



Pre Site Visit Questionnaire

Manna Research (Quebec)

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Site Information

Site location

Manna Research Inc. (Quebec)
1190 A, Rue de Courchevel, Local 203
Lévis, QC
G6W 0M5

Contact Information:

418-839-8572
418-839-8003 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

Number of studies capable per site

6-8 enrolling studies with 8-10 maintenance studies

How long has the site been involved in clinical research?

Site has been doing research for 10 years
PI has 10 years experience with clinical trials

Has the site been audited?

- Health Canada audit (June 2015) - fully compliant
- FDA audit (Feb 2012) – fully compliant
- Sponsor audits for highest enrolling - positive findings only

Emergency response

- All staff are CPR certified annually
- Crash Cart
- Hospital < 2 km from clinic

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Study Staff

Principal Investigators

François Blouin, MD

- 10+ years research experience
- > 50 clinical trials: *Diabetes type 2, vaccine, COPD, Women's Health, Hypogonadism, Gastroenterology, Zoster pain, chronic pain, hypertension, depression, cardiovascular disease, allergy, asthma, obesity*

Education

1991 Doctor of Medicine, University of Montreal
1984 Bachelor in psychology, University of Quebec

Appointments

2014-present Principal Investigator, Manna Research Inc. Levis, Quebec
2005-2014 Principal Investigator, Pro-Recherche Inc., St-Romuald, Qc
2004-2006 General practice, Polyclinique des Ponts, St-Romuald, Quebec
1999-2006 General practice, Clinic St-Prosper, Quebec
1991-2001 Emergency, Port-Cartier, Quebec

Gérald Vallières, MD

- 13+ years research experience
- > 50 clinical trials: *Diabetes type 2, vaccine, COPD, Women's Health, Hypogonadism, Gastroenterology, Zoster pain, chronic pain, hypertension, depression, cardiovascular disease, allergy, asthma, obesity*

Education

1982 Doctor of Medicine, University of Quebec
1976 Bachelor in Social Science, University of Quebec

Appointments

2014-present Principal Investigator, Manna Research Inc. Levis, Quebec
2007-2014 Sub-Investigator, Pro-Recherche Inc., St-Romuald, Qc
2002-present Sub-Investigator, InVentiv, Quebec, Quebec
2004-2012 Evaluator clinic, Clinique d'expertise médicale du Québec, Quebec

Alain Bissonnette, MD

- 3+ years research experience
- > 10 clinical trials: *Diabetes type 2, Women's Health, chronic pain, depression, cardiovascular disease, allergy, asthma*

Education

1988 Doctor of Medicine, University of Quebec

Appointments

2014-present Principal Investigator, Manna Research Inc. Levis, Quebec
2013-2014 Sub-Investigator, Pro-Recherche Inc., St-Romuald, Qc
2013-present General practice, La Cité Médicale, Quebec, Qc
2000-2013 Consultant, Clinic Campanile, Quebec
2008-2009 Clinical Investigator, Clinique Campanile, Quebec

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Patient Population and Recruitment

Number of patients

Database of > 2000 patients

Capability of screening database

Yes – able to note demographic information, medications, medical history, lab values and medical documents

Catchment area

Quebec city and surrounding area

How are subjects recruited to meet the agreed upon targets?

- GP & Specialist referral network
- Advertising - radio, newspaper, central toll free number and capability of central ad campaigns for all LMC and Manna sites
- E-recruitment campaign
- Public forums & expos

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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 implemented

5 Facilities

Equipment available

- Centrifuge (calibrated yearly)
- ECG machine (calibrated daily)
- weight scale (calibrated yearly)
- -20 freezer (calibrated yearly)
- 2x fridge for study medication purposes only (calibrated yearly)
- Manual blood pressure devices calibrated yearly
- Able to do PK analysis, injections & meal tolerance tests

Office hours

- Monday – Thursday (7:00 am - 4:30 pm)
- Weekends as needed

Monitoring space

- 3 rooms dedicated to monitoring
- Phone, analog, wireless and broadband access

Manna Research SOPs

- ERB & HC reviewed

Source documents

- Manna specific templates for source creation and study specific logs

Drug accountability and storage

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

eCRF experience

- *INFORM*
- *RDC*
- *ORACLE*
- *BIRT*
- Medidata RAVE
- Datalabs

IVRS experience

- Clinphone
- Clintrak
- ICON
- Almac
- Cardinal

Data storage

- In house:
 - Secure and locked office
 - Paper charts
- Long term storage:
 - Iron Mountain x 25 yearsAddress:
721 Newton,
Quebec, G1P 4C4
1-418-877-1121

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