Health Canada Santé Canada

Application form for medical device clinical trials under the interim order (COVID-19)

* denotes a mandatory field

Part 1 – Contact information

A) Applicant mailing address

1. Applicant name (full legal name - no abbreviations) *			
2. Street address/suite/post office box *			
3. City *	4. Prov./State *	5. Country *	6. Postal/Zip code*
7. Contact name *	8. Title	9. Telephone number	10. Fax number
11. Language preferred * ○ English ○ French	12. Email *		

B) Manufacturer mailing address

☐ Same as applicant

13. Manufacturer name (full legal name - no abbreviations)			
14. Street address/suite/post office box			
15. City	16. Prov./State	17. Country	18. Postal/Zip code
19. Contact name	20. Title	21. Telephone number	22. Fax number
23. Language preferred ○ English ○ French	24. Email		

Canada

C) Importer mailing address			☐ Same as manufacturer
25. Importer name (full legal name – no abbreviations)			
26. Street address/suite/post office box			
27. City	28. Prov./State	29. Country	30. Postal/Zip code
31. Contact name	32. Title	33. Telephone number	34. Fax number
35. Language preferred ○ English ○ French	36. Email		

Part 2 – Device information			
37. Risk classification of device *	○ Class II	○ Class III	○ Class IV
38. Device name – as it appears on the label. This is the device name for which the authorization will be issued. *			
39. Intended use of device (required for Class III and IV only). Please provide the intended use statement to indicate the disease(s) or condition(s) the device is intended to diagnose, treat, prevent or mitigate. *			

40. Device history. Please indicate whether the device subject to this application has been previously authorized for sale and/or importation in Canada under the Investigational Testing or Special Access provisions of the Medical Device Regulations. *

O Yes O No

If yes, please provide reference to the application number(s), device name(s), and device identification number(s) as per the authorization by filling out **sections 41-44** for each related application.

41. ITA/SAP application number	42. Device name	43. Catalogue/model number	44. Authorization date (YYYY-MM-DD)

45. Device type *

O Single device O Medical device group O Medical device group family

O Medical device family O Test kit O System

46. Is this device a near patient *in vitro* diagnostic device (IVDD)?* O Yes O No

47. Is this device intended to be sold for home use?* O Yes O No

48. Please provide the following information for device details, where applicable for each component device, part or accessory in **sections 49-52**.

49. Name of device, components, parts and/or accessories as per product label	50. Model or catalogue number	51. Total number of units requested	52. Global medical device nomenclature (GMDN)	Health Canada use only Device identification number

Part 3 – Device containing a drug (Note: this question does not apply to In vitro diagnostic devices (IVDDs))

53. Does this device contain a drug?* O Yes O No

If yes, please proceed to **section 54**.

If no, please proceed to **section 58**.

54. Does it have a drug identification number (DIN) issued by Health Canada? O Yes O No

If yes, please provide the DIN(s):	

Please fill out **sections 55-57** for each active pharmaceutical ingredient (API) that is being used.

Drug 1.

55. Active pharmaceutical ingredient(s) (APIs):

56. Please confirm the compliance to pharmacopeia or compendia standards by checking off the box below and please specify.

O Compliance to pharmacopeia or compendia standards and specify:

O Not applicable

57. Master file (MF) number and applicant name:

Drug 2.

55. Active pharmaceutical ingredient(s) (APIs):

56. Please confirm the compliance to pharmacopeia or compendia standards by checking off the box below and please specify.

O Compliance to pharmacopeia or compendia standards and specify:

O Not applicable

57. Master file (MF) number and applicant name:

58. Is this device being used in a drug study? O Yes O No

If yes, please provide the clinical trial application (CTA) number:

If CTA number is unknown, please check the box below to confirm that a CTA will be submitted/has been submitted to Health Canada.

☐ Will obtain CTA number prior to initiation of trial

Part 4 – Device containing biological material

59.

a) Does this device consist of a recombinant material?* ○ Yes ○ No

b) Does this device contain, or is it produced using any animal or human sourced material?* ○ Yes ○ No

If yes to either question, please proceed to **section 60**.

If no to both questions, please proceed to **section 70**.

60. Does it have a drug identification number (DIN) issued by Health Canada? ○ Yes ○ No

If yes, please provide the DIN(s):	

Please fill out **sections 61-66** for each recombinant material that is being used.

Biological material 1.

61. Name of Biological Material	62. Drug substance	63. Dosage	64. Units

65. Master file (MF) number and applicant name:

66. Country of origin (for animals only):

67. Species (e.g.: bovine, ovine, etc.):

68. Tissue type (e.g., bone, heart valve, skin and hair):

69. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

Biological material 2.			
61. Name of biological material	62. Drug substance	63. Dosage	64. Units
65. Master file (MF) number and applicant name:			
66. Country of origin (for animals only):			
67. Species (e.g.: bovine, ovine, etc.):			
68. Tissue type (e.g., bone, heart valve, skin and hair):			
69. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):			

Biological material 3.			
61. Name of biological material	62. Drug substance	63. Dosage	64. Units
65. Master file (MF) number and applicant name:			
66. Country of origin (for animals only):			
67. Species (e.g.: bovine, ovine, etc.):			
68. Tissue type (e.g., bone, heart valve, skin and hair):			
69. Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):			

70. Is this device being used in a biologic study? ○ Yes ○ No

If yes, please provide the clinical trial application (CTA) number:

b) If CTA number is unknown, please check the box below to confirm that a CTA will be submitted/has been submitted to Health Canada

☐ Will obtain CTA number prior to initiation of trial

Part 5 – Protocol identification
71. Protocol title* :
72. Protocol version and date* :
73. Total number of patients in the study (Canadian sites only)* :
74. Total duration of study* :
75. Duration of the study enrolment phase* :
76. Study objectives* :
77. Please list any other ITA application number that uses the protocol listed in section 71:

Part 6 - Supporting information/evidence to be submitted with an application for a medical device clinical trial under the interim order (COVID-19)
78. Please check all the items that are included in the submission.
Required for all applications **(Class II, III, and IV)**
☐ Device identifier & description of features of the device (design philosophy and performance specifications) *
☐ Directions for use
☐ Device labeling *
☐ Institution name(s) and contact information
☐ Study protocol document (date and version) *
☐ Informed consent form (ICF) (date and version) *
☐ Attestation for post-market oversight
☐ **Recommended** for Class II: standards and declaration of conformity (DoC)
Required for Class III and Class IV only **(May include for Class II devices if necessary)**
☐ Device description & intended use
☐ Marketing history
☐ Quality, safety and effectiveness information (e.g. animal studies, clinical studies, risk assessment)
☐ Name of lead qualified investigator and qualifications (academic and/or clinical curriculum vitaes (CV) and evidence of membership in good standing with a health care professional's regulatory body)
☐ Signed agreement from lead qualified investigator
☐ Standards and declaration of conformity (DoC)
☐ Verification and validation: device design (e.g. mechanical, electrical); performance; shelf life; sterilization; bioburden, pyrogenicity; software; packaging stability; and, biocompatibility.
☐ Research ethics board (REB)/Ethics committee (EC)/Investigational research board (IRB) name and contact information

Part 7 – Attestations and signatures	
79. I, the applicant named in **section 7** of this application, hereby attest that I have direct knowledge of the items checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.	
80. Name: *	81. Title:
82. Signature:	83. Date (YYYY-MM-DD):