



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Etobicoke*)

1

Site Information

Site location

LMC Diabetes & Endocrinology (Etobicoke)
1723 Kipling Avenue, 2B
Etobicoke, Ontario
M9R 4E1

Contact Information:

416 645-1035 phone
416 645-1036 fax
800-701-ENDO (3636) Toll Free
etobicokeresearch@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 enrolling studies with 4 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 6 years

Has the site been audited?

- No FDA audit
- Health Canada audit (August 2014) – Fully compliant
- Sponsor audit for highest enrolling - positive findings only

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Emergency response

- Humber River Regional Hospital 5 km
- All staff are CPR certified annually

2

Study Staff

Principal Investigator

Hasnain Khandwala MB, BS, FRCPC

- 9 + years research experience
- > 60 clinical trials: Endocrinology & Metabolism

Sub Investigators

Nadeem Aslam, MD, FACE, FACP

- 16 + years research experience
- > 20 clinical trials: Endocrinology & Metabolism

Amanda Ferrao (Physician Assistant), PA-C, MSHS

- 2 years research experience
- 9 clinical trials: Endocrinology & Metabolism

Investigator Accountability

20% research, 80% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

1987-93	M.B;B.S	Dow Medical College, Karachi
1995-98	Residency in Internal Medicine	Wayne St. University, Detroit, MI
1998	Certification in Internal Medicine	American Board of Internal Medicine
1998-00	Fellowship in Endocrinology	Baylor College of Medicine, Houston, TX
2000	Certification in Endocrinology Diabetes & Metabolism	American Board of Internal Medicine
2003	Certification in Internal Medicine	Royal of Physician & Surgeons of Canada
2003	Certification in Endocrinology & Metabolism	Royal of Physician & Surgeons of Canada

Appointments

2000-06	Associate Professor of Medicine, Division of Endocrinology, University of Saskatchewan, Saskatoon, SK
2000-06	Attending Physician, Royal University Hospital, Saskatoon, SK
2006 – present	Associate Endocrinologist, 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

Capability of screening database

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

Catchment area

Etobicoke, Malton, Brampton & Mississauga

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 SOPs
- GCP/ICH Compliant

Confidentiality

- 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
- 2 x fridge for study medication purposes only
- 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

- 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 / Electronic medical records
- Long term storage:
 - Iron Mountain x 25 years
Address: Records Management Division
70 Talman Court
Concord, Ontario L4K 4L5

1-877-840-2111

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
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