



Pre Site Visit Questionnaire

Manna Research (*Stoney Creek*)

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Site Information

Site location

Manna Research (Stoney Creek)
35 Upper Centennial Parkway, 2nd 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

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

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 4 years

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PI has >4 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

- 3+ 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

- 3+ 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

- 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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Investigator Accountability

10% research, 90% clinic

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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 – 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, Research Review Board, etc.

Informed consent process

- See Manna Research SOPs
- GCP/ICH Compliant

Confidentiality

- PIPEDA

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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

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, 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*
- *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 (Stoney Creek)

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
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