



Pre Site Visit Questionnaire

LMC Diabetes & Endocrinology (Calgary)

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Site Information

Site location

LMC Diabetes & Endocrinology (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
- Private Clinical Research Center

Memberships

- Member of the Society for Clinical Research Sites (SCRS)

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 18 years

Has the site been audited?

- No FDA audit
- Health Canada audit in December 2009 - Compliant with minimal observations
- Sponsor audits - Had positive findings

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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

- 2+ years research experience
- > 15 clinical trials: Endocrinology & Metabolism

Sub Investigators

Stuart Ross MB CHB, FRACP, FRCP

- 20+ years research experience
- > 70 clinical trials: Endocrinology & Metabolism

Investigator Accountability

20% research, 80% clinic

Investigator's Education and/or Academic Appointments

Speciality Areas: Endocrinology & Metabolism

Education

2016	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	Associate Endocrinologist	LMC Diabetes & Endocrinology
08/2014-Present	Academic Clinical Fellow	Pituitary Endocrinology and Gestational Diabetes
10/2012-08/2014	Consultant Endocrinologist	Western Sussex Hospitals NHS Foundation Trust, United Kingdom
08/2011-08/2014	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 24,000 per year and growing

Capability of screening database

Yes - able to note medical history, medications and interest in research

Catchment area

Calgary

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, 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)

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

Informed consent process

- See LMC Diabetes & Endocrinology SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA implemented
- 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
- Able to do PK analysis, injections & meal tolerance tests
- 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 and approved

Source documents

- LMC 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)

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
 - Paper charts/ Electronic medical records
- Long term storage:
 - Iron Mountain x 25 years
Address: Unit 20 5350 86 Ave.SE
Calgary, AB T2C 4L7
Records Management Division

6 | Contract

Sites usual overhead

- 30% overhead

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Research, President: Karri Venn RD, CDE, CCRC
Email: karri.venn@lmc.ca,
Phone: 647-274-4133 direct line
- Budgets and Contracts: Nichelle Farrell
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Regulatory Documentation

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