



Pre Site Visit Questionnaire

Manna Research (Toronto)

1

Site Information

Site location

Manna Research Inc. (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

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 20 years

PI has 4 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

2

Study Staff

Principal Investigator

Azhar Toma, MD, LMCC, CCFP

- 4+ years research experience
- > 75+ 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

3

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
- Clinic referrals
- GP & Specialist referral network
- Online applications through our Improving Health website
- Advertising - TV, radio, newspaper, central toll free number and capability of central ad campaigns for all LMC and Manna sites
- E-recruitment campaigns

4

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 implemented

5

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

Manna Research SOPs

- ERB & HC reviewed

Source documents

- Manna 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

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Business Development Director: Alysa Langburt
Email: alysa.langburt@lmc.ca
Phone: 514-806-3055

Regulatory Documentation

- Regulatory Specialist: Dennis Kha
Email: dennis.kha@lmc.ca
Phone: 416-645-2928 ext 9370
Fax: 416-645-2931
Address: 1929 Bayview Avenue, Suite 106
Toronto, Ontario M4G 3E8