



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Oakville*)

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Site Information

Site location

LMC Diabetes & Endocrinology (Oakville)
1235 Trafalgar Road, Suite 412
Oakville, Ontario
L6H 3P1

Contact Information:

905 337-0040 phone

905 337-0044 fax

oakvilleresearch@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 Center

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 14 years

Has the site been audited?

- No FDA audit
- No Health Canada audit
- Sponsor audit for highest enrolling - positive findings only

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Emergency response

- Oakville Trafalgar Memorial Hospital 2 km
- All staff are CPR certified annually

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Study Staff

Principal Investigator

David Y. Twum-Barima MB, ChB, MSc, FRCPC

- 17+ years research experience
- > 125 clinical trials: Endocrinology & Metabolism

Sub Investigators

Sam Farah MD, FRCPC, FACE

- 2 year 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

1969-74 Bachelor of Medicine, University of Ghana
1979-81 Master of Science, University of Western Ontario
1983-84 Sub-specialty Training in Endocrinology and Metabolism, Ottawa Civic Hospital
1983-84 Certification & Fellowship, Internal Medicine, Fellow, Royal College of Physician Canada

Appointments

1985-88 Active Staff, Victoria General Hospital, Winnipeg, Manitoba
1985-88 Consultant, Internal Medicine, Health Sciences Centre, Winnipeg, Manitoba
1984-88 Consultant Internal Medicine and Endocrinology, Winnipeg, Manitoba
1985-88 Lecturer, Faculty of Medicine, University of Manitoba
1989-92 Director, Intensive Care Unit, Trenton Memorial Hospital
1989-02 Active Staff, Department of Medicine, Belleville General Hospital
1992-96 Director, Continued Medical Education, Trenton Memorial Hospital
1994-02 Chief of Medicine, Quinte Health Care Corporation
2002-current Emergency Specialty Relief Staff – North York General Hospital
2002-current Associate, LMC Diabetes & Endocrinology

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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

Mississauga, Oakville, Burlington, Hamilton & Milton (Peel & Halton Region)

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

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Ethics

Ethics committee (local or central)

- Central Ethics only
- Worked with IRB Services, WIRB, Optimum, Canadian Shield

Informed consent process

- See LMC Diabetes & Endocrinology SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA implemented

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Facilities

Equipment available

- Refrigerated centrifuge (calibrated yearly)
- ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated every 6 months)
- 1 x -20 freezer
- 1 x -75 freezer
- 1 x medical fridge for study medication purposes only
- (don't think we have these anymore)
- Manual and automatic blood pressure devices
- Epi-pen and benedryl
- AED
- 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

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
- Almac

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

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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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