



Pre Site Visit Questionnaire

LMC Manna Research (*Thornhill*)

1

Site Information

Site location

LMC Manna Research (Thornhill)
1600 Steeles Avenue West, Unit 5-10
Concord, Ontario
L4K 4M2

Contact Information:

905 763-8660 phone
905 763-0708 fax
800-701-ENDO (3636) Toll Free
thornhillresearch@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 17 years

Has the site been audited?

- FDA audit (Oct 2014) – No Form 483
- FDA audit (June 2011) – No Form 483

May not be distributed or reproduced without permission from LMC Diabetes & Endocrinology

- Health Canada audit (February 2009) - fully compliant
- Sponsor audit for highest enrolling - positive findings only

Emergency response

- Humber River Hospital 8.8km
- Mackenzie Health 12.5 km
- All staff are CPR certified annually

2

Study Staff

Principal Investigator

Ronald Goldenberg MD, FRCPC, FACE

- 19+ years research experience
- > 169 clinical trials: Endocrinology & Metabolism

Sub Investigators

Robert Schlosser MD, FRCPC

- 19+ years research experience
- > 172 clinical trials: Endocrinology & Metabolism

David Sionit MD

- 3+ years research experience
- > 25 clinical trials: Endocrinology & Metabolism

Amanda Warwick (Physician Assistant), PA-C, MSHS

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

Livia Deda (Physician Assistant), BScPA

- 6+ years research experience
- >12 clinical trials: Endocrinology & Metabolism

Investigator Accountability

25% research, 75% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

2018	Transcelerate GCP Training
1997	Fellowship, American College of Endocrinology
1989	Certification, Endocrinology & Metabolism; Royal College of Physicians & Surgeons, American Board of Internal Medicine
1988	Fellowship, Royal College of Physicians & Surgeons of Canada
1987	Certification, Internal Medicine; Royal College of Physicians & Surgeons, American Board of Internal Medicine

1989 Residency, University of Toronto
1984 Doctor of Medicine, University of Toronto, with honors

Appointments

1999-Present Principal Investigator, LMC Clinical Research Inc.
2014-Present Associate Endocrinologist, LMC Diabetes & Endocrinologist
1999-2014 Endocrinologist & Medical Co-Director, LMC Diabetes & Endocrinology
1989-Present North York General Hospital, Staff Endocrinologist
2010-2013 Steering Committee Member, CDA 2013, Clinical Practice Guidelines, Canadian Diabetes Association
2010-2012 Councillor, CDA Clinical & Scientific Section Executive Committee, Canadian Diabetes Association
2001-03 Diabetes Center, Medical Director, North York General Hospital
1991-03 Diabetes Education Center, Medical Director, North York General Hospital, Branson
1999-02 Ontario Medical Association, Chair, Section on Endocrinology and Metabolism
1998-99 Ontario Medical Association, Co-Chair, Section on Endocrinology and Metabolism
1996-02 Ontario Association of Endocrinologists, Chair

3 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

Thornhill, Vaughan, Markham, Woodbridge & North York

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, internet, 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 (Advarra), Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

Informed consent process

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

Confidentiality

- PIPEDA

5

Facilities

Equipment available

- Refrigerated centrifuge (calibrated yearly)
- ECG machine (Brentwood software) - calibrated daily
- 2 x 330 kg weight scales (calibrated yearly)
- 1 x -70 freezer
- 3 x medical fridge for study medication purposes only
- ABPM machine
- 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 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

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

6

Contract

Sites usual overhead

- 30% overhead

Legal Name

- LMC Clinical Research Inc.

Site Name

- LMC Clinical Research Inc. (Thornhill)

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