



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (Markham)

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Site Information

Site location

LMC Diabetes & Endocrinology (Markham)
110 Copper Creek Drive, Suite 200
Markham, ON
L6B 0P9

Contact Information:

905 294 0800 phone
905 294 0814 fax
markhamresearch@lmc.ca

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 enrolling studies with 4 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 4 years

Has the site been audited?

- No FDA audit
- No Health Canada audit
- No sponsor audit

Emergency response

- Markham Stouffville Hospital < 3 km, Sainte-Justine Hospital < 5 km
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Nikhil Gupta MD, MPH, D. ABIM

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

Sub Investigators

Nupur Agarwal (Physician Assistant), BScN, RN, BScPA

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

Investigator Accountability

20% research, 80% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

2012	Good Clinical Practice Certification	NIDA Clinical Trials Network
October 2010	Board Certified, Internal Medicine	
June 2007 – June 2010	Graduate Medical Resident, Internal Medicine	UPMC, Pittsburgh
August 2005- May 2007	MPH Epidemiology, University of North Carolina (UNC)	Chapel Hill; Research Assistant – GI Division , UNC School of Medicine, Chapel Hill, NC
2006	ECFMG (Educational Commission for Foreign Medical Graduates) certified	
September 2005	Bachelor of Medicine & Bachelor of Surgery (MBBS) degree awarded	
August 1999 – December 2004	Medical school	All India Institute of Medical Sciences (AIIMS), New Delhi, India. AIIMS is the leading tertiary care hospital and research center in India and South -East Asia

Appointments

July 2012 – present	Associate Endocrinologist	LMC Diabetes & Endocrinology
July 2010 – June 2012	Clinical Fellow – Endocrinology, Diabetes and Metabolism	UPMC, Pittsburgh
June 2007 – June 2010	Resident, Internal Medicine	UPMC, Pittsburgh

January – June
2005 Junior Resident (House Officer)

Departments of Radiation-oncology (Institute Rotary Cancer Hospital), National Drug Dependence treatment center and Employees Health Services AIIMS, New Delhi.

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

Markham, Newmarket, Aurora, Pickering, Whitby, Oshawa, Ajax, Scarborough

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, 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
- 1 x medical 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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