



Pre Site Visit Questionnaire

LMC Manna Research (*Montreal*)

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Site Information

Site location

LMC Manna Research (Montreal, Ville Saint-Laurent)
6363 Trans canadienne, Suite 238
Ville Saint-Laurent, QC
H4T 1Z9

Contact Information:

514-744-5620 phone

514-744-5621 fax

montrealresearch@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
- Private Clinical Research Center
- Ministry of Health Funded Diabetes Education 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

6 enrolling studies with 4 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
- Health Canada audit (November 2012) fully compliant
Sponsor audits – Had positive findings

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Emergency response

- Sacre-Coeur Hospital & Jewish General Hospital < 5 km
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Zeina Yared MD, FRCPC

- 6+ year research experience
- > 25 clinical trials: Endocrinology & Metabolism

Sub Investigators

Waheed Rehman MD, DABIM, FRCP (C)

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

Elie Sahyouni MD

- 5+ years research experience
- > 18 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	Transcelerate GCP Training
2005	Diploma in Endocrinology and Metabolism	Royal College of Physicians and Surgeons of Canada and College of Physicians of Quebec
2004	Certificate in Good Clinical Practice	National Institutes of Health (NIH)
2004-2005	Fellowship in Diabetology/Clinical Studies	Royal Victoria Hospital
2002-2004	Residency in Endocrinology and Metabolism	University of Montreal
2003	Diploma in Internal Medicine	Royal College of Physicians and Surgeons of Canada and College of Physicians of Quebec
1999-2002	Residency in Internal Medicine	University of Montreal
1999	Degree in Medicine from Canadian College Part 1	Canadian College
1995-1999	Medical Doctor	University of Montreal
1992-1995	B.Sc. Microbiology and Immunology	McGill University

Appointments

2017-Present	Sub-Investigator	LMC Clincial Research Inc.
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2012-Present	Principal Investigator	LMC Clinical Research Inc.
2012-Present	Associate Endocrinologist	LMC Diabetes & Endocrinology
2009-2012	Associate Professor of department of Medicine	University of Montreal
2005-2012	Endocrinologist	Sacré-Cœur Hospital of Montreal
2005-2011	Consultant	Institute of Clinical Research of Montreal

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

Montreal 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

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
- 330 kg weight scale (calibrated yearly)
- 1 x -20 freezers
- 1 x medical fridge for study medication purposes only
- Manual 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

- 1 room 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
1655 Fleetwood
Laval, Quebec H7N 4B2
1-877-840-2111

6 Contract

Sites usual overhead

- 30% overhead

Legal Name

- LMC Clinical Research Inc.

Site Name

- LMC Clinical Research Inc. (Montreal, Ville Saint-Laurent)

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

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

- Regulatory Specialist: Natalie Gibbs
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