



Pre Site Visit Questionnaire

LMC Manna Research (Ottawa)

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Site Information

Site location

LMC Manna Research (Ottawa)
208-4100 Strandherd Dr.
Nepean, Ontario
K2L 0V2

Contact Information:

613-505-9704 phone
613-505-9707 fax
833-323-JOIN (5646) Toll Free
tailorresearch@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 II - IV 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 6-8 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 1 year

Has the site been audited?

- No FDA audit
- No Health Canada audit

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- No Sponsor audit

Emergency response

- Queensway Carleton Hospital 11.7km
- All staff are CPR certified annually and some staff ACLS certified

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Study Staff

Principal Investigator

Chetna Tailor MD

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

Sub Investigators

Timothy O'Leary MD, FRCPC

- 32+ years research experience
- > 7 clinical trials: Endocrinology & Metabolism

Patricia Peticca CK MD, FRCPC

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

Nadia Malakieh MD, FRCPC

- 1+ years research experience
- > 2 clinical trials: Endocrinology & Metabolism

Investigator Accountability

20% research, 80% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

2018	GCP Training, Transclerate
2010	Fellowship in Endocrinology and Metabolism, Royal College of Canada
2009	Fellowship in Internal Medicine, Royal College of Canada
2007-2010	Endocrinology and Metabolism Residency Program, University of Ottawa
2005	Licentiate of the Medicine Residency Program, Medical Council of Canada
2004-2007	Internal Medicine Residency Program, University of Ottawa
2000-2004	Doctor of Medicine, Faculty of Medicine & Dentistry, University of Western
1996-2000	Scholar's Electives Combined Honors in Genetics and History, with distinction, University of Western Ontario

Appointments

2018-Present	Principal Investigator, LMC Clinical Research Inc.
2017-Present	Associate Endocrinologist, LMC Endocrinology & Diabetes
2010-2017	Endocrinologist, Private Practice
2015-2016	Endocrinologist, Locum Coverage, Foustanelas Diabetes & Endocrine Centre, The Ottawa Hospital
2010-2012	Endocrinologist, Private Practice, Kingsway Health Centre
2011-2012	Endocrinologist, Locum Coverage, Foustanelas Diabetes & Endocrine Centre, The Ottawa Hospital
2008-2009	Chief Resident, Endocrinology and Metabolism Residency Program
2007-2008	Chief Resident, Endocrinology and Metabolism Residency Program
2006	Research Elective, Foustanelas Diabetes & Endocrine Centre
2004-2005	PGY1 Representative, Resident In-Training Committee for Internal Medicine
2005	Physician Skills Development Instructor, Ottawa ON
2001-2002	Research Associate, Neurology, University Hospital, London ON
2000-2004	Editor, University of Western Ontario Medical Journal

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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

Ottawa area

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

- 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 and room temperature centrifuges (calibrated yearly)
- 1 x ECG machine (Welch Allyn) - calibrated daily
- 2 x 330 kg weight scale (calibrated yearly)
- 1 x -20 freezer (calibrated yearly)
- 1 x medical fridge for study medication purposes only (calibrated yearly)
- ABPM machine
- Manual and automatic blood pressure device
- Digital ear thermometer
- Epi-pen and benedryl
- Able to do PK analysis, injections, glucose clamping, & meal tolerance max 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|Manna Research 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 Freezers
- Temperature monitored daily (min, max and average temperatures)
- 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

6 | Contract

Sites usual overhead

- 30% overhead

Legal Name

- LMC Clinical Research Inc.

Site Name

- LMC Clinical Research Inc. (Ottawa)

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
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