



Pre Site Visit Questionnaire

Manna Research (*Vancouver*)

1

Site Information

Site location

Manna Research (Vancouver)
1530 West 7th Ave
Vancouver, BC
V6J 1S3

Contact Information:

604 336-8438 phone
604 336-8439 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 II - IV Experience

Description of site

- Private Clinical Research Centre located in a large medical clinic

Number of studies capable per site

6 enrolling studies with 4 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 3 years
PI has 10 years experience with clinical trials

Has the site been audited?

- Health Canada audit (December 2013) - fully compliant
- Sponsor audit (January 2014) – positive findings only

- **Emergency response**
- All staff are CPR certified annually
- Crash cart and AED on site
- Local hospital <2km away

2

Study Staff

Principal Investigator

Arthur Vasquez MD

- 10+ years research experience
- > 10 clinical trials: Respiratory, Cardiovascular, Gastrointestinal, Obesity, Diabetes, Vaccines, Osteoarthritis, Lipids, Women’s studies, Urology, Gout, Allergies

Education

1991 Doctor of Medicine, University of Saskatchewan

Appointments

2014-present Principal Investigator, Manna Research
2008-present General Practitioner, Burnaby, British Columbia
1992-1994 Locum privileges, Penticton Regional Hospital, Penticton, British Columbia
1992-1994 Locum privileges, Vancouver General Hospital, St. Paul’s Hospital, Vancouver, British Columbia
1996-1999 Associate Staff, Burnaby General Hospital, Burnaby, British Columbia
1996-1999 Associate Staff, Vancouver General Hospital, Vancouver, British Columbia

Sub Investigator

Arjuna Perera, MD

- 1+ years research experience
- > 5 clinical trials: Diabetes, Lipids, Fibromyalgia, HSDD, Over-active bladder

3

Patient Population and Recruitment

Number of patients

Database of 25000 patients

Capability of screening database

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

Catchment area

Greater Vancouver (North, South, West, East Vancouver), Burnaby, Surrey, Coquitlam, New Westminster

How are subjects recruited to meet the agreed upon targets?

- Patient data base
- GP & Specialist referral network
- Advertising - radio, newspaper, central toll free number and capability of central ad campaigns for all LMC and Manna sites
- E-recruitment campaign
- Public forums & expos

4

Ethics

Ethics committee (local or central)

- Central Ethics
- Worked with IRB Services, Schulman, Quorum, WIRB, Veritas, Canadian Shield, Optimum, etc.

Informed consent process

- See Manna Research SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA implemented

5

Facilities

Equipment available

- Centrifuge (calibrated annually every August)
- ECG machine (calibrated annually every August)
- weight scale (calibrated annually every August)
- -20 freezer (maintained according to manufacturer's specifications)
- fridge for study medication purposes only (maintained according to manufacturer's specifications)
- Manual blood pressure devices (calibrated annually every August)
- Able to do PK analysis, injections & meal tolerance tests

Office hours

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

Monitoring space

- 2 rooms dedicated to monitoring
- Phone, analog, wireless and broadband access

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 Drug Cabinets, Medical Fridges and Freezers
- Temperature monitored daily (min, max and average temperatures)

eCRF experience

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

IVRS experience

- Clinphone
- Clintrak
- ICON
- Almac
- Cardinal

Data storage

- In house:
 - Lead study coordinator's office
 - Paper charts
 - Electronic medical records
- Long term storage:
 - Iron Mountain x 25 years
Address: Records Management Division
8088 Glenwood Drive
Burnaby, British Columbia V3N 5E9
1-877-840-2111

6 | Contract

Sites usual overhead

- 30% overhead

Sites turnaround

- 1-2 week turnaround

Budget Negotiations

- Director of Business Development: Alysa Langburt
Email: alysa.langburt@mannaresearch.com
Phone: 514-806-3055

Regulatory Documentation

- Regulatory Specialist: Andrea Magwood
Email: amagwood@mannaresearch.com
Phone: 604-336-8438
Fax: 604-336-8439
Address: 1530 West 7th Ave
Vancouver, British Columbia V6J 1S3