



Pre Site Visit Questionnaire

Manna Research (Toronto)

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Site Information

Site location

Manna Research (Toronto)
2291 Kipling Avenue, Unit 117B
Toronto, ON
M9W 4L6

Contact Information:

416 740-2895 phone
416 740-4517 fax
844-26-MANNA (62662) toll free
research@mannaresearch.com email

Specific clinical studies of interest

- Allergy
- Depression
- Dermatology
- Diabetes
- Digestive Disorders
- Cholesterol
- Infectious Disease
- Men's Health
- Pain & Neurology
- Obesity
- Respiratory Disease
- Rheumatology
- Urology
- Vaccines
- Women's Health

Phase I - IV Experience

Description of site

- 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

8-10 enrolling studies with 20-25 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 21 years

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PI has 5 years experience with clinical trials

Has the site been audited?

- Health Canada audits (January 2009, October 2014) - fully compliant
- FDA audit (January 2015) compliant, no 483
- Sponsor and ethics board audits for highest enrolling - positive findings only

Emergency response

- All staff are CPR certified annually
- Etobicoke General Hospital (3.1km)
- Crash cart, oxygen, and defibrillator on site

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Study Staff

Principal Investigator

Azhar Toma, MD, LMCC, CCFP

- 5+ years research experience
- > 85+ clinical trials: Primary Care

Education

2010 Certification in Family Medicine, College of Family Physicians of Canada
2002 Bachelor of Medicine & Bachelor of Surgery (MB ChB), Baghdad University

Appointments

2012-present Principal Investigator, Manna Research, Etobicoke, Ontario
2013-present Family Physician, Kipling Heights Medical Center, Etobicoke, Ontario
2012-2013 Family Physician, Bloom Clinic, Brampton, Ontario
2011-2012 Family Physician, Bramalea Community Health Center, Brampton, Ontario
2005-2011 Family Physician, Bramalea Community Health Center, Brampton, Ontario
2005-2011 Family Physician, Newfoundland & Labrador
2004- 2005 General Practitioner, Baghdad, Iraq

Sub Investigator:

Sheldon Finkelstein, MD

- 25 + years research experience
- > 320 clinical trials: Primary Care

Investigator Accountability

40% research, 60% clinic

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Patient Population and Recruitment

Number of patients

Database of > 10,000 patients

Capability of screening database

Yes – able to note demographic information, medications, IICD-9 codes, medical history, lab values and medical documents

Catchment area

Toronto and surrounding GTA

How are subjects recruited to meet the agreed upon targets?

- Patient database – able to query for study candidates
- Clinic referrals
- GP & Specialist referral network
- 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, Quorum, WIRB, Veritas, Canadian Shield, Optimum, Research Review Board, etc.

Informed consent process

- See Manna Research SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA

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Facilities

Equipment available

- Centrifuge (calibrated yearly)
- ECG machine (Welch Allyn) - calibrated yearly
- 300 kg digital weight scale (calibrated yearly)
- 2 x -20 freezer (calibrated yearly)
- 1 x -70 freezer (calibrated yearly)
- 6 x fridge for study medication purposes only (calibrated yearly)
- Manual and automatic blood pressure devices
- Emergency crash cart

- Defibrillator
- Able to do PK analysis, meal tolerance tests, injections, and infusions
- Incubator
- Spirometer

Office hours

- Monday & Thursday (8:00 am - 5:00 pm)
- Tuesday & Wednesday (8:00 am – 4:00 pm)
- Friday (8:00 am – 2:00 pm)

Monitoring space

- 4 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 medication room, Fridges and Freezers (-20 & -70)
- Safe for storing schedule II drug
- Temperature monitored daily (min, max and average temperatures)Space for unblinded medication preparation
- Back-up generator

eCRF experience

- *INFORM*
- *RDC*
- *ORACLE*
- *BIRT*
- Medidata RAVE
- Datalabs

IVRS experience

- Clinphone
- Clintrak
- Endpoint
- ICON
- Fisher Clinical Services
- Impala
- Perceptive
- Almac
- Cardinal

Data storage

- In house:
 - Lead study coordinator's office
 - Paper charts
 - Electronic medical records (printed paper copy)

- Long term storage:
 - U-Haul Storage x 25 years
240 Rexdale Blvd.
Unit #1662
Toronto, Ontario M9W 1R2
(416) 740-9963

 - 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. d.b.a. Manna Research

Site Name

- Manna Research (Toronto)

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: Dennis Kha
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