AMT-143: A Phase 1 Randomized Controlled Trial Evaluating AMT-143 in Healthy Volunteers to Assess Sustained Analgesic Release for Non-Opioid Pain Treatments

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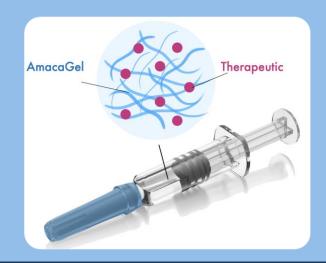






# **Evaluating Canadian Biotech with RCTs**

- AmacaThera Inc.
- AMT-143 (non-opioid anesthetic)
- Post-operative pain









### **Research Question**

 Does AMT-143 provide 3-days of sustained ropivacaine release in humans?

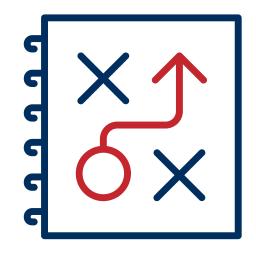






#### **Issue Encountered**

 Due to First-In-Human requirements for Healthy volunteer study with PK testing, study was difficult to run in a hospital setting



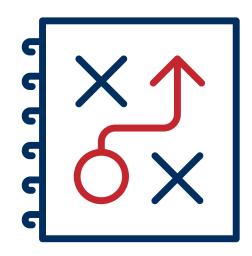




## Design

Subcutaneous administration in healthy volunteers. Dose escalation:

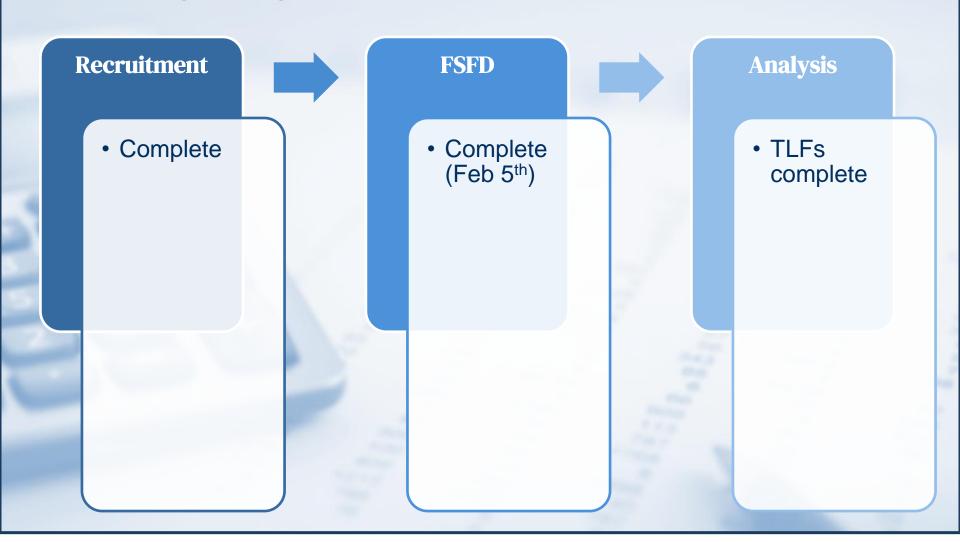
- 100mg
- 200mg
- 400mg







#### Timeline







#### **Updates**

- Significant difficulties were encountered running this Phase 1 trial in a hospital setting
- Identified a site that can run a Phase 2 trial
- Manufactured clinical trial material
- Filed a CTA for Phase 2 study in the hospital setting

