Site Information

Site location
LMC Diabetes & Endocrinology (Montreal - Ville Saint-Laurent)
6363 Trans canadienne, suite 238
Ville Saint-Laurent, QC
H4T 1Z9

Contact Information:
514-744-5620 phone
514-744-5621 fax
montrealresearch@lmc.ca email

Specific clinical studies of interest
- Type 1 & Type 2 Diabetes Mellitus
- Diabetes Complications - Neuropathy, Nephropathy, and Retinopathy
- Lipid Disorders
- Obesity
- Osteoporosis
- Hypertension
- Cardiac & Diabetes Prevention
- Women's Health

Phase 2 - 4 Experience

Description of site
- Private Clinic
- Private Clinical Research Center
- Ministry of Health Funded Diabetes Education Center

Memberships
- Member of the Society for Clinical Research Sites (SCRS)

Number of studies capable per site
6 enrolling studies with 4 maintenance studies

How long has the site been involved in clinical research?
Site has been doing research for 5 years.
PI has been involved with research for 3 year.

Has the site been audited?
- No FDA audit
- Health Canada audit (November 2012) fully compliant
  Sponsor audits – Had positive findings
Emergency response
- Sacre-Coeur Hospital & Jewish General Hospital < 5 km
- All staff are CPR certified annually

2 Study Staff

Principal Investigator
Zeina Yared MD, FRCPC
- 3 year research experience
- > 15 clinical trials: Endocrinology & Metabolism

Sub Investigators
Nahla Aris-Jilwan MD, FRCPC, FACE
- 30 + years research experience
- > 25 + clinical trials: Endocrinology & Metabolism

Investigator Accountability
20% research, 80% clinic

Investigator's Education and/or Academic Appointments
Speciality Areas: Endocrinology & Metabolism

Education
- 2005 Diploma in Endocrinology and Metabolism
- 2004 Certificate in Good Clinical Practice
- 2002-2004 Fellowship in Diabetology/Clinical Studies
- 2003 Diploma in Internal Medicine
- 1999-2002 Residency in Internal Medicine
- 1999 Degree in Medicine from Canadian College Part 1
- 1995-1999 Medical Doctor
- 1992-1995 B.Sc. Microbiology and Immunology

Appointments
- 2012-Present Associate Endocrinologist
- 2009-2012 Associate Professor of department of Medicine
- 2005-2012 Endocrinologist

Royal College of Physicians and Surgeons of Canada and College of Physicians of Quebec
National Institutes of Health (NIH)
Royal Victoria Hospital
University of Montreal
Royal College of Physicians and Surgeons of Canada and College of Physicians of Quebec
University of Montreal
Canadian College
University of Montreal
McGill University

LMC Diabetes & Endocrinology
University of Montreal
Sacre-Cœur Hospital of Montreal

May not be distributed or reproduced without permission from LMC Diabetes & Endocrinology
3  Patient Population and Recruitment

Number of patients
>110,000 for the database plus an additional 20,000 per year and growing
Access to PhysiMed within same office building - 52 MD's (GP's & Specialists) and 200,000 patient database

Capability of screening database
Yes - able to note medical history, medications, lab values and consented interest in research

Catchment area
Montreal area

How are subjects recruited to meet the agreed upon targets?
➢ Patient database
➢ GP & Specialist referral network
➢ Diabetes triage - rapid assessment for newly diagnosed drug naive and metformin only patients failing orals requiring addition of OHA's or insulin initiation
➢ Advertising - radio, newspaper, central toll free number and capability of central ad campaigns for all LMC sites
➢ Public forums & expos
➢ Community involvement - Pharmacy days, and local presentations

4  Ethics

Ethics committee (local or central)
➢ Central Ethics only
➢ Worked with IRB Services, Schulman, Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

Informed consent process
➢ See LMC Diabetes & Endocrinology SOP
➢ GCP/ICH Compliant
➢ Health Canada Division 5 Compliant

Confidentiality
➢ An Act Respecting the Protection of Personal Information in the Private Sector & PIPEDA implemented

5  Facilities

Equipment available
➢ Refrigerated centrifuge (calibrated yearly)
ECG machine (Brentwood software) - calibrated daily
330 kg weight scale (calibrated every 6 months)
1 x 20 freezers
1 x medical fridge for study medication purposes only
Manual blood pressure devices
Epi-pen and benedryl
Able to do PK analysis, injections & meal tolerance tests

Office hours
- Monday - Friday (7:30 am - 6:00 pm)
- Weekends as needed

Monitoring space
- 1 room dedicated to monitoring
- Phone, analog, wireless and broadband access

LMC Diabetes & Endocrinology SOP
- ERB & HC reviewed and approved

Source documents
- LMC specific templates for source creation and study specific logs

Drug accountability and storage
- Secured and Locked Drug Cabinets, Medical Fridge and Freezer
- Temperature monitored daily (min, max and average temperatures)
- Sensaphone (remote monitoring, early detection system)

eCRF experience
- INFORM
- INET
- RDC
- ORACLE
- PHOSCO
- Medidata

IVRS experience
- Clinphone
- S Clinica
- ICON
- Fisher Clinical Services
- Impala

Data storage
- In house:
  - Lead study coordinator’s office
  - Paper charts
  - No electronic medical records

May not be distributed or reproduced without permission from LMC Diabetes & Endocrinology
6  Contract

Sites usual overhead

- 30% overhead

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Director of Research: Karri Venn RD, CDE, CCRC, PMP
  - Email: karri.venn@lmc.ca
  - Phone: 647 274-4133 cell

Regulatory Documentation

- Regulatory & Clinic Specialist: Natalie Gibbs
  - Email: natalie.gibbs@lmc.ca
  - Phone: 416-645-2928 ext 316
  - Fax: 416-645-2931
  - Address: 1929 Bayview Avenue, Suite 106
    Toronto, Ontario M4G 3E8