



Pre Site Visit Questionnaire

LMC Manna Research (*Scarborough*)

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Site Information

Site location

LMC Manna Research (Scarborough)
520 Ellesmere Road, Suite 214
Scarborough, Ontario
M1R 0B1

Contact Information:

647-695-3866 phone
416-309-0495 fax
800-701-ENDO (3636) Toll Free
paddaresearch@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

4 enrolling studies with 2 maintenance studies

How long has the site been involved in clinical research?

New 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 audits

Emergency response

- Scarborough and Rouge Hospital (<11 km from site)
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Jagit Padda MD

- < 1 years research experience
- < 5 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
Jun 2015-Present	Endocrinology and Metabolism Fellowship	The University of Cincinnati, Cincinnati, Ohio
Jun 2012- Jun 2015	Internal Medicine Residency	Jewish Hospital (Mercy Health Partners), Cincinnati, Ohio
	American Board of Internal Medicine, Certified	American Board of Internal Medicine, Cincinnati, Ohio
Jun 2009- Feb 2012	Doctor of Medicine	University of Sint Eustatius School of Medicine, Netherlands Antilles
Sep 2007- Jun 2009	Medical Student	Medical University of the Americas (Nevis), Saint Kitts and Nevis
Sep 2003-Apr 2007	Bachelor of Science, Dean's Honors List	University of British Columbia, Vancouver, British Columbia

Appointments

2018-Present	Principal Investigator	LMC Clinical Research Inc.
2017-Present	Associate, Endocrinologist	LMC Diabetes & Endocrinology

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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

Scarborough, Markham, North York, Pickering, Whitby, Oshawa, Ajax,

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

- 330 kg weight scale (calibrated yearly)
- 1 x 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 (MTT)

On Site Local Lab

- LifeLabs 520 Ellesmere Road, Suite 109, Scarborough, Ontario, M1R 0B1

Office hours

- Monday - Friday (7:30 am - 6:00 pm)
- Weekends as needed

Monitoring space

- 1 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 – 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. (Scarborough)

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Budgets and Contracts: Nichelle Farrell
Email: nichelle.farrell@lmc.ca
Phone: 416-645-2928 ext9205
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Regulatory Documentation

- Regulatory Specialist: Natalie Gibbs
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