



Pre Site Visit Questionnaire

LMC Manna Research (*Calgary*)

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Site Information

Site location

LMC Manna Research (Calgary)
5940 MacLeod Trail SW, Suite 102
Calgary, Alberta
T2H 2G4

Contact Information:

403 288-3224 phone
403 288-6409 fax
800 701-ENDO (3636) Toll Free
calgaryresearch@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 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

5-6 enrolling studies with 5-6 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 19 years

Has the site been audited?

- No FDA audit
- Health Canada audit in December 2009 - Compliant with minimal observations

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- Sponsor audits - Had positive findings

Emergency response

- Rockyview General Hospital - 5 km from site
- All staff are CPR certified annually

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Study Staff

Principal Investigator

Buki Ajala, MBBS

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

Sub Investigators

Stuart Ross MB CHB, FRACP, FRCP

- 21+ years research experience
- > 75 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	Transclerate
2007-2012	Diabetes & Endocrinology PGY4-8	Mersey & Peninsula Deaneries, Peninsula Medical School, United Kingdom
2009	Certificate of Specialty competence in Diabetes & Endocrinology	Board Certification
2004-2007	Internal Medicine PGY1-3	Mersey Deanery, University of Liverpool, United Kingdom
2006	MRCP	Royal College of Physicians, London, United Kingdom
1995-2002	MBBS	College of Medicine, University of Ibadan

Appointments

2016-Present	Principal Investigator	LMC Clinical Research Inc.
2016-Present	Associate Endocrinologist	LMC Diabetes & Endocrinology
Aug 2014-Present	Academic Clinical Fellow	Pituitary Endocrinology and Gestational Diabetes
Oct 2012-Aug 2014	Consultant Endocrinologist	Western Sussex Hospitals NHS Foundation Trust, United Kingdom
Aug 2011-Aug 2014	Associate Lecturer & Academic Tutor	Peninsula Medical School, United Kingdom

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

Calgary

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)

Local ethics only – Health Research Ethics Board of Alberta – Clinical Trials Committee (HREBA-CTC)

Informed consent process

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

Confidentiality

- PIPEDA
- Alberta Health Act

5 Facilities

Equipment available

- Refrigerated and ambient centrifuge (calibrated yearly)
- ECG machine (calibrated yearly)

- 330 kg weight scale (calibrated yearly)
- 1 x -20 freezers
- 1 x medical fridge 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)
- Thermometers (fridge, freezer & drug rooms) - calibrated yearly
- Data loggers - temperature measured every 10 minutes - calibrated yearly

Office hours

- Monday - Friday (7:30 am - 4:00 pm)
- Weekends as needed

Monitoring space

- 1 room dedicated to monitoring - can accommodate 2 monitors
- 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: Unit 20 5350 86 Ave. SE
Calgary, AB T2C 4L7
Records Management Division

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Contract

Sites usual overhead

- 30% overhead

Legal Name

- LMC Clinical Research Inc.

Site Name

- LMC Clinical Research Inc. (Calgary)

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Budgets and Contracts:

Nichelle Farrell
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Regulatory Documentation

- Regulatory Specialist:

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