



# Pre Site Visit Questionnaire

## Manna Research (Quebec)

**1**

### Site Information

---

#### Site location

Manna Research (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](mailto: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

#### 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

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 11 years

May not be distributed or reproduced without permission from LMC / Manna Research

PI has 11 years experience with clinical trials

### Has the site been audited?

- Health Canada audit (June 2015) - fully compliant
- FDA audit (Feb 2012) – fully compliant
- FDA audit (Mar 2018) – 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

2

## Study Staff

---

### Principal Investigators

#### **François Blouin, MD**

- 11+ years research experience
- > 55 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**

- 14+ years research experience
- > 55 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

## 3 Patient Population and Recruitment

---

### Number of patients

Database of > 2000 patients

### Capability of screening database

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

### Catchment area

Quebec city and surrounding area

### 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

## 4 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

## 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

### **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 Freezer
- Temperature monitored twice 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, certified copy)

- Long term storage:
  - Iron Mountain x 25 years
  - Address:  
721 Newton,  
Quebec, G1P 4C4  
1-418-877-1121

---

## 6 | Contract

### Sites usual overhead

- 30% overhead

### Legal Name

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

### Site Name

- Manna Research (Quebec)

### Sites turnaround

- 1-2 week turnaround

### Budget Negotiations

- Budgets and Contracts: Nichelle Farrell
  - Email: [nichelle.farrell@lmc.ca](mailto: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](mailto:dennis.kha@lmc.ca)
  - Phone: 416-645-2928 ext 9370
  - Fax: 416-645-2931
  - Address: 1929 Bayview Avenue, Suite 106  
Toronto, Ontario M4G 3E8