



Pre Site Visit Questionnaire

Manna Research (*Burlington South*)

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Site Information

Site location

Manna Research (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 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

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

3-5 enrolling studies with 8-10 maintenance studies

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How long has the site been involved in clinical research?

Site has been doing research for >6 years
PI has 6+ years experience with clinical trials

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

Principal Investigator / Sub Investigator

Rheumatology:

Vikas Pandith, MD, D.Arim, FRCPC

- 6+ years research experience
- > 25 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 Servicesm Medworks Assessment, a Medical Rehabilitation & Disability Designated Assessment Centre

Cardiology:

Sudip Datta, MD, FRCPC, FACC

- 4 + years research experience
- > 8 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.
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Fatima Merali, MSc, MD, FRCPC

- 6 + 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

- 2 year research experience
- > 7 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

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

Sandra Charman, MD

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

Investigator Accountability

15% research, 85% clinic

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Patient Population and Recruitment

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
- 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

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

5**Facilities**

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)
- Weekends as needed

Monitoring space

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

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 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
- Medrio

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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Contract

Sites usual overhead

- 30% overhead

Legal Name

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

Site Name

Manna Research (Burlington South)

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
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Toronto, Ontario M4G 3E8