Health Canada Santé Canada

Clinical Trial Site Information Form

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1. Clinical Trial Lead (required) ◯ Pharmaceutical ◯ Biologic

2. Reason for Filing (required) ◯ New Site ◯ Change to Existing Site

3. Changes (required for 'Changes to Existing Site') ☐ Clinical Trial Site ☐ Commencement Date ☐ Research Ethics Board ☐ Qualified Investigator

☐ Safety Amendment (when invoking C.05.008(4) of the *Regulations* or Part 2, 24(2) of the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Related to COVID-19*)

4. Protocol Number (field auto-converts text to CAPS) (required)

5. Clinical Trial Parent Control Number (required)

6. Clinical Trial Amendment Control Number(s), if applicable

Clinical Trial Site

7. Name of Site previously provided to Health Canada (full name, no abbreviations)

8. Name of Site (full name, no abbreviations) (required)

9. Street Number (required) | 10. Street Name (required) | 11. Suite/Unit | 12. P.O. Box

13. City/Town (required) | 14. Province/Territory (required) | 15. Postal Code (required)

16. Commencement Date of the Clinical Trial Protocol (YYYY-MM-DD) (required)

Qualified Investigator

Title | 17. First Name (required) | 18. Last Name (required) | 19. Medical Designation(s) (required)

20. Street Number (required) | 21. Street Name (required) | 22. Suite/Unit | 23. P.O. Box

24. City/Town (required) | 25. Province/Territory (required) | 26. Postal Code (required)

27. Email Address (required) | 28. Phone (required) | 29. Ext. | 30. Fax | 31. Language (required)

Research Ethics Board Approval

32. Name of Research Ethics Board, including affiliations (if applicable) (full name, no abbreviations)

33. Street Number (required) | 34. Street Name (required) | 35. Suite/Unit | 36. P.O. Box

37. City/Town (required) | 38. Province/Territory/State (required) | 39. Country | 40. Postal Code/ZIP (required)

41. Title | 42. First Name (required) | 43. Last Name (required)

44. Email Address (required) | 45. Phone (required) | 46. Ext. | 47. Fax | 48. Language (required)

49. Date of Research Ethics Board Approval (YYYY-MM-DD) (required)

It is required that this date be BEFORE the commencement date of the clinical trial

50. Safety Implementation Rationale (required for Safety Amendments) Clear Rationale

Save and rename before submitting

Canada