

**DRAFT CLINICAL TRIAL SITE INFORMATION (CTSI) FORM for:
CLINICAL TRIAL APPLICATIONS and/or AMENDMENTS**

The attached Clinical Trial Site Information (CTSI) form is required to be submitted by the clinical trial sponsor prior to initiating a protocol or implementing subsequent amendment(s) at the clinical trial site for trials that are subject to *Division 5* of Part C of the *Food and Drug Regulations*.

The CTSI form is also accompanied by a guide that provides instructions related to each field of the form. Please read this information in its entirety prior to completing the form. In addition, the Clinical Trial e-Manual's "Frequently Asked Questions" section also provides information that may be of use when completing this form (see: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/cta_frequent_multiple-eng.php#CLINICAL).

The sponsor must submit the information required in the CTSI form to the relevant Directorate (see below) for each clinical trial site.

Where to Send the Clinical Trial Site Information (CTSI) Form

All CTSI forms whether **accompanying** a Clinical Trial Application (CTA) or an Amendment (CTA-A), or sent **independently** of a CTA or CTA-A, must be sent **directly** to the applicable Directorate as indicated below.

The forms can be submitted in Word, WordPerfect or unlocked PDF format. Please note that if the documents are required to be locked, then the sponsor must provide the password for the encrypted/password-protected file.

Pharmaceutical Drugs:

Office of Clinical Trials*
Therapeutic Products Directorate
5th Floor, Holland Cross, Tower B
A.L: 3105A
1600 Scott Street
Ottawa, ON
Canada K1A 0K9

Fax: 613-946-7996

Email: clinical_trials_site@hc-sc.gc.ca

* The Office of Clinical Trials prefers receiving the forms electronically via the email address provided above.

Biologics and Radiopharmaceuticals:

Biologics and Genetic Therapies Directorate
Regulatory Affairs Division
Health Canada, 1st Floor
200 Tunney's Pasture Driveway
A.L: 0701A
Tunney's Pasture
Ottawa, ON
Canada K1A 0K9

Fax: 613-941-1708

WHEN SUBMITTING THE CTSI FORM TO THE RELEVANT DIRECTORATE, THIS PAGE AND THE ACCOMPANYING GUIDE SHOULD BE DELETED.

PART 3 – CLINICAL TRIAL SITE INFORMATION
A) Clinical Trial Site

30. Name of Site (Full Name – No Abbreviation)				
Address				
31. Street #	Street Name	Suite	P.O Box	32. City/Town
33. Province/Territory			34. Postal/Zip Code	
35. Commencement Date: Clinical Trial (YYYY-MM-DD)		OR	Commencement Date: Amendment (YYYY-MM-DD)	

B) Qualified Investigator
A Qualified Investigator Undertaking (QIU) form must be completed by the qualified investigator responsible for the conduct of the clinical trial at the site specified above. The completed QIU form must be retained by the clinical trial sponsor for a period of 25 years.

36. First Name		Surname		Medical Designation(s)	37. Title
<input type="checkbox"/> English <input type="checkbox"/> French		Address			
38. Language Preference	39. Street #	Street Name	Suite	P.O. Box	
40. City/Town		41. Province/Territory	42. Postal Code		
43. Email Address		44. Telephone # (area code - ### - #####)		45. Fax # (area code - ### - #####)	

C) Research Ethics Board Approval
A Research Ethics Board Attestation (REBA) form must be completed by the Research Ethics Board that reviewed and approved the protocol and informed consent form for the clinical trial at the site(s) specified above. The completed attestation form must be retained by the clinical trial sponsor for a period of 25 years.

46. Name of Research Ethics Board, including affiliations (if applicable) (Full Name – No Abbreviation)				
47. Date of Approval: Clinical Trial (YYYY-MM-DD)		OR	Date of Approval: Amendment (YYYY-MM-DD)	
Address				
48. Street #	Street Name	Suite	P.O Box	49. City/Town
50. Province/Territory	51. Postal/Zip Code	52. Salutation	First Name	Surname
53. Telephone # (area code- ### - #####)		54. Fax # (area code - ### - #####)		<input type="checkbox"/> English <input type="checkbox"/> French 55. Language Preference
56. Title		57. Email Address		

GUIDE FOR COMPLETING THE CTSI FORM

Section #	GUIDANCE								
Not Applicable	<p>General Instructions:</p> <p>All fields must be completed prior to submitting this form to the appropriate Directorate. This includes complete dates (YYYY-MM-DD format) for Section 35 and Section 47. In addition, the sponsor may also utilize their cover page to provide additional and relevant information related to specific sections of the form when submitting it to the relevant Directorate, if applicable.</p> <p>For Pharmaceutical Drugs:</p> <p>The preferred format for receiving the CTSI form is electronically in Word, WordPerfect or unlocked PDF format via the clinical_trials_site@hc-sc.gc.ca email address. Please note that passwords should be provided for encrypted/password protected files. However, completed forms may also be submitted via mail, courier or facsimile at the address or fax number for the Office of Clinical Trials as indicated on the first page of this document.</p> <p>For Biologics and Radiopharmaceuticals:</p> <p>Forms may be submitted via mail, courier, or facsimile at the address or fax number indicated on the first page of this document for the Biologics and Genetic Therapies Directorate.</p>								
All	<p>The information for each section should be provided directly above the corresponding title. For example:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="padding: 2px;">John</td> <td style="padding: 2px;">Doe</td> <td style="padding: 2px;">MD, FRCP</td> <td style="padding: 2px;">β Information</td> </tr> <tr> <td style="padding: 2px;">36. First Name</td> <td style="padding: 2px;">Surname</td> <td style="padding: 2px;">Medical Designation(s)</td> <td style="padding: 2px;">β Title</td> </tr> </table>	John	Doe	MD, FRCP	β Information	36. First Name	Surname	Medical Designation(s)	β Title
John	Doe	MD, FRCP	β Information						
36. First Name	Surname	Medical Designation(s)	β Title						
PART 1 – CLINICAL TRIAL PROTOCOL INFORMATION									
Type of Submission	<p>Clinical Trial Site Information submitted to the relevant Directorate in support of a:</p> <p style="padding-left: 40px;">CTA (Clinical Trial Application)</p> <p style="padding-left: 40px;">CTA-A (Clinical Trial Application Amendment).</p> <p>Therefore, please check the appropriate box that reflects the type of submission.</p> <p>Note: A CTSI form must be submitted prior to initiation of a trial or implementation of an amendment at a site. This information may be submitted at the time of filing the CTA or CTA-A (if all information is available) or prior to commencement of the trial or amendment at a site.</p>								
CTSI Changes (if applicable)	<p>In situations where a revised form is submitted, please select all the relevant options.</p> <p>For the change of address, please specify if this was for the site, qualified investigator and/or research ethics board.</p>								
1	Specify the clinical trial protocol title.								
2	Specify the clinical trial protocol number.								
3	<p>For CTAs:</p> <p>Specify the original/parent clinical trial control number, if assigned. Typically this is a 6-digit number.</p> <p>For CTA-As:</p> <p>Specify both the original/parent clinical trial control number, and the control number for the amendment (if assigned).</p>								
4	Specify the Health Canada Central Registry (CR) File Number, if assigned. Typically this is an alpha-numeric sequence that starts with “9427” and ends with the letter “C”.								

PART 2 – DRUG PRODUCT / SPONSOR INFORMATION	
Not Applicable	<p>General Instructions:</p> <p>Drug Product/Sponsor Information: The information to be provided in Part 2 pertains to the sponsor in whose name the CTA is filed with Health Canada and must be consistent with the information provided in Part 1 of the HC/SC 3011 form</p> <p>(see: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/hc3011_sc3011-eng.php), which also includes the information related to the drug product.</p> <p>For CTAs and CTA-As, sponsor is defined in Division 5, Part C of the <i>Food and Drug Regulations</i> as the individual, corporate body, institution or organization that conducts a clinical trial.</p>
Block A	Drug Product Information
5	<p>The brand name or proprietary name is the name assigned by the sponsor to distinguish the drug (product) and under which the drug is to be sold/advertised. This name should be consistent with the name provided in Part I, Section 8 of the HC/SC 3011 form.</p> <p>If the brand name has not yet been determined, the proper or common name of the drug or the research code may be used.</p>
6	<p>The proper name for a product is the name assigned to the drug in Section C.01.002 of the <i>Food and Drug Regulations</i>, or in boldface type in other Sections of the <i>Regulations</i> or the name of the drug in its finished form identified in the title of a monograph or in any of the official publications listed in Schedule B to the <i>Food and Drugs Act</i>.</p> <p style="text-align: center;">Example: Ferrous Sulphate Tablets Immune Globulin Intravenous (human)</p> <p>The common name is the name by which a single ingredient drug is commonly known/designated in scientific or technical journals other than the publications referred to in Schedule B to the <i>Food and Drugs Act</i>. The common name includes the pharmaceutical form when used in relation to the finished drug product.</p> <p>If there is no proper name and the drug is comprised of a single medicinal ingredient, enter the common name. If there is no proper name and the drug is comprised of more than one medicinal ingredient, leave Section 6 blank.</p> <p>The proper/common name should be the same name that is indicated in Part 1, Section 9 of the HC/SC 3011 form.</p>
Block B	Sponsor Information
7	Indicate the full name of the sponsor company in whose name the subject CTA or CTA-A is being filed.
8-12	Provide the full mailing address of the sponsor identified in Section 7. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (8), the city/town (9), the province/state (10), the country (11) and the postal or zip code (12). Include the PO Box number (8) if a post office box is used.
13-18	<p>Provide the name of the principal contact person for the sponsor located at the address (8-12) for the sponsor, as identified in Section 7. This also includes the information needed to contact this individual, i.e., telephone and fax numbers (14-15), position/title (17), e-mail address (18) if applicable, and language preference (16).</p> <p>Note in most cases this is either the regulatory affairs officer responsible for the CTA, but can also be the subject area expert (e.g. a qualified investigator/sponsor initiated trial).</p>

Block C	Contact for THIS clinical trial
19-29	<p>Please complete this section ONLY when this contact is NOT the same as the Contact Person for the Sponsor (e.g. a third party acting on behalf of the Sponsor).</p> <p>Provide the full name of the contact (19), and company/organization name (21) to which the CTA or CTA-A contact belongs to (i.e., is a staff member of company "X"). If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (22), the city/town (23), the province/state (24), the country (25) and the postal or zip code (26). Include the PO Box number (22) if a post office box is used. Provide the e-mail address (20) and language preference (29).</p>
PART 3 – CLINICAL TRIAL SITE INFORMATION	
Block A	Clinical Trial Site
30	<p>Provide the name of the Clinical Trial Site in the format indicated on the form. This information should also provide the name of the group or unit, and subsequent affiliations, if applicable (e.g. Eye Clinic, University Hospital, and University of XYZ).</p> <p>Note: if the site is a private practice, use the Physician's name, or the name of the practice, corporation or partnership. Do not use abbreviations.</p>
31-34	<p>Provide the full mailing address of the clinical trial site identified in Section 30. If a street address is used, provide the suite/unit number (if applicable) in addition to the street name and street number (31), the city/town (32), the province/territory (33), and the postal or zip code (34). Include the PO Box number (31) if a post office box is used.</p>
35	<p>This box is divided into Commencement Date of Clinical Trial OR Commencement Date of Amendment. Therefore, please ensure that you are completing the appropriate section (i.e. when providing the commencement date of the initial protocol, use the left hand box. When providing the commencement date of an amendment, use the right hand box). This approach is also applicable to section 47.</p> <p>For the purposes of the Clinical Trial Site Information form the date of commencement of the trial is defined as the date when the clinical trial site <i>is ready to enrol subjects</i>. For an Amendment, this would be the date when a site <i>is ready to implement the proposed changes</i>. In either case, the commencement date is a date after which the sponsor has both the Health Canada authorization from the appropriate Directorate (date on the No Objection Letter (NOL)) AND approval from the relevant Research Ethics Board(s) (box 47 of the CTSI form).</p> <p>In situations where a clinical trial site becomes active after the sponsor submits an Amendment, the sponsor should specify this in Part 1 of the CTSI form. For example, when filing the CTA the sponsor has 4 sites, but following an Amendment, the sponsor now wants to expand the trial to site #5</p> <p>Note: All dates should be provided in YYYY-MM-DD format.</p>

Block B	Qualified Investigator
36	<p><i>Division 5</i> of Part C of the <i>Food and Drug Regulations</i> defines Qualified Investigator as: The person responsible to the sponsor for the conduct of the clinical trial at the clinical trial site, who is entitled to provide health care under the laws of the province where the clinical trial site is located and who is: (a) in the case of a clinical trials respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and (b) in any other case a physician and a member in good standing of a professional medical association.</p> <p>Provide the name of the Qualified Investigator conducting the clinical trial (36). Include their First and Surname as well as the Medical Designations. i.e. John Doe, MD, FRCPC, etc.</p>
37	This is the title used pertaining to the clinical trial and not the salutation or medical designation of person conducting the trial. Examples of titles would include Qualified Investigator, Principal Investigator, or Clinical Investigator.
38	Indicate language preference of the person conducting the clinical trial.
39-42	<p>Provide the full mailing address of the Qualified Investigator identified in Section 36. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (39), the city/town (40), the province/territory (41), and the postal code (42). Include the PO Box number (39) if a post office box is used. Provide language preference (38).</p> <p>Note: The address of the Qualified Investigator may be different than the address of the clinical trial site as identified in Sections 31-34.</p>
43-45	Provide the information requested to contact the Qualified Investigator, i.e., telephone and fax numbers (44-45), and e-mail address (43) if applicable.
Block C	Research Ethics Board
46	Provide the name of the Research Ethics Board (REB) providing approval of the protocol and informed consent forms for this clinical trial. Provide the affiliation, if applicable (e.g. University of “XYZ” or “New Province Health Sciences” Research Ethics Review Board etc.).
47	<p>See Notes pertaining to section 35 above and similar to that section, this section is also divided into Date of Approval for the Clinical Trial OR for the Clinical Trial Amendment.</p> <p>Note: All dates should be provided in YYYY-MM-DD format.</p>
48-51	Provide the full mailing address of the Research Ethics Board contact identified in Section 52. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (48), the city/town (49), the province/state and country (50), and the postal or zip code (51). Include the PO Box number (48) if a post office box is used.
52-57	Provide the name of the Contact (52) for the Research Ethics Board (REB) as noted in Section 46. Provide the Salutation, First Name and Surname and the telephone number (53), facsimile number (54) and Email address (57) for this Contact. Finally, provide the Contact’s title as it pertains to this role (e.g. Chair of REB, President of REB, etc.) and their language preference (55).

**CLINICAL TRIAL SITE INFORMATION (CTSI) FORM for:
CLINICAL TRIAL APPLICATIONS and/or AMENDMENTS**

The attached Clinical Trial Site Information (CTSI) form is required to be submitted by the clinical trial sponsor prior to initiating a protocol or implementing subsequent amendment(s) at the clinical trial site for trials that are subject to *Division 5* of Part C of the *Food and Drug Regulations*.

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The sponsor must submit the information required in the CTSI form to the relevant Directorate (see below) for each clinical trial site.

Where to Send the Clinical Trial Site Information (CTSI) Form

All CTSI forms whether **accompanying** a Clinical Trial Application (CTA) or an Amendment (CTA-A), or sent **independently** of a CTA or CTA-A, must be sent **directly** to the applicable Directorate as indicated below.

The forms can be submitted in Word, WordPerfect or unlocked PDF format. Please note that if the documents are required to be locked, then the sponsor must provide the password for the encrypted/password-protected file.

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Biologics and Radiopharmaceuticals:

Biologics and Genetic Therapies Directorate
Regulatory Affairs Division
Health Canada, 1st Floor
200 Tunney's Pasture Driveway
A.L: 0701A
Tunney's Pasture
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Canada K1A 0K9

Fax: 613-941-1708

WHEN SUBMITTING THE CTSI FORM TO THE RELEVANT DIRECTORATE, THIS PAGE AND THE ACCOMPANYING GUIDE SHOULD BE DELETED.

CLINICAL TRIAL SITE INFORMATION FORM

**INSTRUCTIONS: ALL FIELDS MUST BE COMPLETED PRIOR TO SUBMITTING THIS FORM TO THE RELEVANT DIRECTORATE.
PLEASE REFER TO THE GUIDE IN ITS ENTIRETY WHEN COMPLETING THIS FORM.**

PART 1 – CLINICAL TRIAL PROTOCOL INFORMATION				
Please select the appropriate box				
<input type="checkbox"/> Clinical Trial Application (CTA) <input type="checkbox"/> Clinical Trial Application Amendment (CTA-A)	<input type="checkbox"/> Change of Address (please specify): _____ <input type="checkbox"/> Change in Qualified Investigator <input type="checkbox"/> Change in Research Ethics Board <input type="checkbox"/> Other (please specify): _____			
Type of submission	CTSI Changes (if applicable)			
1. Clinical Trial Protocol Title				
	Original/Parent No.: _____ Amendment No.: _____			
2. Clinical Trial Protocol Number	3. Clinical Trial Control Number (if assigned)		4. Health Canada's Central Registry (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 Information				
7. Name of Sponsor (Full Name – No Abbreviation)				
<small>Address</small>				
8. Street #	Street Name	Suite	P.O Box	9. City/Town
10. Province/State		11. Country		12. Postal/Zip Code
Contact Person for Sponsor				
13. Salutation	First Name	Surname	14. Telephone # (area code - ### - #####)	15. Fax # (area code - ### - #####)
<input type="checkbox"/> English <input type="checkbox"/> French				
16. Language Preference		17. Title		18. Email address
C) Contact for THIS Clinical Trial				
Please complete this section ONLY when this contact is NOT the same as the Contact Person for the Sponsor.				
19. Salutation	First Name	Surname	20. Email address	
21. Company/Organization Name (Full Name – No Abbreviations)				
<small>Address</small>				
22. Street #	Street Name	Suite	P.O Box	23. City/Town
24. Province/State		25. Country		26. Postal/Zip Code
27. Telephone # (area code - ### - #####)		28. Fax # (area code - ### - #####)		<input type="checkbox"/> English <input type="checkbox"/> French
				29. Language Preference

PART 3 – CLINICAL TRIAL SITE INFORMATION
A) Clinical Trial Site

30. Name of Site (Full Name – No Abbreviation)				
Address				
31. Street #	Street Name	Suite	P.O Box	32. City/Town
33. Province/Territory			34. Postal/Zip Code	
35. Commencement Date: Clinical Trial (YYYY-MM-DD)		OR	Commencement Date: Amendment (YYYY-MM-DD)	

B) Qualified Investigator
A Qualified Investigator Undertaking (QIU) form must be completed by the qualified investigator responsible for the conduct of the clinical trial at the site specified above. The completed QIU form must be retained by the clinical trial sponsor for a period of 25 years.

36. First Name		Surname		Medical Designation(s)	37. Title
<input type="checkbox"/> English <input type="checkbox"/> French		Address			
38. Language Preference	39. Street #	Street Name		Suite	P.O. Box
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C) Research Ethics Board Approval
A Research Ethics Board Attestation (REBA) form must be completed by the Research Ethics Board that reviewed and approved the protocol and informed consent form for the clinical trial at the site(s) specified above. The completed attestation form must be retained by the clinical trial sponsor for a period of 25 years.

46. Name of Research Ethics Board, including affiliations (if applicable) (Full Name – No Abbreviation)				
47. Date of Approval: Clinical Trial (YYYY-MM-DD)		OR	Date of Approval: Amendment (YYYY-MM-DD)	
Address				
48. Street #	Street Name	Suite	P.O Box	49. City/Town
50. Province/Territory	51. Postal/Zip Code	52. Salutation	First Name	Surname
53. Telephone # (area code- ### - #####)		54. Fax # (area code - ### - #####)		<input type="checkbox"/> English <input type="checkbox"/> French 55. Language Preference
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GUIDE FOR COMPLETING THE CTSI FORM

Section #	GUIDANCE								
Not Applicable	<p>General Instructions:</p> <p>All fields must be completed prior to submitting this form to the appropriate Directorate. This includes complete dates (YYYY-MM-DD format) for Section 35 and Section 47. In addition, the sponsor may also utilize their cover page to provide additional and relevant information related to specific sections of the form when submitting it to the relevant Directorate, if applicable.</p> <p>For Pharmaceutical Drugs:</p> <p>The preferred format for receiving the CTSI form is electronically in Word, WordPerfect or unlocked PDF format via the clinical_trials_site@hc-sc.gc.ca email address. Please note that passwords should be provided for encrypted/password protected files. However, completed forms may also be submitted via mail, courier or facsimile at the address or fax number for the Office of Clinical Trials as indicated on the first page of this document.</p> <p>For Biologics and Radiopharmaceuticals:</p> <p>Forms may be submitted via mail, courier, or facsimile at the address or fax number indicated on the first page of this document for the Biologics and Genetic Therapies Directorate.</p>								
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John	Doe	MD, FRCP	β Information						
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PART 1 – CLINICAL TRIAL PROTOCOL INFORMATION									
Type of Submission	<p>Clinical Trial Site Information submitted to the relevant Directorate in support of a:</p> <p style="padding-left: 40px;">CTA (Clinical Trial Application)</p> <p style="padding-left: 40px;">CTA-A (Clinical Trial Application Amendment).</p> <p>Therefore, please check the appropriate box that reflects the type of submission.</p> <p>Note: A CTSI form must be submitted prior to initiation of a trial or implementation of an amendment at a site. This information may be submitted at the time of filing the CTA or CTA-A (if all information is available) or prior to commencement of the trial or amendment at a site.</p>								
CTSI Changes (if applicable)	<p>In situations where a revised form is submitted, please select all the relevant options.</p> <p>For the change of address, please specify if this was for the site, qualified investigator and/or research ethics board.</p>								
1	Specify the clinical trial protocol title.								
2	Specify the clinical trial protocol number.								
3	<p>For CTAs:</p> <p>Specify the original/parent clinical trial control number, if assigned. Typically this is a 6-digit number.</p> <p>For CTA-As:</p> <p>Specify both the original/parent clinical trial control number, and the control number for the amendment (if assigned).</p>								
4	Specify the Health Canada Central Registry (CR) File Number, if assigned. Typically this is an alpha-numeric sequence that starts with “9427” and ends with the letter “C”.								

PART 2 – DRUG PRODUCT / SPONSOR INFORMATION	
Not Applicable	<p>General Instructions:</p> <p>Drug Product/Sponsor Information: The information to be provided in Part 2 pertains to the sponsor in whose name the CTA is filed with Health Canada and must be consistent with the information provided in Part 1 of the HC/SC 3011 form</p> <p>(see: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/hc3011_sc3011-eng.php), which also includes the information related to the drug product.</p> <p>For CTAs and CTA-As, sponsor is defined in Division 5, Part C of the <i>Food and Drug Regulations</i> as the individual, corporate body, institution or organization that conducts a clinical trial.</p>
Block A	Drug Product Information
5	<p>The brand name or proprietary name is the name assigned by the sponsor to distinguish the drug (product) and under which the drug is to be sold/advertised. This name should be consistent with the name provided in Part I, Section 8 of the HC/SC 3011 form.</p> <p>If the brand name has not yet been determined, the proper or common name of the drug or the research code may be used.</p>
6	<p>The proper name for a product is the name assigned to the drug in Section C.01.002 of the <i>Food and Drug Regulations</i>, or in boldface type in other Sections of the <i>Regulations</i> or the name of the drug in its finished form identified in the title of a monograph or in any of the official publications listed in Schedule B to the <i>Food and Drugs Act</i>.</p> <p style="text-align: center;">Example: Ferrous Sulphate Tablets Immune Globulin Intravenous (human)</p> <p>The common name is the name by which a single ingredient drug is commonly known/designated in scientific or technical journals other than the publications referred to in Schedule B to the <i>Food and Drugs Act</i>. The common name includes the pharmaceutical form when used in relation to the finished drug product.</p> <p>If there is no proper name and the drug is comprised of a single medicinal ingredient, enter the common name. If there is no proper name and the drug is comprised of more than one medicinal ingredient, leave Section 6 blank.</p> <p>The proper/common name should be the same name that is indicated in Part 1, Section 9 of the HC/SC 3011 form.</p>
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13-18	<p>Provide the name of the principal contact person for the sponsor located at the address (8-12) for the sponsor, as identified in Section 7. This also includes the information needed to contact this individual, i.e., telephone and fax numbers (14-15), position/title (17), e-mail address (18) if applicable, and language preference (16).</p> <p>Note in most cases this is either the regulatory affairs officer responsible for the CTA, but can also be the subject area expert (e.g. a qualified investigator/sponsor initiated trial).</p>

Block C	Contact for THIS clinical trial
19-29	<p>Please complete this section ONLY when this contact is NOT the same as the Contact Person for the Sponsor (e.g. a third party acting on behalf of the Sponsor).</p> <p>Provide the full name of the contact (19), and company/organization name (21) to which the CTA or CTA-A contact belongs to (i.e., is a staff member of company "X"). If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (22), the city/town (23), the province/state (24), the country (25) and the postal or zip code (26). Include the PO Box number (22) if a post office box is used. Provide the e-mail address (20) and language preference (29).</p>
PART 3 – CLINICAL TRIAL SITE INFORMATION	
Block A	Clinical Trial Site
30	<p>Provide the name of the Clinical Trial Site in the format indicated on the form. This information should also provide the name of the group or unit, and subsequent affiliations, if applicable (e.g. Eye Clinic, University Hospital, and University of XYZ).</p> <p>Note: if the site is a private practice, use the Physician's name, or the name of the practice, corporation or partnership. Do not use abbreviations.</p>
31-34	<p>Provide the full mailing address of the clinical trial site identified in Section 30. If a street address is used, provide the suite/unit number (if applicable) in addition to the street name and street number (31), the city/town (32), the province/territory (33), and the postal or zip code (34). Include the PO Box number (31) if a post office box is used.</p>
35	<p>This box is divided into Commencement Date of Clinical Trial OR Commencement Date of Amendment. Therefore, please ensure that you are completing the appropriate section (i.e. when providing the commencement date of the initial protocol, use the left hand box. When providing the commencement date of an amendment, use the right hand box). This approach is also applicable to section 47.</p> <p>For the purposes of the Clinical Trial Site Information form the date of commencement of the trial is defined as the date when the clinical trial site <i>is ready to enrol subjects</i>. For an Amendment, this would be the date when a site <i>is ready to implement the proposed changes</i>. In either case, the commencement date is a date after which the sponsor has both the Health Canada authorization from the appropriate Directorate (date on the No Objection Letter (NOL)) AND approval from the relevant Research Ethics Board(s) (box 47 of the CTSI form).</p> <p>In situations where a clinical trial site becomes active after the sponsor submits an Amendment, the sponsor should specify this in Part 1 of the CTSI form. For example, when filing the CTA the sponsor has 4 sites, but following an Amendment, the sponsor now wants to expand the trial to site #5</p> <p>Note: All dates should be provided in YYYY-MM-DD format.</p>

Block B	Qualified Investigator
36	<p><i>Division 5</i> of Part C of the <i>Food and Drug Regulations</i> defines Qualified Investigator as: The person responsible to the sponsor for the conduct of the clinical trial at the clinical trial site, who is entitled to provide health care under the laws of the province where the clinical trial site is located and who is: (a) in the case of a clinical trials respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and (b) in any other case a physician and a member in good standing of a professional medical association.</p> <p>Provide the name of the Qualified Investigator conducting the clinical trial (36). Include their First and Surname as well as the Medical Designations. i.e. John Doe, MD, FRCPC, etc.</p>
37	This is the title used pertaining to the clinical trial and not the salutation or medical designation of person conducting the trial. Examples of titles would include Qualified Investigator, Principal Investigator, or Clinical Investigator.
38	Indicate language preference of the person conducting the clinical trial.
39-42	<p>Provide the full mailing address of the Qualified Investigator identified in Section 36. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (39), the city/town (40), the province/territory (41), and the postal code (42). Include the PO Box number (39) if a post office box is used. Provide language preference (38).</p> <p>Note: The address of the Qualified Investigator may be different than the address of the clinical trial site as identified in Sections 31-34.</p>
43-45	Provide the information requested to contact the Qualified Investigator, i.e., telephone and fax numbers (44-45), and e-mail address (43) if applicable.
Block C	Research Ethics Board
46	Provide the name of the Research Ethics Board (REB) providing approval of the protocol and informed consent forms for this clinical trial. Provide the affiliation, if applicable (e.g. University of “XYZ” or “New Province Health Sciences” Research Ethics Review Board etc.).
47	<p>See Notes pertaining to section 35 above and similar to that section, this section is also divided into Date of Approval for the Clinical Trial OR for the Clinical Trial Amendment.</p> <p>Note: All dates should be provided in YYYY-MM-DD format.</p>
48-51	Provide the full mailing address of the Research Ethics Board contact identified in Section 52. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (48), the city/town (49), the province/state and country (50), and the postal or zip code (51). Include the PO Box number (48) if a post office box is used.
52-57	Provide the name of the Contact (52) for the Research Ethics Board (REB) as noted in Section 46. Provide the Salutation, First Name and Surname and the telephone number (53), facsimile number (54) and Email address (57) for this Contact. Finally, provide the Contact’s title as it pertains to this role (e.g. Chair of REB, President of REB, etc.) and their language preference (55).