible for the scientific integrity of this initiative, protocol design and data analysis. The **CHOLASTABETES QuERI** is supported by Valeant Canada Inc. through an Investigator initiated grant request.

CHOLESTABETES QuERI Background:

Lowering of the total and LDL-C cholesterol has been shown to be the key step in lowering the risk of cardiovascular morbidity and mortality in patients at risk. Despite guideline recommendations, up to 50% of high-risk patients do not achieve the recommended LDL-C target. Additionally, a recent CHRC survey from 479 Canadian physicians involving over 5,000 patients with type 2 diabetes mellitus has revealed that an even greater care-gap in the comprehensive care of high-risk patients exists, whereby only 13% of patients achieved a triple target of glycemic, LDL-C, and blood pressure control. Given these data and the need for greater control of these risk factors, the **CHOLESTABETES QuERI** will aim to identify challenges Canadian physicians experience in managing patients with diabetes.

The **CHOLESTABETES QuERI** is an observational prospective quality enhancement research initiative of high-risk patients with diabetes who have not yet achieved guideline recommended LDL-C and A1C targets. Additionally, this program incorporates knowledge translation through clinical decision making support but the decision to follow the recommendations is left to the participating physician's discretion.

The **primary objective** of the program is to evaluate the impact of combination therapy and the clinical decision making support algorithm in achieving the dual LDL-C and A1C targets in patients with diabetes after 24±6 weeks. ***Please reference the overview document included with the invitation letter to familiarize yourself with the program components.***

If you are interested in participating in this program, please complete the online registration form:
Register: www.CHOLESTABETES.ca **Your Unique ID:**

Should you have any questions, please do not hesitate to contact the CHRC at 416-977-8010 ext. 296 (Toll-Free: 1-800-725-6585) or via email at info@cholestabetes.ca

Thank you for taking the time to review this invitation and we hope to have the opportunity to collaborate with you.

Sincerely,

Anatoly Langer MD, M.Sc., FRCP (C), FACC
Program Co-Chair
Chair, Canadian Heart Research Centre
Professor of Medicine, University of Toronto

Lawrence A. Leiter, MD, FRCP (C), FACP, FAHA
Program Co-Chair
Division of Endocrinology and Metabolism, St. Michael's Hospital
Professor of Medicine and Nutritional Sciences, University of Toronto

Lianne Goldin
Executive Director, Department of Continuing Medical Education
lgoldin@CHRC.net
416.977.8010 ext 229

Dija Chang Kit
Project Leader
changkitdija@chrc.net
416.977.8010 ext 296

Elana Dikchtein
Project Coordinator
dikchteine@chrc.net
416.977.8010 ext 291

CANADIAN HEART RESEARCH CENTRE

PROGRAM OVERVIEW

OVERVIEW AND SCOPE:

- Observational, prospective Quality Enhancement Research Initiative
- 150 Primary Care Physicians in Canada
- 1,500 patients (10 per physician)
- Decision to follow recommendations left to the participating physicians' discretion
- Three (3) visits → part of routine clinical practice
- User-friendly, secure web-based platform for document management and e-CRF entry
- Program Duration: 24±6 weeks
- Central Ethics Approved

Inclusion Criteria (all of the criteria must be present):

1. Male and female patients older than 18 years of age
2. Diagnosis of hypercholesterolemia and type 2 diabetes mellitus (CDA definition)
3. High risk for cardiovascular disease defined as one of:
   a. 10-year risk of cardiovascular event ≥ 20% based on the Framingham risk score
   b. prior diagnosis of CAD (PCI, CAMG, MI, stenosis > 50% on angiogram)
   c. prior diagnosis of CeVD (TIA, CVA, Carotid disease on ultrasound > 50%)
   d. prior history of abdominal aortic aneurysm surgery
   e. prior history of PAD (AFB, stent, or ABI <0.7 with symptoms of intermittent claudication)
4. LDL-C > 2.0 mmol/L despite optimal statin therapy (e.g. Atorvastatin ≥ 20 mg, Rosuvastatin ≥ 10 mg, Simvastatin ≥ 40 mg)
5. A1C > 7% and < 9% despite optimal metformin therapy (e.g. ≥ 1500 mg / day)
6. Patient's consent to participate

Exclusion Criteria (none of the criteria present):

1. Clinically significant concomitant illness or co-morbid condition (e.g. cancer)
2. Liver, muscle or kidney abnormalities (e.g. compro mises patient management according to physician)
3. Secondary causes of hypercholesterolemia (e.g. hypothyroidism, nephrotic syndrome)

Participating physician responsibilities:

- ✓ Read and understand a Memorandum of Understanding (MOU) and the CHOLESTABETES QuERI program materials, timelines and ensure that all person(s) in their practice who may be associated with the CHOLESTABETES QuERI program also understand these materials;
- ✓ Maintain chart notes that were used for the CHOLESTABE-TES QuERI submitted data until notified by the CHRC that the program is completed;
- ✓ Complete e-CRFs and feedback forms on patients that meet the program eligibility criteria in adherence with the program timelines;
- ✓ Obtain and retain a copy of an Informed Consent Form for each eligible patient included in the program;
- ✓ Provide a copy of a current curriculum vitae and medical license if requested from the CHRC;
- ✓ Exercise reasonable and diligent efforts and professional expertise in the conduct and completion of the program documents in an efficient and timely manner and in compliance with the program instructions:
- ✓ Be available to answer data queries.

CHRC responsibilities:

- ✓ Provide all the necessary program materials to the participating physician;
- ✓ Be available to answer questions in relation to the CHOLESTABETES program documents, instructions and/or the completion of the e-CRF/Feedback Forms;
- ✓ Provide physicians with remuneration for properly completed forms as following:
  - **Visit 1 (Baseline Visit) - $ 125.00 per interactive e-CRF** (up to $1,250.00 for completing interactive e-CRFs on 10 patients)
  - **Visit 2 (14±6 weeks) - $ 75.00 per interactive e-CRF** (up to $750.00 for completing interactive e-CRFs on 10 patients)
  - **Visit 3 (24±6 weeks) - $ 50.00 per interactive e-CRF** (up to $500.00 for completing interactive e-CRFs on 10 patients)

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