



# Pre Site Visit Questionnaire

## LMC Manna Research(Oakville)

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### Site Information

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#### Site location

LMC Manna Research (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](mailto: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)
- Member of the Canadian Association of Independent Clinical Research (CAICR)

#### Number of studies capable per site

8-12 enrolling studies with 10-14 maintenance studies

#### How long has the site been involved in clinical research?

Site has been doing research for 17 years

#### Has the site been audited?

- No FDA audit
- Health Canada Audit (May 2017) – fully compliant

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- Sponsor audit for highest enrolling - positive findings only

## 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

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### Principal Investigator

*David Y. Twum-Barima MBChB, MSc, FRCPC*

- 20+ years research experience
- >139 clinical trials: Endocrinology & Metabolism

### Sub Investigators

*Alexander Abitbol, MD*

- 3+ year research experience
- >17 clinical trials: Endocrinology & Metabolism

*Tayyab Khan, MD*

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

*Anh Hoa Tran (Physician Assistant), BScPA*

- 2+ year research experience
- >9 clinical trials: Endocrinology & Metabolism

### Investigator Accountability

25% research, 75% clinic

### Investigator's Education and/or Academic Appointments

#### Speciality Areas: Endocrinology & Metabolism

##### Education

2017	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

2002-Present	Principal Investigator, LMC Clinical Research Inc.
2002-Presnt	Associate Endocrinologist, LMC Diabetes & Endocrinology
2002-Present	Emergency Specialty Relief Staff – North York General Hospital
1994-02	Chief of Medicine, Quinte Health Care Corporation
1992-96	Director, Continued Medical Education, Trenton Memorial Hospital
1989-92	Director, Intensive Care Unit, Trenton Memorial Hospital

1989-02	Active Staff, Department of Medicine, Belleville General Hospital
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

## 3 Patient Population and Recruitment

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### Number of patients

> 200,000 for the database plus an additional 30,000 per year (60% diabetes) – all of LMC Diabetes & Endocrinology locations

### Capability of screening database

Yes - able to note medical history, medications, most recent 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 – able to query for study candidates
- GP & Specialist referral network
- Diabetes triage - rapid assessment for newly diagnosed T1D & T2D 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|Manna sites
- Community engagement - public forums, pharmacy days, educational events & expos
- E-recruitment & social media campaigns – patient advocates & testimonials

## 4 Ethics

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### Ethics committee (local or central)

- Central Ethics only
- Worked with IRB Services, Schulman (Advarra), Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

### Informed consent process

- See LMC|Manna Research SOPs
- GCP/ICH Compliant

### Confidentiality

- PIPEDA

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## Facilities

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### 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
- Digital ear thermometer
- Epi-pen and benedryl
- AED
- Able to do PK analysis, injections & meal tolerance tests (MTT)

### 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

### Source documents

- LMC|Manna Research 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)
- Pharmacy for study-specific storage and dispensing requirements
- Back-up generator available

### 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 – locked cabinets
  - Paper charts / electronic medical records – clinic chart & certified copy for paper research chart
- 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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## 6 | Contract

### Sites usual overhead

- 30% overhead

### Legal Name

- LMC Clinical Research Inc.

### Site Name

- LMC Clinical Research Inc. (Oakville)

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Budgets and Contracts: Nichelle Farrell  
Email: [nichelle.farrell@lmc.ca](mailto:nichelle.farrell@lmc.ca)  
Phone: 416-645-2928 ext 9205  
Fax : 416-645-2931

## **Regulatory Documentation**

➤ Regulatory Specialist: Natalie Gibbs

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