



Australian Government

Department of Health

Therapeutic Goods Administration

Clinical trial notification (CTN) form - user guide

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TGA Health Safety
Regulation

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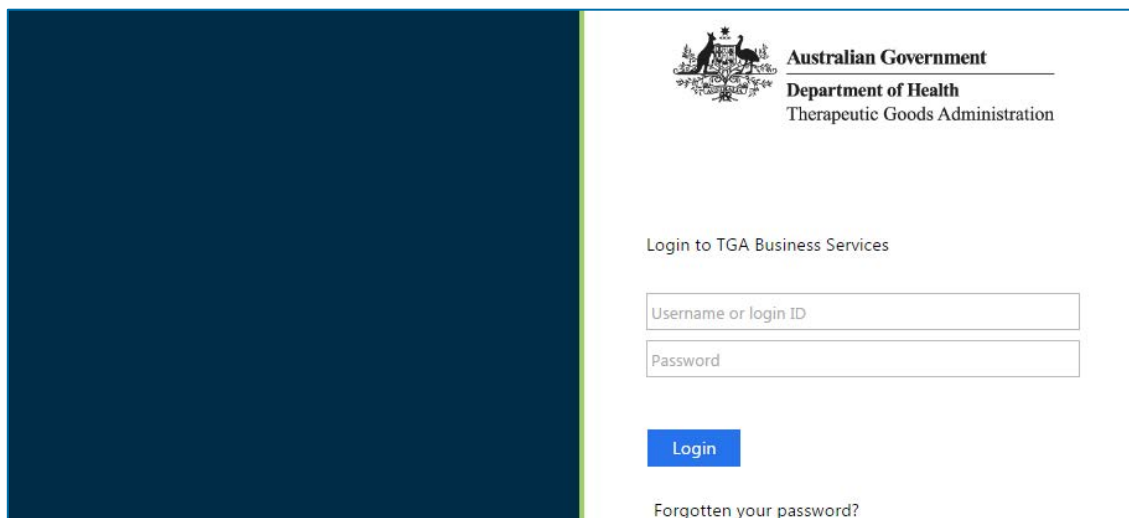
Accessing the online CTN form

The Clinical Trial Notification (CTN) form is available online through our secure [TGA Business Services \(TBS\)](#) site.

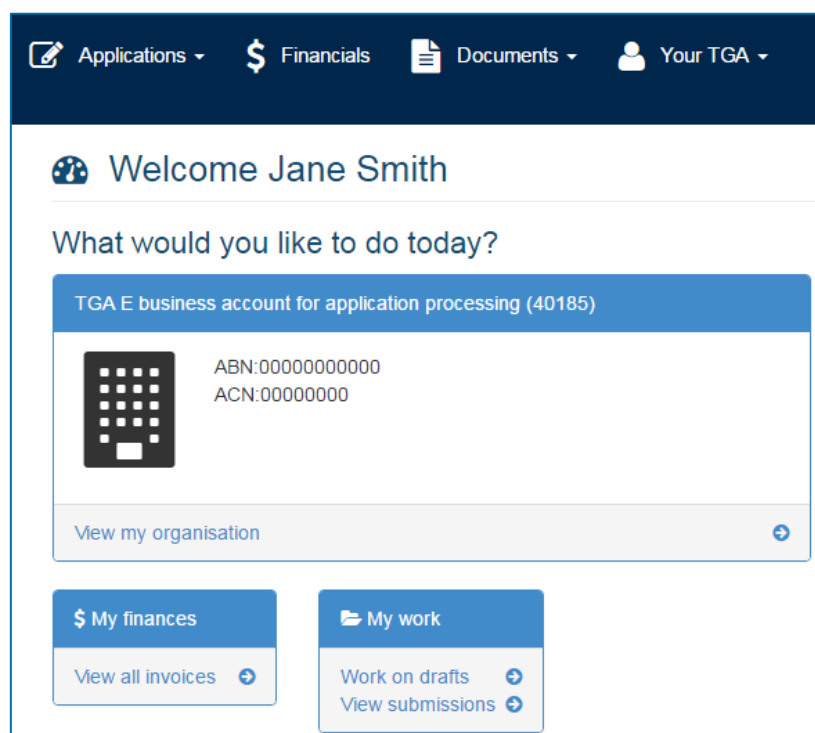
To apply for a TGA client ID and access to TGA Business Services (TBS) please see [TGA Business Services: getting started with the TGA](#). Information regarding the various 'roles' within TBS can be found at [TGA Business services - how to use the site](#) under [Roles: what each user can do](#).

How to login

Once you have received your login details, go to the [TGA Business Services \(TBS\)](#) site. You will then be prompted to enter your login details on the right hand side of the screen.

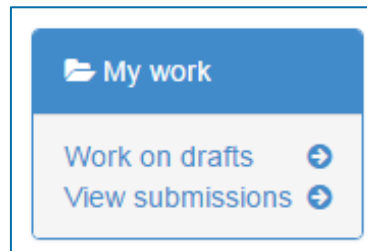


Once logged in, you will see a personalised work page or 'dashboard'. What you can see and do on the dashboard will depend on what [user role](#) (access level) you have been given.



Across the top of the TGA Business Portal dashboard there are three main menus: **Applications**; **Documents**; and **Your TGA**. If you also have financial access, there will be an additional **Financials** menu displayed.

You will also find a **My work** menu on the dashboard with the options **Work on drafts** or **View Submissions**.



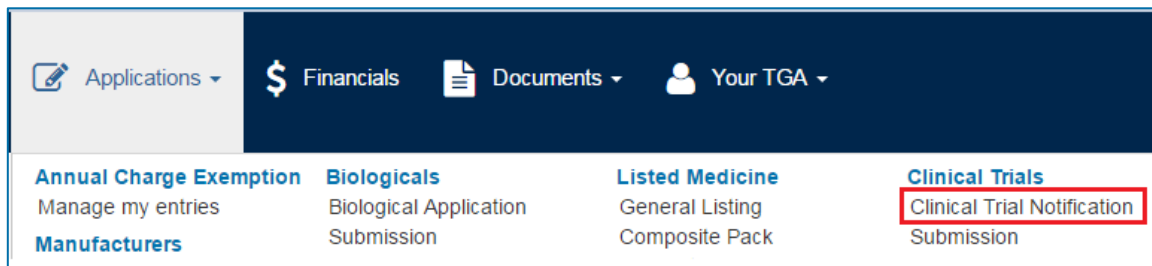
You can select either **Work on drafts** or **View Submissions** which will take you to the online **Portal** menu.

Creating a new CTN form

The two options below can be used to create a new CTN form.

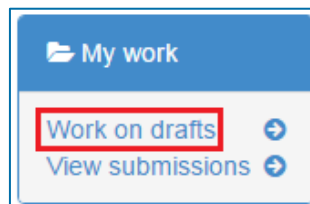
Option 1

- Access the dashboard as described in [How to login](#).
- Select **Applications** from the top menu on the dashboard.
- Select **Clinical Trial Notification**.

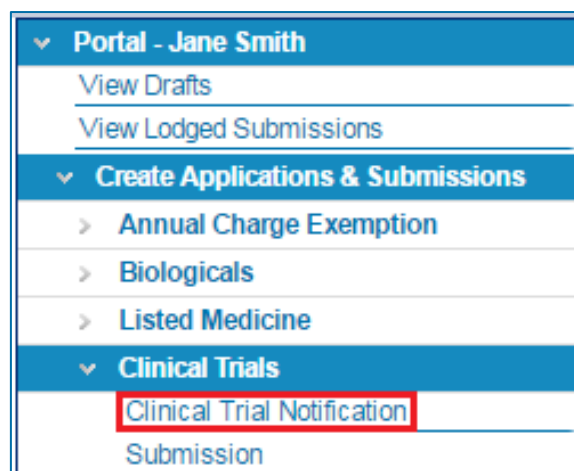


Option 2

- Access the dashboard as described in [How to login](#).
- Select **Work on drafts** under the **My work** menu on the dashboard. The online **Portal** menu will be displayed on the left hand side.



- Select **Portal** at the top of the menu. This will open further menu options.
- Select **Create Applications & Submissions**.
- Select **Clinical Trials** and then select **Clinical Trial Notification**.



A blank CTN form will open.

There are six (6) possible tabs that may appear through the CTN process: **Application**, **Trial Details**, **Change to Trial Details**, **Completion**, **Validation messages** and **Changes made**. Depending on the stage of the CTN, only the applicable tabs will display.

New:

Only **Trial Details** is editable.

Variation:

Only the **Change to Trial Details** tab is editable. Any changes made will display in the **Changes Made** tab.

Completion:

Only the **Completion** tab is editable.

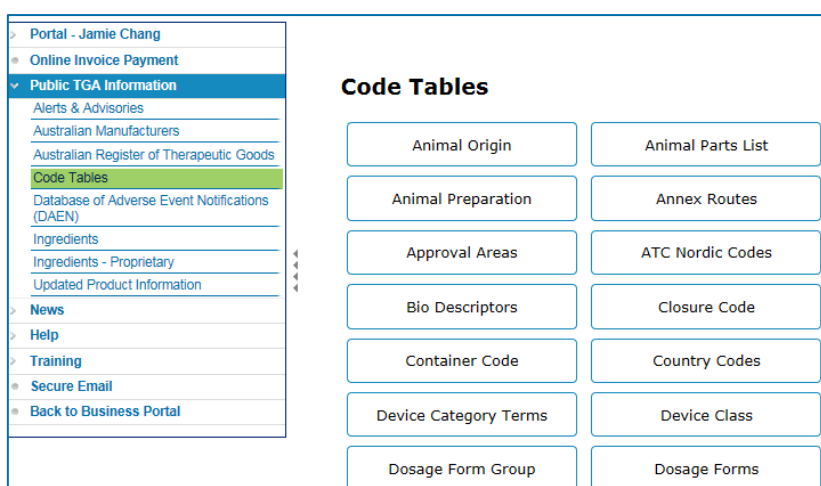
The top right hand side of the CTN form displays:

- the CTN **Application ID** and version number (this is generated when the form is first opened)
- the **Status** of the CTN (for example, 'Draft Loaded')
- the **Client Reference** field (this field can be used by the sponsor to enter notes or other additional identifying information. This field is not used as a reference by the TGA).

A red asterisk * indicates a mandatory field.

A grey * asterisk indicates a conditionally mandatory field (the field must be completed if certain conditions are met).

Data in certain drop-down lists is populated from TGA **Code Tables**. Sponsors can view the TGA **Code Tables** under the **Public TGA Information** tab in the online **Portal** menu.



Select the **Application** tab to begin entering details in the form.

Application tab

Field Name	Information required
Sponsor Name*	This field is pre-populated based on the TBS logon ID used.
Sponsor Address*	Select the address recorded in TBS for the sponsor from the drop-down list.
Notification Fee	This field will be automatically populated with a dollar amount by the system when the form is validated (see Paying for your CTN for further details).

Trial details tab

Field Name	Information required
Contact Name*	<p>Contact name is the name of the person nominated by your organisation to receive correspondence from TGA regarding the CTN.</p> <p>Please note, the contact email address and phone number originally entered on the eBS account will auto-populate to the contact details. If you wish to edit the phone number, please refer to 'Changing contact information' for guidance.</p>
Contact Phone Number*	<p>Please note, the phone number of the nominated person will auto-populate. If you wish to edit the phone number, please refer to 'Changing contact information' for guidance.</p>

Field Name	Information required
Contact Email*	Please note, the email address of the nominated person will auto-populate. If you wish to edit the email address please refer to ‘Changing contact information’ for guidance.
Alternative Contact	An alternative contact, may be chosen from the contacts for the agent or sponsor organisation submitting the CTN. The ‘Alternative Contact’ option is non-mandatory and is available on the top right hand side of the page.
Protocol Number*	Enter the protocol number provided by the sponsor or principal investigator of the clinical trial. This is a unique reference number used to easily identify your trial. This number may be no fewer than 4 and no more than 20 characters.
Expected Trial Start Date*	Enter the date you estimate the trial will be initiated at the first Australian site in the format dd/mm/yyyy or select from the pop-up calendar. The ‘expected trial start date’ indicated on the CTN form cannot be a retrospective date.
Expected Completion Date*	Enter the date you estimate the trial will be completed at all Australian sites in the format dd/mm/yyyy or select from the pop-up calendar. The ‘expected completion date’ must be a date after the ‘expected trial start date’.
Potential use of restricted goods*	Select ‘Yes’ if the trial involves the use of substance(s) that require permission to import under the Customs (Prohibited Imports) Regulations 1956 . Otherwise select ‘No’.
Title of Study*	Enter the title of the clinical trial. The title should include the aim and provide a broad description of the trial. Include, for example: phase, indication(s) being treated, main investigational product and comparators, use of placebo-control, focus of the study, patient population and any other significant or novel aspects.
This Trial*	See information below.

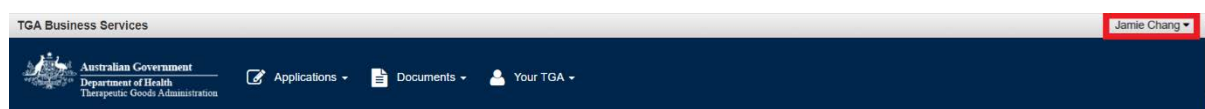
Field Name	Information required
Trial Type*	<p>Select the correct check box on the left hand side of the correct trial type(s). More than one check box may be selected.</p> <p>Medicine or Biological:</p> <ul style="list-style-type: none"> Select the trial phase(s) for the medicine or biologicals under investigation. <p>Medical Device:</p> <ul style="list-style-type: none"> If the trial is investigating a device, select the Device check box. <p>Bioavailability/Bioequivalence:</p> <ul style="list-style-type: none"> If the trial is investigating bioavailability or bioequivalence, select the Bioavailability/Bioequivalence check box.
Brief Description of Trial	This is a non-mandatory free text field to provide any additional information relating to the trial.
Total number of participants*	Select a range of the estimated total number of participants to be enrolled in the trial in Australia from the drop-down list.
Therapeutic area*	Select the therapeutic area for the investigational product from the drop-down list.

Changing contact information

The contact information reflected in your eBS account will be auto-populated as per the contact details sections of your CTN submission. Instructions for editing the contact information are included below.

Once a user account has been created, the functionality to update the email address and/or contact name becomes a locked field. To update your email address or contact name, please send an email request to the TBS Helpdesk at ebs@health.gov.au. The TBS Helpdesk team will assist you and update these details on your behalf.

To update your contact number, select your name from the top right corner of your personalised work page or 'dashboard' after signing in. (If you have already proceeded to the "view drafts" or "Submissions" page select 'Back to business portal' from the left hand drop down menu).



Go to **Account Settings**, then **Edit my Profile**. From this screen you will be able to edit your title, phone, mobile, fax and change your listed address. Update the relevant fields and click **Update Details**. This may take up to an hour to reflect accurately on the Clinical Trial Notification submission.

This Trial*

Select all of the check boxes relevant to your trial. More than one check box may be selected. When selected, check boxes may prompt an additional sub-form that you will need to complete. Additional sub-forms appear at the end of the **Trial Details** page (above **Trial Site Details**).



A [therapeutic good](#) must be selected in order for the CTN form to be processed. You must select one or more of the following check boxes:

- Involves the use of a Medicine
- Involves the use of a Medical Device
- Involves the use of a Biological

Involves the use of a Medicine

- Select the check box **Involves the use of a Medicine** to add [medicines](#) to the CTN form.



Placebo details should be entered in the [Placebo Details sub-form](#) (see below).

- Scroll down to the **Medicine Details*** sub-form.
- Select the **Add Medicine** button. This opens a pop-up form with the fields below.

Field Name	Information required
Trade/Product/Code Name*	Enter an identifying name(s) of the medicine. If the product has a trade name, product name and code name, enter all three names in the format Trade/Product/Code Name.
Is this a combination product?*	Select 'Yes' if the product is comprised of two (or more) active ingredients. Each active ingredient should be entered under 'Formulation' (see below).
Is this a cannabis product?*	Select 'Yes' if the product is medicinal cannabis.
Is the cannabis plant used in the manufacture of the product?*	Select 'Yes' if the product contains or is manufactured from any part of the cannabis plant.

Field Name	Information required
Type of container*	<p>Enter the type of container as defined below.</p> <p><i>The container means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion.</i></p> <p>Examples of type of container include 2mL ampoule, 5mL syringe, blister pack, bottle. The terms Various or N/A are not acceptable.</p>
Dosage Form*	<p>Select a dosage form from the drop-down list.</p> <p><i>Dosage form is the pharmaceutical form in which a product is presented for therapeutic administration, e.g. tablet, cream. See TGA approved terminology for medicines.</i></p>
Route of Administration*	<p>Select a route of administration from the drop-down list.</p> <p><i>Route of administration means the route by which a therapeutic good is applied on or introduced into the body.</i></p>
Formulation*	<p><i>Formulation is a list of ingredients used in the manufacture of a dosage form and a statement of the quantity of each ingredient in a defined weight, volume, unit or batch.</i></p> <p><i>An active ingredient is the therapeutically active component in a medicine's final formulation that is responsible for its physiological action. An excipient is any component of a finished dosage form other than an active ingredient.</i></p> <p>You must at least enter the active ingredient(s). We recommended that you list both the active ingredient(s) and excipient(s) if possible.</p> <ul style="list-style-type: none"> • Select the Add Ingredients button. This opens a pop-up form with the fields below. <ul style="list-style-type: none"> – Ingredient Name*: Enter one ingredient name. – Quantity*: Enter the numeric part of the ingredient strength/concentration. For example, if the strength of the ingredient is 25 mg, enter 25. – Unit*: Select a unit of measurement of the strength/concentration from the drop-down list. For example, if the strength of the ingredient is 25 mg, select milligram. • Select the Save and Close button. • The details will be added to the list on the Formulation sub-form. • Repeat this process for each ingredient you need to add.

Field Name	Information required
	<p>To edit ingredients:</p> <ul style="list-style-type: none"> Select the Open button beside the ingredient you wish to edit. <p>To remove ingredients:</p> <ul style="list-style-type: none"> Select the check box next to the ingredient(s) you wish to remove. Select the Remove Selected Ingredient(s) button.
Indication*	<p>Enter the indication the medicine will be used for in the trial.</p> <p><i>The indication means the specific therapeutic use(s) of the goods.</i></p>
Dosage and Frequency*	<p>Enter the dosage regimen.</p> <p><i>The dosage regimen is the number of doses per given time period, the time that elapses between doses or the quantity of a medicine that is given at each specific time of dosing.</i></p>
Intended Use*	Select if the medicine is a Comparator; Investigational Medicinal Product; or Standard Care Therapy or Other.
Intended Use other Description*	Please provide a description if 'Other' is selected under 'Intended Use'.
Is the medicine manufactured in Australia?*	Select 'Yes' if the medicine is manufactured in Australia. If not, select 'No'.
Manufacturer details*	Please enter the name and address of the manufacturer.
GMP licence/clearance number or relevant exemption	Please provide the relevant licence number or exemption if available

- Select the **Save and Close** button.
- The details will be added to the list on the **Medicine Details*** sub-form.
- Repeat this process for each different medicine and **each different medicine strength**.

To edit a medicine:

- Select the **Open** button beside the medicine you wish to edit.
- Update any details as needed.

To remove a medicine(s):

- Select the check box next to the medicine(s) you wish to remove.

- Select the **Remove Selected Medicine(s)** button.



Select the checkbox **Involves the use of a Medical Device** if the product is regulated by us as a medical device.

Review the definition of a medical device at '[What is a medical device?](#)'

'[Overview of the regulatory framework for in vitro diagnostic medical devices \(IVDs\)](#)' also provides further information and definitions of IVDs.

- Scroll down to the **Device Details*** sub-form.
- Select the **Add Device** button.

Field Name	Information required
Product Name*	Enter the product or trade name of the medical device.
Is this a:*	Select the most suitable option from: <ul style="list-style-type: none"> Medical Device In Vitro Diagnostic Medical Device (IVD)
Classification	Select Medical Device Classification from the drop down menu. Include the medical device classification (such as Class I, Class III etc. - refer to ' Medical device overview ').
GMDN Search Context	To search for a GMDN, select either 'GMDN name' or 'GMDN code'.
GMDN*	<p><i>The Global Medical Device Nomenclature (GMDN) is a collection of internationally recognised terms used to accurately describe and catalogue medical devices, in particular, those products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.</i></p> <p>Once you have selected the search context above, type in the name or code in the GMDN search field.</p> <ul style="list-style-type: none"> Select the Search button. A list of possible matches will be returned. Select the correct GMDN from the drop-down list. Select New Search to start again. <p>You may need to contact the manufacturer to ascertain which GMDN code is the most relevant for the device. Further information on GMDN is available on the TGA website.</p>

Field Name	Information required
	If a GMDN is not available then you are not required to enter it, however, a 'Description' must be entered in the field below in order for the form to validate.
Description/Intended purpose for Medical Device*	Provide a description of the device including details of design, composition, specification, method of use, mode of action and application.
Intended Purpose for Trial*	Select the purpose of the medical device in your trial from: <ul style="list-style-type: none"> • Comparator • Investigational product • Standard care therapy • Other.
If 'Other' please provide a description*	Please provide a description if 'Other' is selected under 'Intended Purpose'.
Manufacturer details*	Please enter the name and address of the manufacturer. Manufacturer is defined under section 41BG of the Therapeutic Goods Act 1989 . (see Manufacturer section for more details)

- Select the **Save and Close** button.
- The details will be added to the list on the **Device Details*** sub-form.
- Repeat this process for each different medical device you wish to add.

To edit a medical device:

- Select the **Open** button beside the medical device you wish to edit.
- Update any details as needed.

To remove a medical device:

- Click on the check box next to the medical device(s) you wish to remove.
- Select the **Remove Selected Device(s)** button.

Involves the use of a Biological

- Select the check box **Involves the use of a Biological** to add biologicals to the CTN form.



Use the **Biological Details** sub-form to notify products that are regulated by us as biologicals.

Review the information at '[Products regulated as biologicals](#)' to ensure that the product(s) meet the TGA definition of a biological.

Use the [Medicine Details sub-form](#) to notify products that are regulated by us as medicines (such as vaccines and recombinant products).

- Scroll down to the **Biological Details*** sub-form.
- Select the **Add Biological** button. This opens a pop-up form with the fields below.

Field Name	Information required
Trade/Product/Code Name*	Enter an identifying name(s) of the biological. If the product has a trade name, product name and code name, enter all three names in the format Trade/Product/Code Name.
Is this a combination product?*	Select 'Yes' if the product is comprised of two (or more) active ingredients. Each active ingredient should be entered under 'Formulation' (see below).
Product Description*	Enter a description of the biological under clinical investigation, including a name, biological class (e.g. Class 2 etc.), intended use, indication, details of the design, composition, specifications, mode of action and application, list any associated devices and/or medicines and the method of use of the whole biological product.
Class of Biological	Select a class of Biological from the drop-down list.
Type of container*	<p>Enter the type of container as defined below.</p> <p><i>The container means the vessel, bottle, tube, ampoule, syringe, vial, sachet, strip pack, blister pack, wrapper, cover or other similar article that immediately covers the goods, but does not include an article intended for ingestion.</i></p> <p>Examples of type of container include 2mL ampoule, 5mL syringe, blister pack, bottle.</p>
Dosage Form*	<p>Select a dosage form from the drop-down list.</p> <p><i>Dosage form is the pharmaceutical form in which a product is presented for therapeutic administration, e.g. tablet, cream.</i></p>
Route of Administration*	<p>Select a route of administration from the drop-down list.</p> <p><i>Route of administration means the route by which a therapeutic good is applied on or introduced into the body.</i></p>
Ingredients*	<p>Enter the ingredients used in the manufacture of the biological.</p> <p>You must at least enter the active ingredient(s). We recommended that you list both the active ingredient(s) and excipient(s) if possible.</p> <ul style="list-style-type: none"> • Select the Add Ingredients button. This opens a pop-up form with the fields below. <ul style="list-style-type: none"> – Ingredient Name*: Enter one ingredient name.

Field Name	Information required
	<ul style="list-style-type: none"> – Quantity*: Enter the numeric part of the ingredient strength/concentration. For example, if the strength of the ingredient is 25 mg, enter 25. – Unit*: Select a unit of measurement of the strength/concentration from the drop-down list. For example, if the strength of the ingredient is 25 mg, select milligram. – Country of Origin: Select the country of origin from the drop-down list. <ul style="list-style-type: none"> ▪ Select the Add Country button to add the country to the list. ▪ To remove a country select the check box next to the country you wish to remove. Select the Remove Country(ies) button. • Select the Save and Close button. • The details will be added to the Ingredients* list. • Repeat this process for each ingredient you need to add. <p>To edit ingredients:</p> <ul style="list-style-type: none"> • Select the Open button beside the ingredient you wish to edit. • Update any details as needed. <p>To remove ingredients:</p> <ul style="list-style-type: none"> • Select the check box next to the ingredient(s) you wish to remove. • Select the Remove Selected Ingredient(s) button.
Indication*	<p>Enter the indication the biological will be used for in the trial.</p> <p><i>The indication means the specific therapeutic use(s) of the goods.</i></p>
Dosage and Frequency*	<p>Enter the dosage regimen.</p> <p><i>The dosage regimen is the number of doses per given time period, the time that elapses between doses or the quantity of a biological that is given at each specific time of dosing.</i></p>
Intended Use*	Select if the Biological is a Comparator; Investigational Medicinal Product; Standard Care Therapy or Other.
Intended Use 'other' Description*	Please provide a description if 'Other' is selected under 'Intended Use'.

Field Name	Information required
Is the Biological manufactured in Australia?*	Select 'Yes' if the Biological is manufactured in Australia. If not, select 'No'.
Manufacturer details*	Please enter the name and address of the manufacturer.
GMP licence/clearance number or relevant exemption	Please provide the relevant licence number or exemption if available.

- Select the **Save and Close** button.
- The details will be added to the list on the **Biological Details*** sub-form.
- Repeat this process for each different biological and each different biological strength.

To edit a biological:

- Select the **Open** button beside the biological you wish to edit.
- Update any details as needed.

To remove a biological:

- Select the check box next to the biological(s) you wish to remove.
- Select the **Remove Selected Biologicals(s)** button.

The fields below also appear below the **Biological Details*** sub-form.

Involves a Genetically Modified Organism

- Select the check box **Involves a Genetically Modified Organism** to add details of [genetically modified organisms \(GMOs\)](#).



Enter details of GMOs if any of the therapeutic goods you have listed on the CTN form contain or are produced by GMOs.

Refer to '[Guidance 21: Medicines produced by genetic manipulation](#)' and '[Products regulated as biologicals](#)' for further guidance regarding the regulation of GMOs.

- A single free text field **Details of Genetically Modified Organism** will open under the **Therapeutic Area** field.
- Enter details of the GMO such as organism name, source, gene technology used.
- In addition you will then need to enter the GMO product as either a medicine or biological (as applicable) by selecting the check box **Involves the use of a Medicine** or **Involves the use of a Biological**.

Involves Gene Therapy

- Select the check box **Involves Gene Therapy** to enter details of gene therapy.



Gene therapy involves the deliberate introduction of genetic material into somatic cells for therapeutic, prophylactic or diagnostic purposes.

Refer to '[Guidance 21: Medicines produced by genetic manipulation](#)' for further guidance regarding gene therapy.

- A single free text field **Details of Gene Therapy*** will open.
- Enter a description of the gene therapy such as the origin of genetic material, delivery techniques etc.

Is Placebo Controlled

- Select the check box **Is placebo controlled** to add placebos to the CTN form.
- Scroll down to the **Placebo Details*** sub-form.
- Select the **Add Placebo** button. This opens a pop-up form with the fields below.

Field Name	Information required
Product Name*	Enter the product name of the placebo.
Route of Administration*	Select a route of administration from the drop-down list. <i>Route of administration means the route by which a therapeutic good is applied on or introduced into the body.</i>
Description (including dosage form)*	Enter a description of the placebo including dosage form, formulation (ingredients), composition, indications, directions for use, and type of container.

- Select the **Save and Close** button.
- The details will be added to the list on the **Placebo Details*** sub-form.
- Repeat this process for each placebo you need to add.

To edit a placebo:

- Select the **Open** button beside the placebo you wish to edit.
- Update any details as needed.

To remove a placebo:

- Select the check box next to the placebo(s) you wish to remove.
- Select the **Remove Selected Placebo(s)** button.

Is Comparator Controlled

- Select the check box **Is comparator controlled** if your study is a comparator controlled trial.
- This check box does not open a new sub-form and no additional information is required to be entered at this stage.

Involves Animal Excipients

- Select the check box **Involves Animal Excipients** to add animal excipients to the CTN form.



Enter animal excipient details if any of the therapeutic goods you have listed on the CTN form contain animal excipients.

An animal excipient is any component of a finished dosage form other than an active ingredient that contains animal products or is animal derived.

- Scroll down to the **Animal Excipient Details*** sub-form.
- Select the **Add Animal Excipient** button. This opens a pop-up form with the fields below.

Field Name	Information required
Product Name	Enter the name of the product that contains the animal excipient.
Species of Origin	Select the species of origin from the drop-down list.
Tissue	Select the tissue from which the animal excipient originated from the drop-down list.
Preparation	Select the preparation of the animal excipient from the drop-down list.
Country of Origin	Select the country of origin of the animal excipient from the drop-down list.

- Select the **Save and Close** button.
- The details will be added to the list on the **Animal Excipient Details*** sub-form.
- Repeat this process for each animal excipient you need to add.

To edit animal excipients:

- Select the **Open** button beside the animal excipient you wish to edit.
- Update any details as needed.

To remove animal excipients:

- Select the check box next to the animal excipient(s) you wish to remove.
- Select the **Remove Selected Excipient(s)** button.

Has relevant preceding trials

- Select the check box **Has relevant preceding trials** if applicable.



Relevant preceding trials may include trials involving the same investigational product conducted by the same sponsor or a follow-on trial conducted after a primary/parent study. The relevant preceding trials are populated from your **Clinical Trials Repository**.

- Scroll down to the **Preceding Trials*** sub-form.
- Select the check-box beside the relevant preceding trial(s) from the list.

Multicentre trial in Australia

- Select the check box **Is a multicentre trial in Australia** if the trial is being conducted at more than one clinical trial site in Australia.
- This check box does not open a new sub-form and no additional information is required to be entered at this stage.

Is being conducted in other countries

- Select the check box **Is being conducted in other countries** if the trial is also being conducted overseas.
- Scroll down to the **This trial is being conducted in the following Countries*** sub-form.
- Select a country from the drop-down list.
- Select the **Add Country** button to add the country to the sub-form.
- Repeat this process for each country you need to add.

To Remove a Country

- Select the check box next to the country you wish to remove.
- Select the **Remove Country(ies)** button.

Trial Site Details*

- The **Trial Site Details** sub-form automatically appears at the bottom of the CTN form. You will need to use this sub-form to add details of each site the trial will be conducted at.
- Select the **Add Site** button.

Field Name	Information required
Site Name*	Enter the name of the trial site.
Physical Location*	Enter the physical address (street address) of the trial site, including postcode. A postal address will not be accepted.
State/Territory*	Select the state/territory of the trial site from the drop-down list.

Field Name	Information required
Expected Site Start Date*	<p>Enter the date you estimate the trial will be initiated at this trial site in the format dd/mm/yyyy or select from the pop-up calendar.</p> <p>This date must fall within the range determined by the 'Expected Trial Start Date' and 'Expected Completion Date' for the form to validate.</p>
Principal Investigator Name*	Enter the full name and title of the Principal Investigator at this trial site.
Contact Phone Number*	Enter the phone number (including area code) of the Principal Investigator.
Contact Email*	Enter the email address of the Principal Investigator.
HREC Name*	Enter the name of the Human Research Ethics Committee (HREC) responsible for approving the clinical trial protocol and for monitoring the conduct of the trial.
HREC Code*	Enter the unique HREC Code issued by the National Health and Medical Research Council (NHMRC) for this HREC. A list of HRECs registered with NHMRC (which includes the HREC code) is published on the NHMRC website . The current list is available at Human Research Ethics Committees (HRECs) under 'Registration'.
HREC Contact Officer*	Enter the name of a member of the HREC named above. Where possible, this should be the chair or the deputy-chair of the HREC.
Position*	Enter the position description or title of the HREC contact officer.
Contact Phone*	Enter the phone number (including area code) of the HREC Contact Officer.
Contact Email*	Enter the email address of the HREC Contact Officer.
Name of Approving Authority*	Enter the name of the body, organisation or institution that is responsible for approving the conduct of the trial at the particular trial site.
Approving Authority Contact Officer*	Enter the name of the person authorised to represent the body, organisation or institution above.
Position*	Enter the position description or title of the Approving Authority contact officer.

Field Name	Information required
Contact Phone*	Enter the phone number (including area code) of the Approving Authority Contact Officer.
Contact Email*	Enter the email address of the Approving Authority Contact Officer.

- Select the **Save and Close** button.
- The details will be added to the list on the **Trial Site Details*** sub-form.
- Repeat this process for each trial site you wish to add.

To **edit a trial site**:

- Select the **Open** button beside the trial site you wish to edit.
- Update any details as needed.

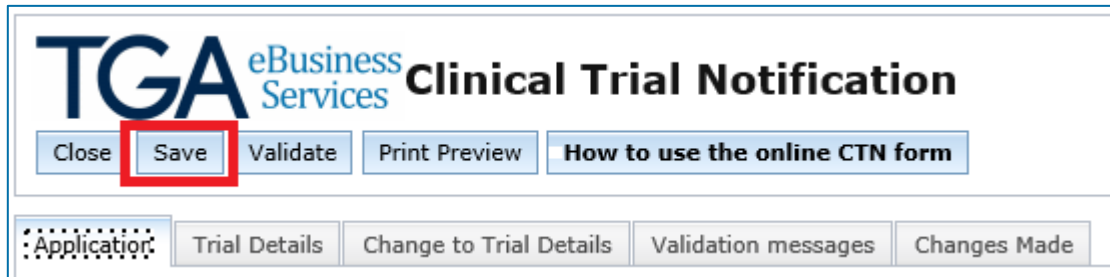
To **remove a trial site**:

- Click on the check box next to the site(s) you wish to remove.
- Select the **Remove Selected Site(s)** button.

Saving and editing drafts

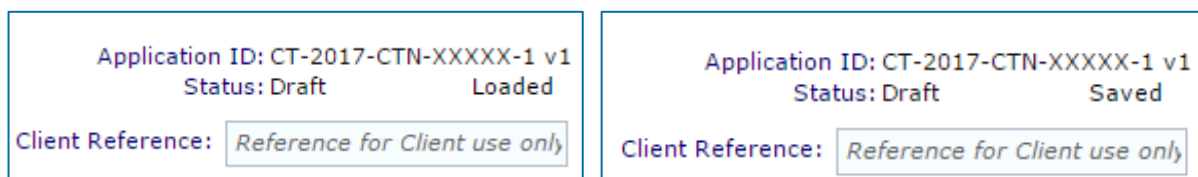
Save a draft

You can save a draft notification at any time by selecting the **Save** button on the top left hand side of the form. We recommend you **save the application at regular intervals** to ensure no ongoing work is lost.



The screenshot shows the top of the 'TGA eBusiness Services Clinical Trial Notification' form. At the top left is the TGA logo. Below it are several buttons: 'Close', 'Save' (highlighted with a red box), 'Validate', 'Print Preview', and a link 'How to use the online CTN form'. Below these buttons is a row of tabs: 'Application' (active), 'Trial Details', 'Change to Trial Details', 'Validation messages', and 'Changes Made'.

When the form is saved for the first time, the status will update from **Draft Loaded** to **Draft Saved**.



The image shows two side-by-side screenshots of the application status screen. Both show 'Application ID: CT-2017-CTN-XXXXX-1 v1' and 'Client Reference: Reference for Client use only'. The left screen shows 'Status: Draft Loaded', while the right screen shows 'Status: Draft Saved'.

After saving the draft:

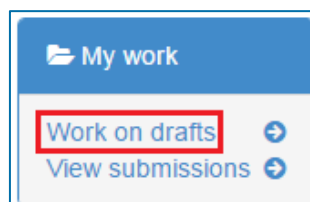
- You can select the **Close** button to return to the **Drafts** page. You will be able to exit the online portal and return at any time to edit the draft.
- Alternatively, if you have finished filling in the CTN form, skip to the [Validation](#) section for information on how to validate the CTN form prior to submitting it to us.

View saved drafts

The two options below can be used to view a list of saved drafts.

Option 1

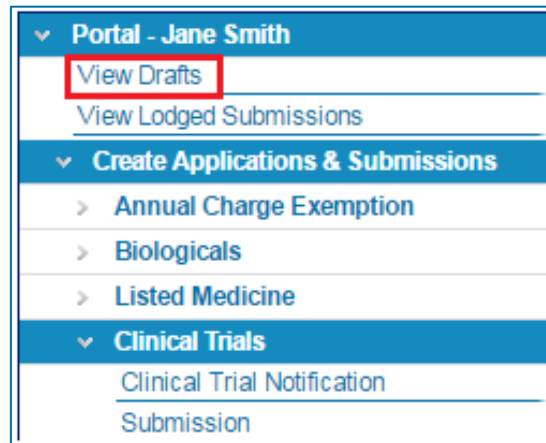
- Access the dashboard as described in [How to login](#).
- Select **Work on drafts** under the **My work** menu on the dashboard.



Option 2

- If you are already working within the online **Portal** menu, select **Portal** at the top of the menu.

- Select **View Drafts**.



You will then see a list of all of the saved drafts that your access allows on the **Drafts** page.

You may have more than one page of drafts in your online portal. If you are unable to see the draft notification you are looking for, select the next page in your drafts screen.

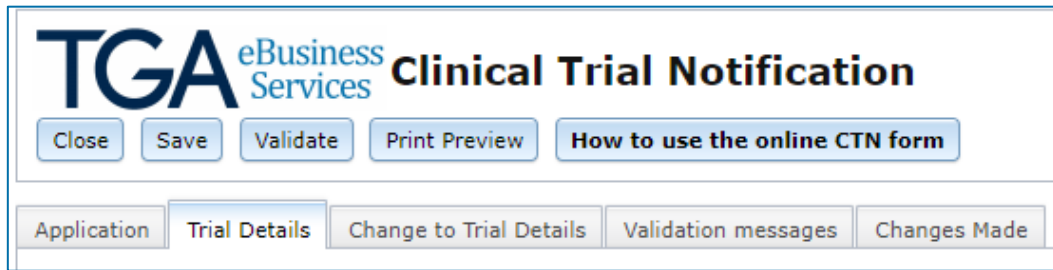
You can also search using the **Filter on** drop-down menu. You can filter drafts using parameters such as **Date**, **Status**, **Client Reference** or **Identifier**. Enter the parameters you wish to search on and then select the **Go** button.

Edit a saved draft

You can edit your saved drafts at any time **prior to submitting them**.

- Access a list of saved drafts as outlined in [View saved drafts](#) above.
- Select the CTN you wish to edit. The CTN will open.

- Select the **Trial Details** tab and go to the relevant fields to make any changes.



The screenshot displays the TGA eBusiness Services Clinical Trial Notification interface. At the top, the TGA logo is followed by 'eBusiness Services' and 'Clinical Trial Notification'. Below this, there are five buttons: 'Close', 'Save', 'Validate', 'Print Preview', and 'How to use the online CTN form'. A horizontal tabbed menu is located below the buttons, with tabs for 'Application', 'Trial Details' (which is highlighted), 'Change to Trial Details', 'Validation messages', and 'Changes Made'.

Once you have finished editing the draft, you will need to save the draft as outlined in the [Save a draft](#) section above.

After saving the draft:

- You can select the **Close** button to return to the **Drafts** page. You will be able to exit the online portal and return at any time to edit the draft.
- Alternatively, if you have finished filling in the CTN form, move on to the [Validation](#) section for information on how to validate the CTN form prior to submitting it to us.

Copying and deleting drafts

Delete a saved draft

You can delete a draft CTN any time before you submit it.

- Access your list of **Drafts** as described in [View saved drafts](#) above.
- Select the drop-down arrow (located at the far left of each draft notification - it will turn green when selected), then select **Delete**.

Drafts

Approval Area: All Approval Areas

Sponsor: All Sponsors

Filter on: Date for

Date	Identifier	Client Reference	Information
2017-08-28	CT-2017-CTN-XXXXX-1-v1		(Protocol) Title of Study

Copy
Delete
Print Preview

- A dialog box will ask you if you are sure you want to delete this draft. Select **OK** and the draft will be deleted.

www.ebsacceptance.tga.gov.au says:

Are you sure you want to delete this draft?

OK Cancel

Copy a saved draft

You can copy any draft CTN form to create a new draft. Information from the copied draft is retained for every field.

- Access your list of **Drafts** as described in [View saved drafts](#) above.
- Select the drop-down arrow (located at the far left of each draft notification - it will turn green when selected), then select **Copy**.

Drafts

Approval Area: All Approval Areas

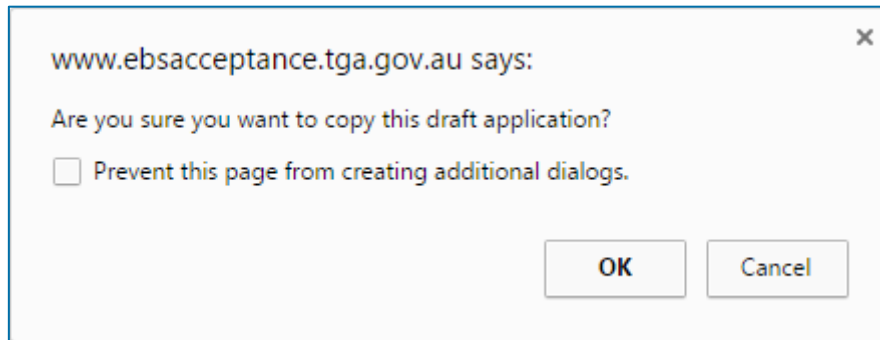
Sponsor: All Sponsors

Filter on: Date for

Date	Identifier	Client Reference	Information
2017-08-28	CT-2017-CTN-XXXXX-1-v1		(Protocol) Title of Study

Copy
Delete
Print Preview

- A dialog box will ask if you are sure you want to copy this draft.



- Selecting **OK** creates a new draft CTN form which opens with a **new Application ID**.

Validation and submission

The CTN form must be validated before it can be submitted to us.



Before selecting validate, you will need to save your draft as described in the [Save a draft](#) section above.

All mandatory fields must be completed for the form to validate.

Validating the form

To validate the form, select the **Validate** button at the top left of the form.

The screenshot shows the top of the TGA eBusiness Services Clinical Trial Notification form. It includes a header with the TGA logo and the text 'eBusiness Services Clinical Trial Notification'. Below the header is a row of buttons: 'Close', 'Save', 'Validate', 'Submit', 'Print Preview', and 'How to use the online CTN form'. The 'Validate' button is highlighted with a red rectangular box.

The validation process checks that all compulsory fields are completed, and that information has been entered in the correct format (e.g. email addresses).

Validation messages and automatic submission

After selecting the **Validate** button, you will be taken to the **Validation messages** tab.

The **Validation messages** tab displays a list of fields that need to be corrected before validation can proceed.

If there are **validation messages displayed**:

- The status of the notification form will change to **Draft Not Valid**.

The screenshot shows a section of the form with the following text: 'Application ID: CT-2017-CTN-XXXXXX-1 v1'. Below this, there is a red box containing the text 'Status: Draft Not Valid'. Further down, it says 'Client Reference: Reference for Client use only'.

- Select a validation message in the list. This will take you to the field in the form that requires editing.

The screenshot shows the TGA eBusiness Services Clinical Trial Notification form with the 'Validation messages' tab selected. The tab bar at the top includes 'Application', 'Trial Details', 'Change to Trial Details', 'Validation messages', and 'Changes Made'. Below the tabs, there is a section titled 'Validation Messages' with the instruction 'Click on a validation message to jump to the part of the notification that needs review.' Two validation messages are listed: 'Enter Protocol Number in Change to Trial Details.' and 'Enter Approving Authority Contact Email for in Site Details.'

- Once you have corrected all the invalid fields, save the form and validate again.

- You will need to correct all errors and successfully validate your draft to be able to submit it.

If there are **no validation messages**:

- The status of the notification form (top right of window) will change from **Draft** to **Validated**.

- The **validation messages** tab will display the message 'No validation messages to display'.

Once the form has validated, **Submit** will appear at the top of the page next to **Validate**. If you select this button, you will be automatically taken to the submissions page for submitting your CTN.

If you select the **Save** button again **after successfully validating** the form, it will **revert back to draft status** and you will need to validate the form again before you can submit it. Remember to complete the steps as follows:



After validating and submitting the form, you will be taken to the '**Clinical Trials Submissions**' page as displayed in [Option 2](#) of the **Manual Submitting** section below.

Alternatively, if you need to edit the validated form again for any reason (prior to submission), it can be accessed by selecting **View Drafts** on the **Portal** menu. See [Edit a saved draft](#) above for more information. You will be required to save and validate the CTN again to ensure the information has been updated before submitting.

Manual submission

Once the CTN form has been validated, the form can then be submitted to us by a user with a 'submitter role'.

Note: If you clicked **Submit** in the drafts section after validating, you will be automatically re-directed to the **Submissions** page.



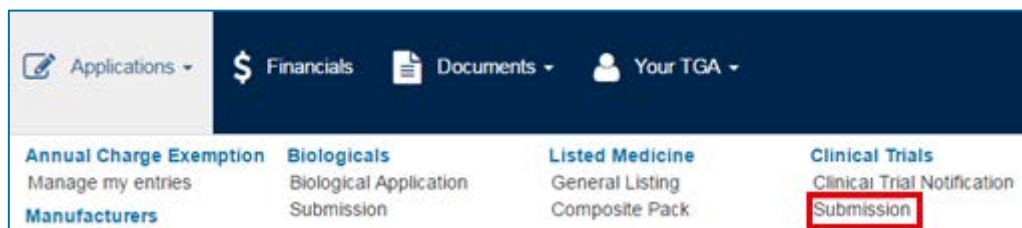
If you are unable to select **Submit** or **Submission** in your online portal, you may not have a 'submitter user role'. You will need to contact your organisation's administrator to update your system role. See [Roles: what each user can do](#) and [Drafter/submitter role specific information](#).

Manually access submission page

The two options below can be used to manually access the **Clinical Trials Submissions** page. If you selected **Submit** from the drafts screen you will automatically be taken to the **Submission** page.

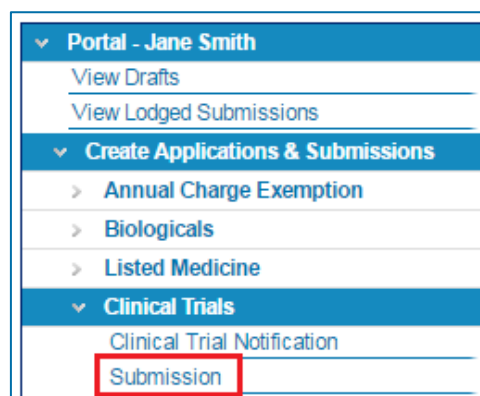
Option 1

- Access the dashboard as described in [How to login](#).
- Select **Applications** from the top menu on the dashboard.
- Select **Submission** under the **Clinical Trials** heading.



Option 2

- If you are already working within the online **Portal** menu, select **Portal** at the top of the menu.
- Select **Create Applications & Submissions**.
- Select **Clinical Trials** and then select **Submission**.



The **Clinical Trials Submissions** page will then open.

TGA eBusiness Services Clinical Trials Submissions

Close Submit

Client Name: TGA Clinical Trials Demonstration

Applicant Billing Address*: PO Box 100 Woden ACT 2606

Sponsor Name*: TGA Clinical Trials Demonstration

Application Type*: Clinical Trials Notification

Invoice Selected Sponsor? ☒ Yes ☐ No

Eligible Applications*:

	Application ID	Version	Title Of Study	Type	Sponsor Name
<input checked="" type="checkbox"/>	CT-2017-CTN-XXXXX-1	v1	Title of Study	Notification	TGA Clinical Trials Demonstration

Choose the relevant details:

Field Name	Information required
Client Name	This field is pre-populated based on the TBS logon ID used.
Applicant Billing Address*	Select the billing address from the drop-down list. This will auto-populate if there is only one option.
Sponsor Name*	Select the sponsor name from the drop-down list. This will auto-populate if there is only one option.
Application Type*	Select Clinical Trial Notification.
Invoice Selected Sponsor?	Select Yes or No as applicable.
Eligible Applications*	Select the check box beside the CTN form you wish to submit. Select only one CTN form per submission. If you access this screen from the drafts submission the CTN you were working on will be automatically selected (ticked off) for submission.

When you have completed the required information, click the **Submit** button at the top of the form.

TGA eBusiness Services Clinical Trials Submissions

Close Submit

Sponsor declaration

After selecting submit, you will be required to accept (or decline) a declaration, which includes acknowledging that the sponsor is taking overall responsibility for the trial. The [full text of the sponsor declaration](#) can be found below.

TGA eBusiness Services Clinical Trials Submissions

Close Decline Accept

Before submitting your application(s) please read the declaration below and click the **Accept** button to proceed with this submission; or click on the Decline button to return to the Submission form.

In this declaration, unless the contrary intention appears:
I means the individual assigned to the eBS login ID associated with the submission of this form to the TGA.
Secretary means the Secretary of the Department of Health and includes a delegate of the Secretary.
Sponsor means the company, organisation, institution, body or individual that is notifying the TGA as named in the 'Sponsor Name' field located on the application tab of this notification.

Declaration

By clicking the **Accept** button:

I **declare** that I am authorised by the sponsor to notify the TGA on its behalf in relation to this clinical trial.

I **acknowledge** that:

- If you select the **Decline** button you will be taken back to the **Clinical Trials Submissions** page.
- If you select the **Close** button you will be taken back to the online **Portal**.
- If you select the **Accept** button you will be taken to a page which advises you the submission of your CTN has been successful.

TGA eBusiness Services Clinical Trials Submissions

Close

Thank You. The Submission of your application(s) has been successful.

Thank-you for the submission of your application. Should this application incur a fee, a copy of the invoice will be emailed to you.

Submitted Application(s):

Please double click on a row to preview and print a Submission document for the data package. This action may be performed on multiple rows.

Application ID	Sponsor Name
----------------	--------------

Select the **Close** button to exit. Your CTN has now been submitted to us for processing. See [How to check the status of your CTN](#) below for information on checking the status of your CTN.

If you have submitted a notification and you need to make changes before it is processed, see [Editing a submitted form or a push back](#).

Otherwise you can now move on to [Paying for your CTN](#).

Once the CTN form has been submitted and paid for, we will review the CTN to ensure data has been entered correctly.

Paying for your CTN

A fee is incurred for:

- new CTNs; and
- certain changes ('variations') to an existing CTN.

Review our [clinical trials FAQs](#) to find out which variations to an existing CTN incur a fee.

The current fees for CTNs can be found on the [TGA Schedule of fees and charges](#).

Once you have submitted your CTN, an invoice will be sent via email to the submitter of the CTN and to the billing contact of your organisation as provided to TGA Business Services.

If you have a 'financial role' you will also be able to view and print the invoice from the online portal. See [Financial role specific information](#) for more information on the 'financial role'.

We recommend that you wait for the invoice before making payment as this ensures that there are no delays in matching payment.

The TGA provides a range of payment options as outlined at [TGA Payment Options](#).

Payment through the [online payment portal](#) is the preferred option.

Australian Government
Department of Health
 Therapeutic Goods Administration

Make an online payment (Please note: all fields are mandatory)

Biller Code: 1 - Payment of Invoice (dropdown menu)
 (Therapeutic Goods Administration)

Client Identification Number: [text input field]

Invoice Number: [text input field]

Email Address for Tax Receipt: [text input field]

Amount (AUD): [text input field] ?

Select your payment option: MasterCard VISA AMEX
 AMEX EXPRESS CHECKOUT

To make a payment of an invoice enter the following information:

Field Name	Information required
Biller Code	Select Biller code '1 - Payment of Invoice' from the drop-down list.
Client Identification Number	Enter your Client Identification Number (as shown on your invoice).

Field Name	Information required
Invoice Number	Enter your Invoice Number (as shown on your invoice).
Email Address for Tax Receipt	Enter an email address for tax receipt.
Amount (AUD)	Enter the amount to be paid (this should correspond to the amount on your invoice).
Select your payment option	Select your payment option and follow the online prompts.

Editing a submitted form or a 'push back'

Editing a submitted form

You can only edit a CTN when it is in draft status. See [Edit a saved draft](#) for more information.

However, if you have submitted a CTN form with an administrative error and it **has not been processed**:

- We can return the CTN form to your **Drafts** list for editing (called a 'push back') upon request. See [Editing a 'push back'](#) below.

If you have submitted a CTN form to us and it **has been processed**:

- Any further changes will need to be made by varying the notification via your **Clinical Trials Repository**. Please refer to [Varying trial details](#) for further information.

Editing a 'push back'

A submitted CTN form may be returned to your **Drafts** list for editing (called a 'push back') before it is processed. A 'push back' may occur upon request or may be initiated by us during processing.

- You can contact us at clinical.trials@health.gov.au to request a 'push back' to correct an administrative error. Provide the details of the CTN such as the Application ID and the reason for the 'push back'.
- During processing, we may initiate a 'push back' if it appears you have entered data incorrectly on the CTN form.



The returned CTN form will appear in **red** in your **Drafts** list.

To access your **Drafts** list, select **View Drafts** from within the **Portal menu**. See [Edit a saved draft](#) for information on how to access and edit a draft CTN.

Make the required changes to your draft. The returned CTN form will need to be saved and validated before it can be submitted again. See [Validation](#) above.

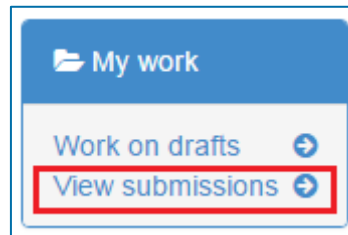
How to check the status of your CTN

View lodged submissions

The two options below can be used to view lodged submissions.

Option 1

- Access the dashboard as described in [How to login](#).
- Select **View Submissions** under the **My work** menu on the dashboard.



Option 2

- If you are already working within the online **Portal** menu, select **Portal** at the top of the menu.
- Select **View Lodged Submissions**.

A list of **Submissions** will be displayed.

 A screenshot of the 'Submissions' page in a web application. On the left is a sidebar menu with options like 'Portal - Jane Smith', 'View Drafts', 'View Lodged Submissions', 'Create Applications & Submissions', 'Annual Charge Exemption', 'Biologicals', 'Listed Medicine', 'Clinical Trials', 'Clinical Trial Notification Submission', and 'Export Only Medicine'. The main area is titled 'Submissions' and contains filters for 'Approval Area' (All Approval Areas), 'Sponsor' (All Sponsors), and 'Filter on' (Identifier). Below the filters is a table with columns 'Received', 'Identifier', and 'Workflow Status'. The table shows two entries, both dated 2017-08-28, with identifiers 'CT-2017-CTN-XXXXX-1-v1' and a 'Workflow Status' of 'Under Review'.

Received	Identifier	Workflow Status
2017-08-28	CT-2017-CTN-XXXXX-1-v1	Under Review
2017-08-28	CT-2017-CTN-XXXXX-1-v1	Under Review

The status of your submitted CTN will be displayed in the **Workflow Status** column.

- **Submitted:** This means that you have submitted your CTN but payment has not been received or the TGA has not yet started processing your submission.
- **Under Review:** The TGA is processing your submission.
- **Withdrawn:** Your CTN has been withdrawn by the TGA.
- **Pending Write to Repository:** Your CTN is in the process of updating to your **Clinical Trials Repository**.

If you have submitted a notification and you need to make changes before it is processed, see [Editing a submitted form or a push back](#) above.

During processing we review the CTN form to ensure data is entered correctly. If any corrections are required, the CTN form will be returned to you for editing. See [Editing a submitted form or a push back](#) for more information.

View the Clinical Trials Repository

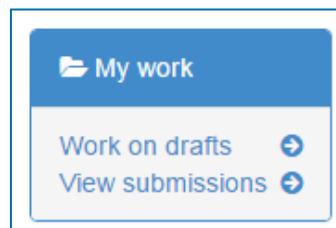
When the TGA has processed your CTN and no further corrections are required, it will move from the **Submissions** list to the **Clinical Trials Repository**.

The two options below can be used to access the **Clinical Trials Repository**.

Option 1

Access the dashboard as described in [How to login](#).

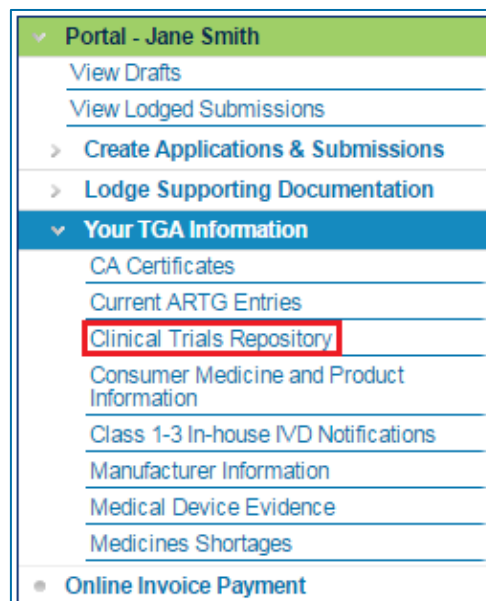
Select **Work on drafts** or **View Submissions** under the **My work** menu on the dashboard.



The online **Portal** menu will be displayed on the left hand side. Follow the steps in **Option 2** below to access the **Clinical Trials Repository**.

Option 2

- If you are already working within the online **Portal** menu, select **Portal** at the top of the menu.
- Select **Your TGA Information**.
- Select **Clinical Trials Repository**.



If your CTN appears in the **Clinical Trials Repository**, then it has been processed by the TGA.

Clinical Trials Repository

Sponsor:

Filter on: ▼ for

Date	Identifier	Client Reference	Stage
------	------------	------------------	-------

The status of your acknowledged CTN is displayed in the **Stage** column.

- **Trial Details:** This is a new CTN.
- **Completion:** This is a completed CTN.
- **Variation:** This is a variation to an existing CTN.

Refer to the section [Print a TGA acknowledgement](#) below for details on printing a TGA acknowledgement from the **Clinical Trials Repository**.

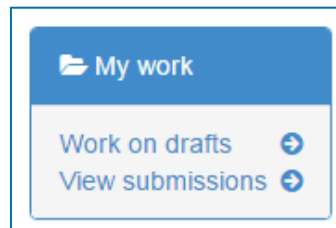
Varying trial details

To vary or make changes to a CTN that has been processed by the TGA you will need to access the **Clinical Trials Repository**. The two options below can be used to access the **Clinical Trials Repository**.

Option 1

Access the dashboard as described in [How to login](#).

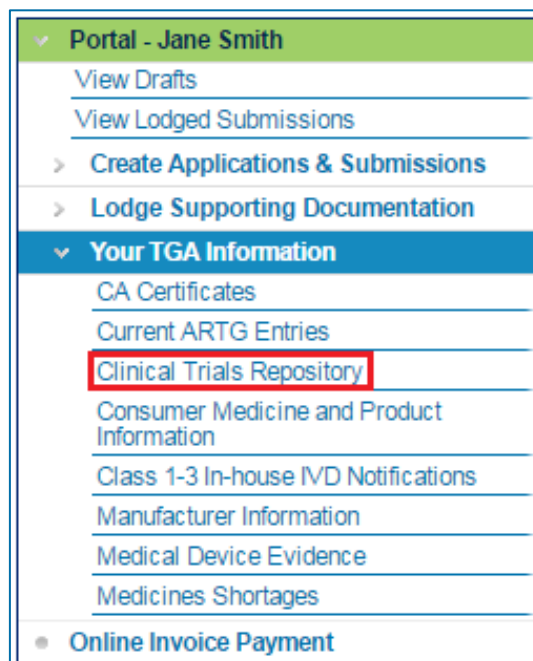
Select **Work on drafts** or **View Submissions** under the **My work** menu on the dashboard.



The online **Portal** menu will be displayed on the left hand side. Follow the steps in **Option 2** below to access the **Clinical Trials Repository**.

Option 2

- If you are already working within the online **Portal** menu, select **Portal** at the top of the menu.
- Select **Your TGA Information**.
- Select **Clinical Trials Repository**.



- You will then see a list of processed CTNs in the **Clinical Trials Repository**.

- Select the drop-down arrow beside the CTN you want to vary (located at the far left of each CTN - it will turn green when selected), then select **Vary**.

Clinical Trials Repository

Sponsor: All Sponsors

Filter on: Date for

Date	Identifier	Client Reference	Stage
2017-08-23	CT-2017-CTN-XXXXX-1-v1		Trial Details
	2017-CTN-XXXXX-1-		Trial Details
	2017-CTN-XXXXX-1-		Trial Details

Context menu options: Next Stage, **Vary**, Complete, Print Preview

- After selecting **Vary**, a web page message will appear. Select **OK** to proceed.

www.ebsacceptance.tga.gov.au says:

Are you sure you want to vary this trial?

OK Cancel

The CTN you wish to vary will then open as a draft.

To make changes to the CTN:

- You can make changes to any of the fields displayed in the tab or add new details as required. The information required in each field is the same as described under the [Trial details tab](#) above.

TGA eBusiness Services Clinical Trial Notification

Close Save Validate Print Preview How to use the online CTN form

Application Trial Details **Change to Trial Details** Validation messages Changes Made

* Always Required * Required under certain conditions

Contact Name * Jamie Chang

Contact Phone Number * 0487456321

Contact Email * anz_incident_report@bsci.com

Trial Details

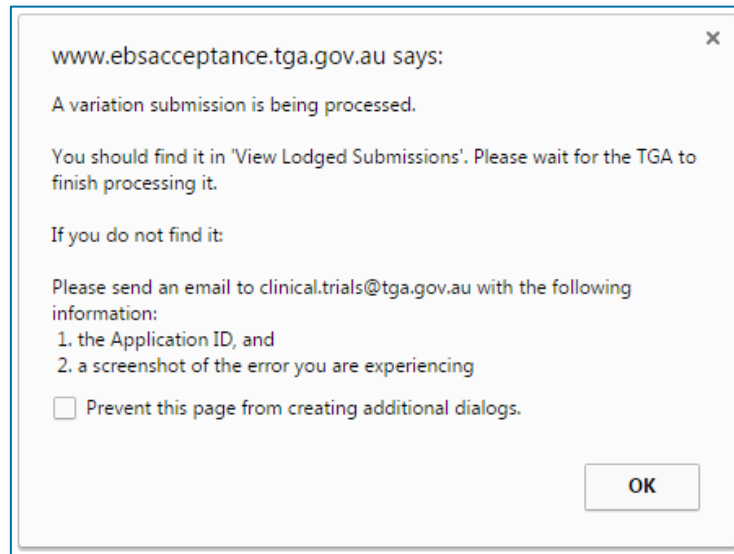
Protocol Number * Protocol

- You will need to save and validate the CTN form and then submit the CTN form to us. Refer to the [Validation](#) and [Submitting](#) sections above.

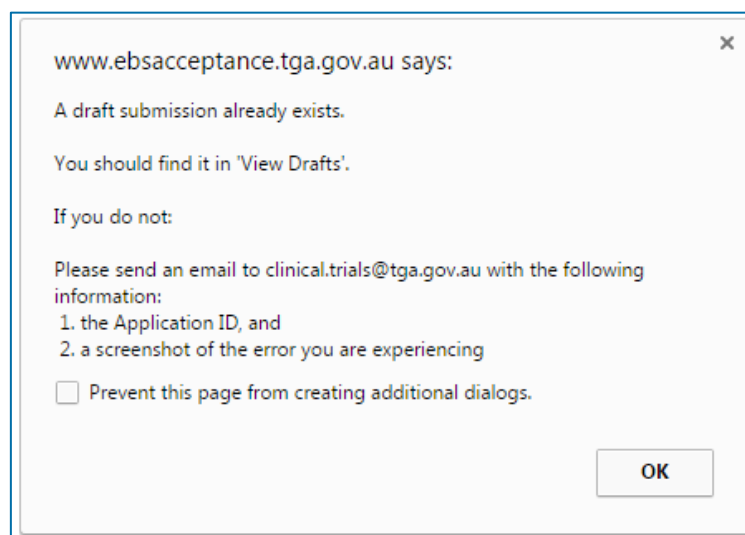
- Certain changes to an existing CTN incur a fee. See [Paying for your CTN](#) for more information.
- See [How to check the status of your CTN](#) for information on checking the status of your CTN.
- Once the CTN form has been submitted and paid for, we will review the CTN to ensure data has been entered correctly.

Error messages

If the submission is currently being processed by us you will not be able to vary the trial and the following message will appear. You will need to wait until we have processed the previous submission for you to make a variation.



If a draft submission already exists for the CTN, then you will receive the error message below. You will need to find the existing draft in **View Drafts**.



Submitting a completion advice

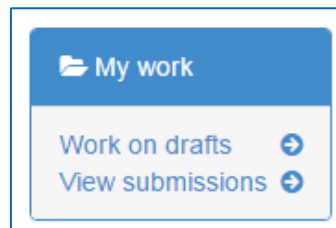
To submit a completion advice to us, you will need to access the **Clinical Trials Repository**.

The two options below can be used to access the **Clinical Trials Repository**.

Option 1

Access the dashboard as described in [How to login](#).

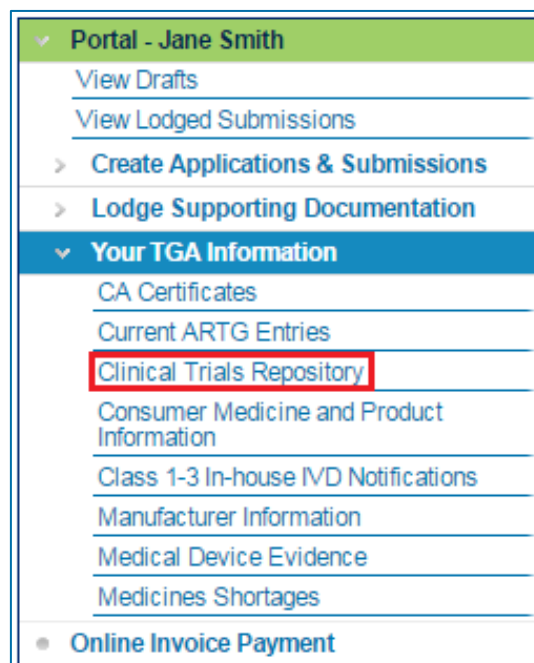
Select **Work on drafts** or **View Submissions** under the **My work** menu on the dashboard.



The online **Portal** menu will be displayed on the left hand side. Follow the steps in **Option 2** below to access the **Clinical Trials Repository**.

Option 2

- If you are already working within the online **Portal** menu, select **Portal** at the top of the menu.
- Select **Your TGA Information**.
- Select **Clinical Trials Repository**.



- You will then see a list of processed CTNs in the **Clinical Trials Repository**.

- Select the drop-down arrow beside the CTN you wish to complete (located at the far left of each CTN - it will turn green when selected), then select **Complete**.

Clinical Trials Repository

Sponsor: All Sponsors

Filter on: Date for

Date	Identifier	Client Reference	Stage
2017-08-23	CT-2017-CTN-XXXXX-1-v1		Trial Details
2017-08-23	CT-2017-CTN-XXXXX-1-v1		Trial Details
	CT-2017-CTN-XXXXX-1-v1		Trial Details

Next Stage
Vary
Complete
Print Preview

After selecting **Complete**, a web page message will appear. Select **OK** to proceed.

www.ebsacceptance.tga.gov.au says:

Are you sure you want to complete this trial?

☐ Prevent this page from creating additional dialogs.

OK Cancel

The CTN you wish to complete will then open as a draft.

- Select the **Completion** tab and enter the following details:

Field Name	Information required
Name*	Name will auto-populate.
Contact Phone Number*	Contact phone number will auto-populate.
Contact Email*	Contact email address will auto-populate.
Date Trial Completed*	Enter the date the trial was completed at all Australian sites in the format dd/mm/yyyy or select from the pop-up calendar.
Completion Reason*	Select the reason for trial closure from the drop-down list.

- Note: If you need to make any changes to the CTN before submitting the completion advice, you will need to vary the CTN as described in [Varying trial details](#).
- Save and validate your notification and submit the completion advice to us. Refer to [Validation](#) and [Submitting](#) sections above.
- See [How to check the status of your CTN](#) for information on checking the status of your CTN.

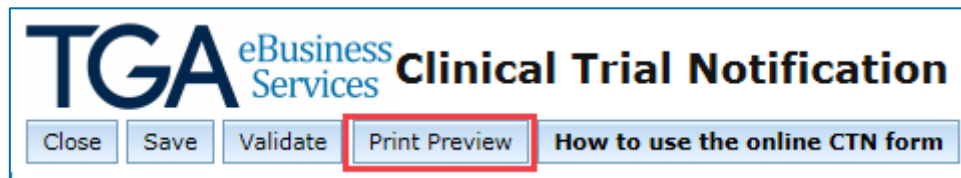
Printing

You can preview and print the CTN form at any time before or after submitting it.

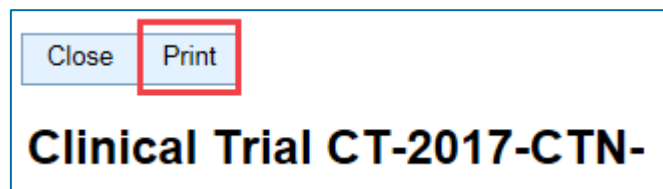
Print a CTN from within a draft

You can preview and print a draft CTN while you are working on it:

- Select the **Save** button at the top of the form.
- Select the **Print Preview** button at the top of the form.

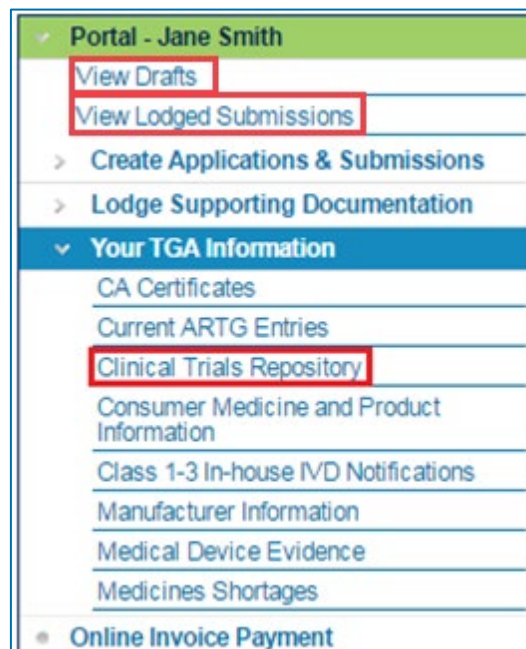


The print preview will open in a new window. Select the **Print** button at the top to print a copy of the CTN you are working on.



Print a CTN from the online portal

Within the online portal, there are three different stages during the CTN submission process at which you can preview and print the submission: **Drafts**, **Lodged Submissions** and **Clinical Trials Repository**.



To preview and print a submission you will need to access the relevant area of the CTN form.

- To access your list of **Drafts** see [View saved drafts](#)
- To access your list of **Lodged Submissions** see [View lodged submissions](#)
- To access your **Clinical Trials Repository** see [View the Clinical Trials Repository](#)
- Once you have accessed your **Drafts/Lodged Submissions/Clinical Trials Repository**, select the drop-down arrow beside the CTN you wish to preview and print (located at the far left of each CTN - it will turn green when selected).
- Select **Print Preview**.

- The print preview will open in a new window. Select the **Print** button at the top to print a copy of the CTN.

Close
Print

Clinical Trial CT-2017-CTN- xxxxx-1 v1 Repository

Submission Date: 23/08/2017
Acknowledged by TGA

- You can then print the CTN as a hard copy. Alternatively, you can create a PDF version by selecting the relevant PDF program (e.g. Adobe PDF) from your printer options.
- You can then save this PDF file.

Print a TGA acknowledgement

- Access your **Clinical Trials Repository** as outlined in [View the Clinical Trials Repository](#).
- Select the drop-down arrow beside the CTN you wish to preview and print (located at the far left of each CTN - it will turn green when selected).
- Select **Print Preview**.

The screenshot shows the 'Clinical Trials Repository' interface. On the left is a sidebar menu with categories like 'Portal - Jane Smith', 'Create Applications & Submissions', 'Clinical Trials', and 'Your TGA Information'. The 'Clinical Trials' section is expanded, showing options like 'Clinical Trial Notification Submission'. The main area displays a table with columns 'Date' and 'Identifier'. A row is selected, and a context menu is open over it, showing options: 'Next Stage', 'Vary', 'Complete', and 'Print Preview'.

- The print preview will open in a new window. Select the **Print** button at the top to print a copy of the CTN.

The screenshot shows a print preview window. At the top, there are 'Close' and 'Print' buttons. Below them, the title 'Clinical Trial CT-2017-CTN-xxxxx-1 v1 Repository' is displayed. On the right side, the 'Submission Date: 23/08/2017' and 'Acknowledged by TGA' are shown.

- You can then print the CTN as a hard copy. Alternatively, you can create a PDF version by selecting the relevant PDF program (e.g. Adobe PDF) from your printer options.
- You can then save this PDF file.

Refer to our [clinical trial FAQs](#) for quick tips on how to resolve any issues with the print preview function.

How to use the online form

This button will link you to the online CTN form user guide (this document) which is available on the TGA website.

Full text of sponsor declaration

Before submitting your application(s) please read the declaration below and click the **Accept** button to proceed with this submission; or click on the **Decline** button to return to the Submission form.

In this declaration, unless the contrary intention appears:

I means the individual assigned to the eBS login ID associated with the submission of this form to the TGA.

Secretary means the Secretary of the Department of Health and includes a delegate of the Secretary.

Sponsor means the company, organisation, institution, body or individual that is notifying the TGA as named in the 'Sponsor Name' field located on the application tab of this notification.

Declaration

By clicking the **Accept** button:

I **declare** that I am authorised by the sponsor to notify the TGA on its behalf in relation to this clinical trial.

I **acknowledge** that:

- the sponsor is taking overall responsibility for the trial
- the relevant goods only remain exempt by reason of their use in the clinical trial only for so long as:
 - the approval of the goods for the trial has been given by the sponsor (if the sponsor is conducting the trial), or by the body or organisation conducting the trial for the sponsor, having regard to the advice of the ethics committee responsible for monitoring the conduct of the trial, on terms no less restrictive than terms advised by that committee
 - the sponsor has not received advice from the ethics committee that is inconsistent with the continuation of the trial
 - the requirements in regulation 12AD of the Therapeutic Goods Regulations 1990 (in the case of therapeutic goods other than medical devices) and regulation 7.5 of the Therapeutic Goods (Medical Devices) Regulations 2002 (in the case of medical devices) are complied with, including that the use of therapeutic goods in the trial must be in accordance with the Guidelines for Good Clinical Practice and the National Statement on the Ethical Conduct in Research Involving Humans published by the National Health and Medical Research Council, as defined in the Therapeutic Goods Regulations
 - the Secretary has not under Item 3 of Schedule 5A of the Therapeutic Goods Regulations (in the case of therapeutic goods other than medical devices) or Item 2.3 in Part 2 of Schedule 4 of the Therapeutic Goods (Medical Device) Regulations 2002 directed that the trial not be conducted on the basis that the Secretary has become aware that to conduct the trial would be contrary to the public interest
- the Secretary can under the *Therapeutic Goods Act 1989* (the Act), require the sponsor to provide specified information or documents relating to any exempt goods

- the Secretary can provide information obtained in response to an authority or the Commonwealth, or a State or Territory that has functions in relation to therapeutic goods or the registration of medical practitioners or pharmacists in the relevant State or Territory
- it is an offence under the Act to fail to provide that information or documents required by the Secretary, or to provide information or documents that are false or misleading in a material particular, to the Secretary
- it is a requirement of the Guidelines on Good Clinical Practice that the sponsor report all serious and unexpected adverse reactions arising from the use of the relevant goods in the trial to the TGA
- it is a serious offence under Commonwealth law to provide information for the purposes of this notification that is false or misleading in a material particular.

I **declare** that all information provided for the purposes of the notification is true and accurate and that all required information has been included.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Therapeutic Goods Administration	December 2017
V1.1	Updated to reflect changes to paying an invoice	Therapeutic Goods Administration	March 2018
V1.2	Minor enhancements to the current online CTN form such auto-population of contact details, and updated submission process.	Therapeutic Goods Administration	August 2020

Therapeutic Goods Administration

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<https://www.tga.gov.au>

Reference/Publication #