



# Pre Site Visit Questionnaire

## Manna Research Inc. (*Burlington South*)

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### Site Information

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#### Site location

Manna Research Inc. (Burlington South)  
2079 Lakeshore Road,  
Burlington, ON  
L7R 1E2

2119 Lakeshore Road  
Burlington, ON.  
L7R 1A4

#### Contact Information:

905-662-3303 ext 619 phone  
289-812-0225 fax  
[lydia.frost@lmc.ca](mailto: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 II - IV Experience

#### Description of site

- Private Clinical Research Center

#### Number of studies capable per site

3-5 enrolling studies with 8-10 maintenance studies

#### How long has the site been involved in clinical research?

Site has been doing research for >5 years  
PI has 5+ years experience with clinical trials

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## Has the site been audited?

- Health Canada audit (2016)

## Emergency response

- All staff are CPR certified annually
- Joseph Brant Hospital (1.6 km)
- Crash cart, oxygen, and defibrillator on site

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## Study Staff

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### Principal Investigator / Sub Investigator

#### *Rheumatology:*

#### **Vikas Pandith, MD, D.Abim, FRCPC**

- 5+ years research experience
- > 20 clinical trials: Rheumatology

#### **Education**

Jul 1994 – Jun 1996	Fellowship Program – Rheumatology	Queen’s University
1991 – Jul 1994	Internal Medicine Residency	Queen’s University
1987 – 1991	MD	University of Toronto
1985 – 1987	B.Sc.	University of Ottawa

#### **Professional Activities**

May 2012 -Present	Principal Investigator/ Sub Investigator	Aviva Clinical Trial Group Inc.
Dec 2008 – Present	Private Practice	Wharton Medical Clinic
Sep 1996 – Present	Active staff, Rheumatology & Internal Medicine	Joseph Brant Memorial Hospital
Jun 1995 – Present	Independent Third party Assessments for Insurance Companies	CompreMed Inc., Odyssey Health Services Medworks Assessment, a Medical Rehabilitation & Disability Designated Assessment Centre

#### *Cardiology:*

#### **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
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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.
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### ***Fatima Merali, MSc, MD, FRCPC***

- 5 + years research experience
- > 20 clinical trials: Cardiology

### Education

2001 – 2004	Cardiology Fellowship	McMaster University
1998 – 2011	Internal Medicine Residency	McMaster University
1995 – 1998	Doctor of Medicine	McMaster University
1993 – 1995	Masters of Science	McMaster University
1989 – 1993	B.Sc.	McMaster University

### Professional Activities

2016 – Present	Principal Investigator / Sub Investigator	Manna Research Inc.
2012 – 2016	Principal Investigator / Sub Investigator	Aviva Clinical Trials Group Inc.
2005 - Present	Clinical Cardiologist	Private Practice
2005 – 2008	Clinical Cardiologist	William Osler Hospitals

### *Endocrinology:*

### ***Mohammed Azharuddin, MD***

- 1 year research experience
- > 5 clinical trials: Endocrine / Metabolic

### Education

Jul 2011 – Jun 2013	FRCPC – Endocrinology and Metabolism	McMaster University
2008 – 2011	FRCPC - Internal Medicine	McMaster University
2011	ABIM	Diplomat American Board of Internal Medicine
2008	Clinical Fellow	SunnyBrook Health Sciences Centre

## Professional Activities

2016 – Present	Principal Investigator / Sub Investigator	Manna Research Inc.
2013 – Present	Endocrinology Specialist	Aviva Medical Specialists Clinic
2013 - Present	Staff Internist	Oakville Hospital

## Sub Investigators

### *Ali Hadi, MD*

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

### *Sandra Charman, MD*

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

## Investigator Accountability

15% research, 85% clinic

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## Patient Population and Recruitment

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### Number of patients

Database of > 40,000 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, Oakville, St Catherines, Guelph, Milton

### 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

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## **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**

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### **Equipment available**

- Centrifuge (calibrated yearly)
- ECG machine
- 500 kg digital 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 (calibrated yearly)
- Emergency crash cart
- Defibrillator
- Incubator
- Able to do PK analysis, meal tolerance tests, injections, and infusions

### **Office hours**

- Monday – Friday (8:00 am - 4:00 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, Fridges and Freezers (-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:
  - Lead study coordinator's office
  - Paper charts
  - Electronic medical records (printed paper copy)
- Long term storage:
  - Iron Mountain x 25 years  
Address: Records Management Division  
70 Talman Court  
Concord, Ontario L4K 4L5  
1-877-840-2111

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## **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  
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Address: 1929 Bayview Avenue, Suite 106  
Toronto, Ontario M4G 3E8