



Pre Site Visit Questionnaire

Manna Research Inc. (Stoney Creek)

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Site Information

Site location

Manna Research Inc. (Stoney Creek)
35 Upper Centennial Parkway, 3rd Floor
Stoney Creek, ON
L8J 3W2

Contact Information:

416-294-0724 phone
289-812-0225 fax
lydia.frost@lmc.ca email

Specific clinical studies of interest

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

Phase III - IV Experience

Description of site

- Private Clinical Research Center

Number of studies capable per site

2-4 enrolling studies with 5-8 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 3 years
PI has >2 years experience with clinical trials

Has the site been audited?

- None

Emergency response

- All staff are CPR certified annually
- St Joseph’s Community Health (6.5 km)
- Crash cart, oxygen, and defibrillator on site

2 Study Staff

Principal Investigator / Sub Investigator

Mehul Patel, MD

- 2+ years research experience
- > 2 clinical trials: Primary Care

Education

| | | |
|---------------------|-----------------------------------|--|
| Nov 2015 | CCFP | College of Family Physicians of Canada |
| Sep 2013 | Medical License, Ontario | The College of Physicians and Surgeons of Ontario |
| Aug 2013 | ABFM Certification | American Board of Family Medicine |
| Jun 2010 – Jun 2013 | Residency: Family Medicine | University Hospitals Case Medical Centre, Case Western Reserve University School of Medicine, Cleveland OH |
| Aug 2013 | Medical License, Ohio | State Medical Board of Ohio |
| May 2004 | Medical Doctor | Saba University School of Medicine, Netherland Antilles |
| Apr 2004 | Hon. Bachelor of Science, Biology | McMaster University |

Professional Activities

| | | |
|---------------------|---|-------------------------------|
| 2016 - Present | Principal Investigator / Sub-Investigator | Manna Research Inc. |
| Sep 2013 – Present | Family Practice Physician | Southmount Health Care Centre |
| Sep 2013 – Apr 2014 | Urgent Case | Halton Family Health Centre |

Asif Ashraf, MD

- 2+ years research experience
- > 2 clinical trials: Primary Care

Education

| | | |
|-------------|---|-----------------------|
| 2011 – 2013 | Residency Training, Department of Family and Community Medicine | University of Toronto |
| 2007 – 2011 | Doctor of Medicine | University of Ottawa |
| 2006 – 2007 | Health Research Methodology (Master’s Program, incomplete) | McMaster University |

| | | |
|-------------|---|---------------------|
| 2003 – 2006 | Bachelor of Health Sciences (Honours) | McMaster University |
| 2002 – 2003 | First year of Bachelor of Health Sciences Honours Programme (Completed) | Brock University |

Professional Activities

| | | |
|---------------------|---|-------------------------------|
| 2016 - Present | Principal Investigator / Sub-Investigator | Manna Research Inc. |
| Aug 2013 – Present | Family Medicine | Southmount Health Care Centre |
| Jul 2013 – Sep 2013 | Family Medicine | Locke Street Medical Clinic |
| 2013 – 2014 | Family Medicine | PRG Medical Clinic |

Sudip Datta, MD, FRCPC, FACC

- 3 + years research experience
- > 6 clinical trials: Cardiology

Education, Certificates and Training

| | | |
|-------------|---|---|
| 2007 – 2009 | Fellowship in Cardiovascular Imaging with PET/CT | London Health Sciences Centre, University of Western Ontario and Brigham and Women’s Hospital, Harvard University |
| 2004 – 2007 | Fellowship in Clinical Cardiology, Royal College and American Board Certified | University of Western Ontario |
| 2001 – 2004 | Residency in Internal Medicine, Royal College and American Board Certified | McMastery University |
| 1998 – 2001 | Doctor of Medicine | University of Calgary |
| 1994 – 1998 | Bachelor of Science in Biochemistry and Neuoscience, with Honors | McGill University |

Professional Activities

| | | |
|-------------------|--|---------------------|
| May 2012 -Present | Principal Investigator/ Sub Investigator | Manna Research Inc. |
|-------------------|--|---------------------|

Investigator Accountability

10% research, 90% clinic

3 | Patient Population and Recruitment

Number of patients

Database of > 50,000 patients

Capability of screening database

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

Catchment area

Burlington, Hamilton, St. Catherines, Stoney Creek, Niagara region

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

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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 SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA implemented

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Facilities

Equipment available

- Centrifuge (calibrated yearly)
- ECG machine
- Weight scale (calibrated yearly)
- 1 x -20 freezer (calibrated yearly)
- 1 x fridge for study medication purposes only (calibrated yearly)
- Manual and automatic blood pressure devices
- Able to do PK analysis, meal tolerance tests, injections, and infusions

Office hours

- Monday to Friday (8:00 am - 5:00 pm)
- Saturdays as needed

Monitoring space

- 1 room dedicated to monitoring
- Phone, analog, wireless and broadband access
- Access to a fax and photocopy machine

SOPs

- ERB & HC reviewed

Source documents

- Specific templates for source creation and study specific logs

Drug accountability and storage

- Secured and Locked medication room, Fridge and Freezer (-20)
- Temperature monitored daily (min, max and average temperatures)
- Space for un-blinded medication preparation

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:
 - Study coordinator's office
 - Paper charts
 - Electronic medical records (printed paper copy)
- 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