



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Montreal Glen*)

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Site Information

Site location

LMC Diabetes & Endocrinology (Montreal Glen)
5325 Crowley Avenue, Suite 301
Montreal, Quebec
H4A 2C6

Contact Information:

438 802-4536 phone
438 738-4144 fax
800-701-ENDO (3636) Toll Free
yaleresearch@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
- Ministry of Health Funded Diabetes Education Center
- Private Clinical Research Centre

Memberships

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

Number of studies capable per site

6-8 enrolling studies with 10 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for <1 year

Has the site been audited?

- No, site established 2017

Emergency response

- Montreal General Hospital 1.5 km

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- Royal Victoria Hospital 5.4km
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Jean-François Yale MD, CSPQ

- 30+ years research experience
- > 100 clinical trials: Endocrinology & Metabolism

Sub Investigators

Mark Sherman, MDCM, FRCPC

- 10+ years research experience
- > 50 clinical trials: Endocrinology & Metabolism

Wen Hu, MD, FRCPC, LMCC

- 5+ years research experience
- <5 clinical trials: Endocrinology & Metabolism

Investigator Accountability

25% research, 75% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

2017	Transclerate GCP Training
1983-1985	Post-Doctoral Fellow, McGill Nutrition, McGill University
1983	Certification in Endocrinology, Centre de services partagés du Québec
1980	License Registration, Corporation Professionnelle des Médecins du Québec
1980	License of the Medical Council of Canada
1975-1979	Doctor of Medicine, Université de Sherbrooke

Appointments

2017-present	Associate Endocrinologist, LMC Diabetes & Endocrinologist
2001-present	Geographical Full-Time Professor, Department of Medicine, McGill University
2000-present	Senior Physician with Admitting Privileges special privileges <i>in vitro</i> radioisotopes, Department of Medicine, McGill University Health Centre
1991-2008	Director, Metabolic Day Centre, Royal Victoria Hospital
1991-2005	Consultant, >35 Associations, Companies & Governments
1991-2001	Assistant Physician with Admitting Privileges, special privileges <i>in vitro</i> radioisotopes, Department of Medicine, Royal Victoria Hospital

1990-present	Associate Member in the School of Dietetics and Human Nutrition, Faculty of Agriculture and Environmental Sciences, McGill University
1985-1991	Geographical Full-Time Assistant Professor, Department of Medicine and Nutrition and Food Science, McGill University
1985	Assistant Physician with Admitting Privileges, Department of Medicine, Royal Victoria Hospital

3 Patient Population and Recruitment

Number of patients

>200,000 for the database plus an additional 24,000 per year and growing

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, internet, 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 SOPs
- GCP/ICH 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 yearly)
- 1 x -75 freezer
- 1 x medical fridge for study medication purposes only
- ABPM machine
- Manual and automatic 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

- 2 rooms dedicated to monitoring
- Phone, analog, wireless and broadband access
- Access to a fax and photocopy machine

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 RAVE

IVRS experience

- Clinphone
- S Clinica
- ICON
- Fisher Clinical Services
- Impala
- Almac
- Perceptive

- IXRS
- IWRS

Data storage

- In house:
 - Lead study coordinator's office
 - Paper charts / Electronic medical records
- Long term storage:
 - Iron Mountain x 25 years
Address: Records Management Division
1655 Fleetwood
Laval, Quebec H7N 4B2
1-877-840-2111

6 Contract

Sites usual overhead

- 30% overhead

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Research, President: Karri Venn RD, CDE, CCRC
Email: karri.venn@lmc.ca
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- Budgets and Contracts: Nichelle Farrell
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Regulatory Documentation

- Regulatory Specialist: Natalie Gibbs
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