

Pre Site Visit Questionnaire

Manna Research (Vancouver)

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Site Information

Site location

Manna Research (Vancouver) 470 S.W. Marine Drive, Suite 301 Vancouver, BC V5X 0C4

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

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

6 enrolling studies with 4 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 4 years

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PSV Questionnaire Site: (Manna Vancouver)

PI has 11 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 <6km away</p>

2 Study Staff

Principal Investigator

Arthur Vasquez, MD

- > 11+ 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

Satnam Cubra, MB., Ch.B

- > 1 year research experience
- > 2 clinical trials

Education

MRCGP, General Practice (Family Medicine) East Midlands Healthcare Workforce Deanery

2006 MB.,Ch.B University of Leicester

Bachelor of Science, Physiology King's College of London, U. Of London

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Appointments

2016 – Present Sub-Investigator Manna Research Inc.

Oct2016 – Present Family physician Marine Gateway Medical Clinic Inc.

Feb2013 – Sep2016 Family physician Vivacare Inc.

Nov2012 – Jan2013 Emergency Medicine Physician Northampton General Hospital
Aug2010 – Jan2013 General Medical Practitioner Rushden Medical Centre

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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 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, etc.

Informed consent process

- See Manna Research SOPs
- ➢ GCP/ICH Compliant

Confidentiality

PIPEDA

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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

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

eCRF experience

- > IINFORM
- ► RDC
- ORACLE
- ➢ BIRT
- Medidata RAVE
- Datalabs
- Medrio

IVRS experience

- Clinphone
- Clintrak
- > Endpoint
- > ICON
- Fisher Clinical Services

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- > Impala
- Perceptive
- 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

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Contract

Sites usual overhead

> 30% overhead

Legal Name

> LMC Clinical Research Inc. d.b.a. Manna Research

Site Name

Manna Research (Vancouver)

Sites turnaround

> 1-2 week turnaround

Budget Negotiations

➤ Budgets and Contracts: Nichelle Farrell Email: nichelle.farrell@lmc.ca
Phone: 416-645-2928 ext 9205

Fax: 416-645-2931

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

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