



CLINICAL TRIAL SITE INFORMATION FORM

A separate form for each clinical trial site must be completed by the sponsor and filed with Health Canada. **All fields must be completed prior to submitting this form to Health Canada.**

PART 1 - Clinical Trial Protocol Information					
Please check one of the following: Clinical Trial Application (CTA) <input type="checkbox"/> Clinical Trial Application Amendment (CTA-A) <input type="checkbox"/>					
1. Clinical Trial Protocol Title					
2. Clinical Trial Protocol Number (if applicable)		3. Clinical Trial Control Number (if assigned)		4. CR File Number (if assigned)	
PART 2 - Drug Product / Sponsor Information					
A) Drug Product Information					
5. Brand Name					
6. Proper or Common Name					
B) Sponsor of Clinical Trial					
7. Name of Sponsor (Full Name - No Abbreviations)					
8. Street / Suite / PO Box		9. City / Town	10. Prov. / State	11. Country	12. Postal/ZIP Code
Contact Person for Sponsor					
13. Name		14. Telephone No.	15. Fax No.	16. Language Preferred <input type="checkbox"/> English <input type="checkbox"/> French	
17. Title		18. E-mail			
C) Contact for THIS Clinical Trial					
19. Contact Name			20. E-mail		
21. Company Name (Full Name - No Abbreviations)					
22. Street / Suite / PO Box		23. City / Town	24. Prov. / State	25. Country	26. Postal/ZIP Code
27. Telephone No.		28. Fax No.		29. Language Preferred <input type="checkbox"/> English <input type="checkbox"/> French	



PART 3 - Clinical Trial Site Information			
A) Clinical Trial Site			
30. Name of Site (Full Name - No Abbreviations)			
31. Street / Suite / PO Box	32. City / Town	33. Province	34. Postal Code
35. Commencement Date of Clinical Trial or Clinical Trial Amendment ¹			
B) Qualified Investigator A Qualified Investigator Undertaking must be completed by the qualified investigator responsible for the conduct of the clinical trial at the site specified above. The completed undertaking must be retained by the clinical trial sponsor for a period of 25 years.			
36. Name	37. Title	38. Language Preferred <input type="checkbox"/> English <input type="checkbox"/> French	
39. Street / Suite / PO Box	40. City / Town	41. Province	42. Postal Code
43. E-mail		44. Tel. No.	45. Fax No.
C) Research Ethics Board Approval A Research Ethics Board Attestation must be completed by the Research Ethics Board that reviewed and approved the protocol and informed consent form for this clinical trial at the site specified above. The completed attestation must be retained by the clinical trial sponsor for a period of 25 years.			
46. Name of Research Ethics Board		47. Date of Approval	
48. Street / Suite / PO Box	49. City / Town	50. Province	51. Postal Code
52. Name of Contact Person	53. Telephone No.	54. Fax No.	55. Language Preferred <input type="checkbox"/> English <input type="checkbox"/> French
56. Title		57. E-mail	

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Date of commencement of the trial: For the purposes of the Clinical Trial Site Information form - this is defined as the date when the clinical trial site is ready to enrol patients in the clinical trial. (Before a start date can be determined, both Health Canada and Research Ethics Boards approval must be obtained).