



Pre Site Visit Questionnaire

LMC Manna Research (Brampton)

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Site Information

Site location

LMC Manna Research (Brampton)
2979 Bovaird Drive East
Brampton, ON
L6S 0C6

Contact Information:

905 595 0560 phone
905 595 0562 fax
800-701-ENDO (3636) Toll Free
bramptonresearch@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)
- 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 7 years

Has the site been audited?

- No FDA audit
- No Health Canada audit

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- Sponsor audit for highest enrollment – positive findings only

Emergency response

- William Osler Hospital – 2.3 km from site
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Harpreet Bajaj MBBS, MPH, DAIBM

- 8+ years research experience
- > 51 clinical trials: Endocrinology & Metabolism

Sub Investigators

Prakash Chandra MBBS, MS, DABIM

- 6+ years research experience
- > 36 clinical trials: Endocrinology & Metabolism

Nupur Bahl MD

- 5+ years research experience
- > 23 clinical trials: Endocrinology & Metabolism

Keerat Singh BScPA

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

Investigator Accountability

20% research, 80% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

2017	GCP Training	Transcelerate GCP Training
1995-99	Bachelor of Medicine and Bachelor of Surgery	Maulana Azad Medical College, University of Delhi, India
2002-04	Master of Public Health (MPH), Epidemiology	University of Albany SUNY, NY

Appointments

2000-01	Clinical Internship
2001-02	Junior Residency (Externship) in Emergency Medicine
2004-07	Internship and Residency in Internal Medicine
2007	GCP Training (CITI Collaborative Institutional Training Initiative)
2007-09	Clinical Fellowship in Endocrinology, Diabetes and Metabolism
2009-current	Associate Endocrinologist, LMC Diabetes & Endocrinology

2009-current Principal Investigator, LMC Clinical Research Inc.

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Patient Population and Recruitment

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

Brampton, Streetsville, Caledon, Malton, Georgetown, Mississauga

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

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Ethics

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

Equipment available

- Refrigerated centrifuge (calibrated yearly)
- ECG machine (Brentwood software) - calibrated daily
- 330 kg weight scale (calibrated yearly)

- 1 x -70 freezer
- 3 x fridges for study medication purposes only
- Manual and automatic blood pressure devices
- Digital ear thermometer
- Epi-pen and benedryl
- 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

- 2 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 Fridges and Freezers
- 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
 - 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

Legal Name

- LMC Clinical Research Inc.

Site Name

- LMC Clinical Research Inc. (Brampton)

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

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

Regulatory Documentation

- Regulatory Specialist: Natalie Gibbs
 - Email: natalie.gibbs@lmc.ca
 - Phone: 416-645-2928 ext 9316
 - Fax: 416-645-2931
 - Address: 1929 Bayview Avenue, Suite 106
 - Toronto, Ontario M4G 3E8