



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (*Oakville*)

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Site Information

Site location

LMC Diabetes & Endocrinology (Oakville)
3075 Hospital Gate, Suite 301
Oakville, Ontario
L6M 1M1

Contact Information:

905 337-0040 phone
905 337-0044 fax
800-701-ENDO (3636) Toll Free
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 16 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 (OTMH), located on the same grounds as LMC Oakville
- All staff are CPR certified annually

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Study Staff

Principal Investigator

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

- 19+ years research experience
- >135 clinical trials: Endocrinology & Metabolism

Sub Investigators

Alexander Abitol, MD

- 2+ year research experience
- >13 clinical trials: Endocrinology & Metabolism

Livia Deda (Physician Assistant), BScPA

- 5+ year research experience
- >10 clinical trials: Endocrinology & Metabolism

Investigator Accountability

25% research, 75% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

2015	GCP Training, Transcelerate
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

>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

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, Schulman, Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

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 yearly)
- 1 x -20 freezer
- 1 x -75 freezer

- 1 x medical fridge for study medication purposes only
- 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

- 3 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

