Australian Government
Department of Health
Therapeutic Goods Administration

Introduction to changes to the TGA's Clinical Trial Notification (CTN) process

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Scientific Evaluation and Special Product Access Branch
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ARCS Scientific Congress 2015

5 May 2015

TGA Health Safety Regulation

Australian Government
Department of Health
Therapeutic Goods Administration

Introduction overview

- Background
- Benefits
- What preparation is required by clinical trial sponsors?

Background

- The current CTN process is paper based and quite burdensome administratively
- Responding to sponsors request for an electronic lodgement system – improved efficiency
- Errors in data reporting

Inaccuracies in clinical trial statistics for the reporting period 2009-2012

Benefits

- Improved external and internal tracking of documents (no lost signed originals)
- Reduction in need to follow up information that may not be legible (typed over hand written)
- Sponsor instantly knows that the CTN has been received by the TGA (no need to contact the TGA to confirm receipt)

Benefits

- The status of the CTN is known to the sponsor e.g. under review
- Variations to the original application are streamlined by using the original data set
- Reports will be more detailed and with a higher degree of accuracy

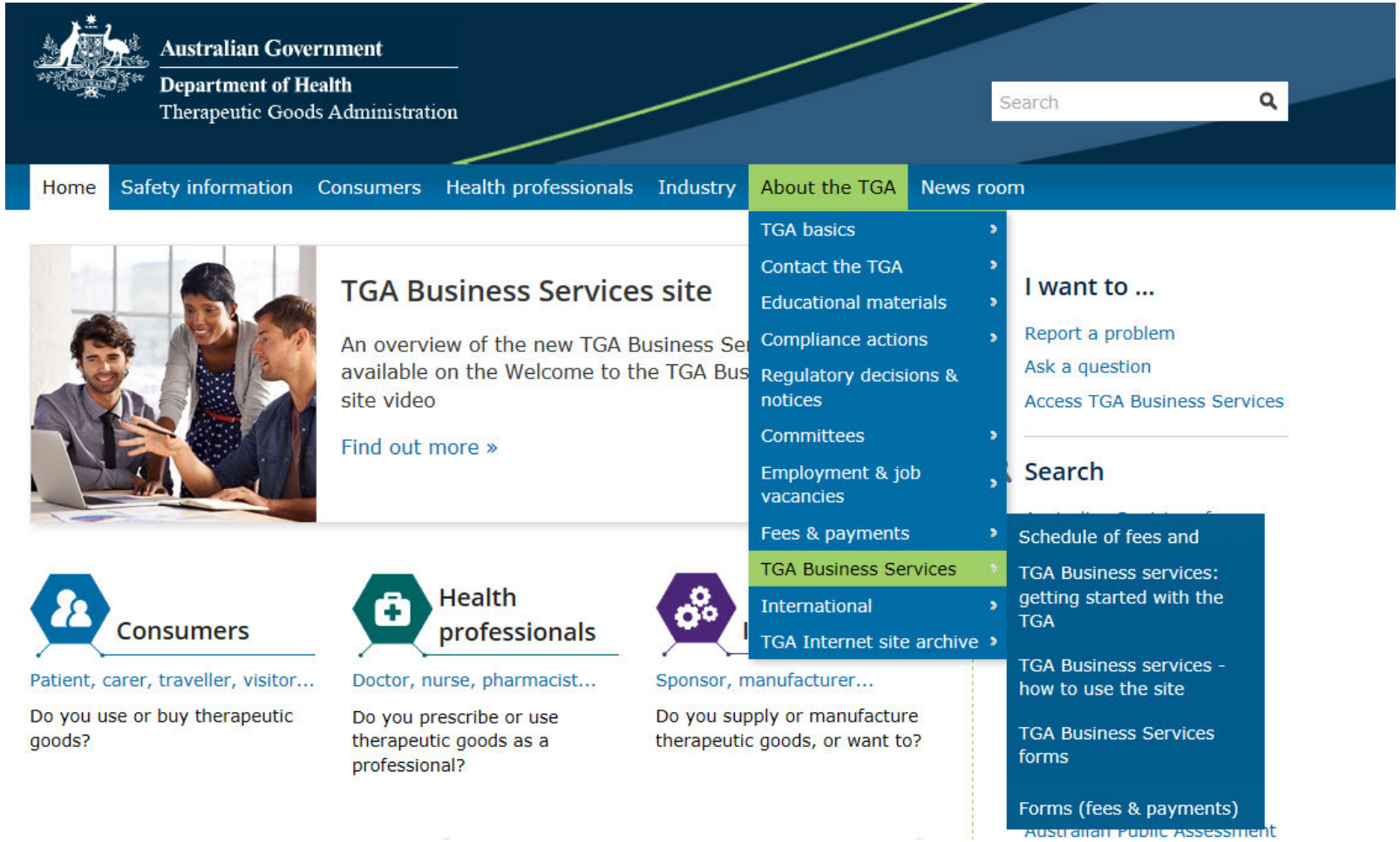
Benefits

- All clinical trial documentation relevant to the CTN will be accessible on TGA Business Services (TBS)
- There will be no need for Sponsor, Principal Investigator (PI), Human Research Ethics Committee (HREC) or Approving Authority (AA) certification on the form
- A guide on how to complete the CTN form will be available on TBS and the form will contain tool tips

Benefits

- More accurate, timely and detailed reports, if organisations request information from the TGA
- Clinical trial activities and trends can be identified - could improve Australia as a better choice for the conduct of clinical trials
- TGA time currently spent on administrative activities can be value added to review of CTN submissions space
- Closing the loop - much easier for sponsors to inform the TGA when a clinical trial is complete

What preparation is required by clinical trial sponsors?



About the TGA

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- Compliance actions
- Regulatory decisions & notices
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  - TGA Business services: getting started with the TGA
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TGA Business Services

28 April 2015

TGA Business Services establishes a base for electronic commerce, electronic lodgement of data packages in support of applications for entry of products onto the Australian Register of Therapeutic Goods and enables online client access to legally appropriate information. The Terms and Conditions for using TGA Business Services are available.

TGA Business Services

Open TGA Business Services

Go to the TGA Business Services website.

TGA Business services: getting started with the TGA

Introduction to TGA online services for sponsors, agents and manufacturers.

TGA Business Services: how to use the site

The TGA Business Services site allows industry to manage some therapeutic good registration applications, and view and cancel their current entries on the Australian Register of Therapeutic Goods (ARTG).

TGA Business Services forms

Top of page

What preparation is required by clinical trial sponsors?

- Apply for your client identification number – about 3 working days
- Apply for access to TBS – about 3 working days
- Once the TBS Helpdesk receives your completed Organisation details form, a Administrator Account is created for the nominated person – this enables that person to control who has access to the information

What preparation is required by clinical trial sponsors?

- Administrator for the organisation will be able to set up different user accounts e.g. Drafter, Submitter, Finance
- The users of your account can then access your secure TBS portal to:
  - submit CTN forms
  - pay invoices online

What preparation is required by clinical trial sponsors?

- TGA webpage – TGA Business Services – how to use the site
  - ✓Video
  - ✓Frequently asked questions
- TBS Helpdesk available to answer further enquiries
  - ✓Email: ebs@tga.gov.au
    phone: 1800 010 624

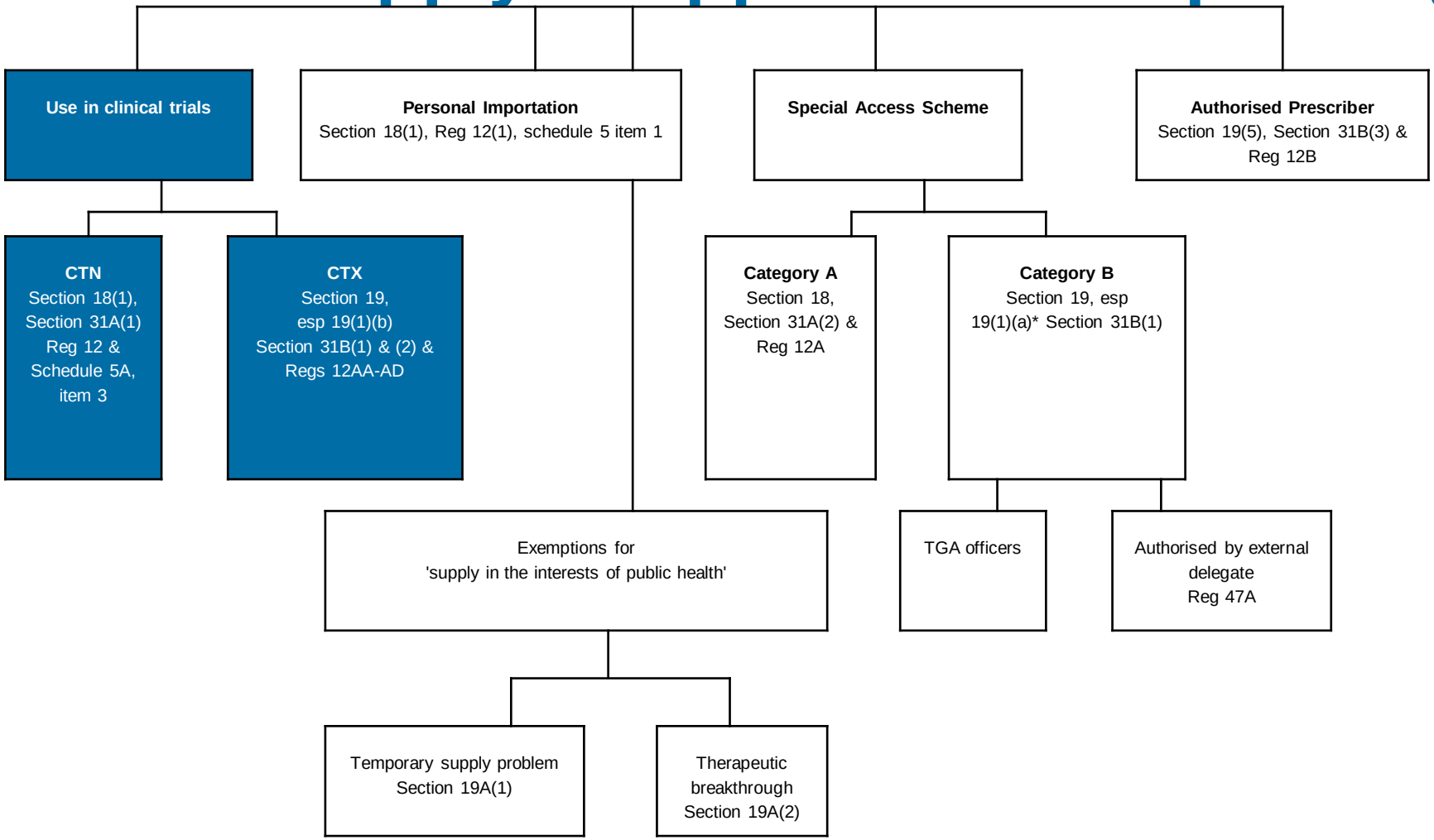
CTN/ Clinical Trial Exemption (CTX) online submission - overview

- Unapproved therapeutic goods
- Clinical trials
- Online submission form for CTN/CTX

What is an unapproved therapeutic good?

- Generally, therapeutic goods must be entered in the Australian Register of Therapeutic Goods (ARTG) to be lawfully supplied in or exported from Australia
- Goods that do not appear on the ARTG, or ARTG goods being used outside of marketing approval are considered unapproved goods
- Unapproved goods have not been evaluated by the TGA for quality, safety or efficacy

Avenues to supply unapproved therapeutic goods



TGA's role in clinical trials differs from some other regulators

- Main focus is on **access to unapproved medicines and devices** for trials rather than end-to-end regulation of trials

- **CTX/CTN schemes required** for any product not entered on the ARTG or use of a product in a clinical trial beyond the conditions of its marketing approval

CTN vs CTX Schemes - overview

CTN

- Notification process
- One step process
- Medicines, devices or biologicals
- No TGA review of data prior to trial
- Trial cannot commence without valid notification and fee paid
- Assurances pertaining to the trial conduct and protocol are provided by the sponsor, HREC, PI and AA
- Each additional trial site notified before commencing trial at that site

CTX

- Approval process
- Two step process – part 1 (approval) part 2 (notification)
- Medicines, devices or biologicals but **required** for certain class 4 biologicals
- TGA evaluates the proposed Usage Guidelines
- Trial cannot commence without Part 1 being approved
- Assurances pertaining to the trial conduct and protocol are provided by the sponsor, HREC, PI and AA
- May conduct **any number of clinical trials**, provided use of the product falls within the original approved Usage Guidelines
- Each trial must be notified to the TGA

Legal responsibilities

- **All trials must have an Australian sponsor** who initiates, organises and supports a clinical study and carries the medico-legal responsibility

Guidelines for Clinical Trials

- Conduct of the proposed trial should be in accordance with:
  - National Health Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans* (2007)
  - *Declaration of Helsinki*
  - *Note for Guidance on GCP* or the ISO 14155 Clinical Investigation of Medical Devices
  - relevant Commonwealth and/or State/Territory laws

Guidelines for manufacturing

- Generally, a facility manufacturing therapeutic goods, including Investigational Medicinal Products (IMP) and placebo, for supply in Australia must comply with appropriate GMP standards and must be licensed accordingly
- The TGA has adopted the *PIC/S Guide for Good Manufacturing Practice for Medicinal Products 2009*, with Annex 13 of this guide referring to the manufacture of IMP

Clinical trial statistics

2014 total new trials – 967

Total notifications (number of sites) – 3762

New trial notifications that include a therapeutic good received by phase

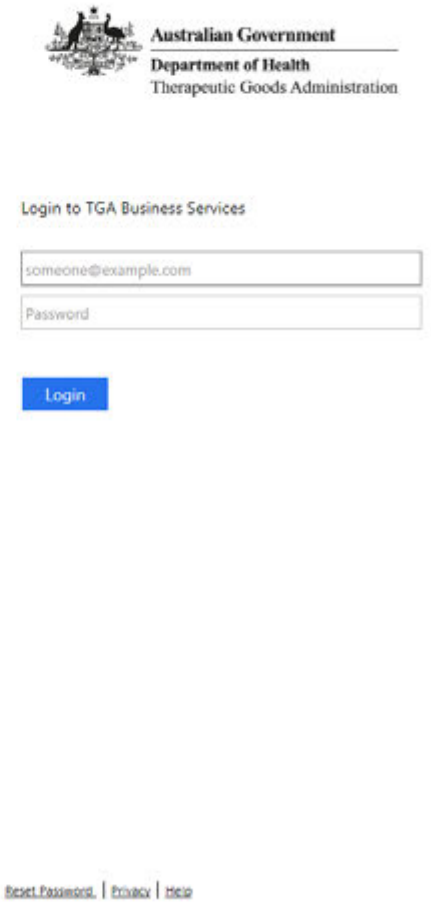
	2012	2013		2014	
	Jul-Dec	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec
Phase 1	85	65	132	68	83
Phase 2	128	86	102	130	124
Phase 3	155	131	70	153	198
Phase 4	34	28	32	32	34
Bioavailability/equivalence	5	4	5	2	3
None specified	9	12	14	64*	76*
Total	416	326	355	449*	518*

*this number now combines those CTNs which involve device(s)

Online submission of CTN / CTX

- Currently paper driven, manually entered into a database
- New form completed and submitted online


TGA


Australian Government
Department of Health
Therapeutic Goods Administration
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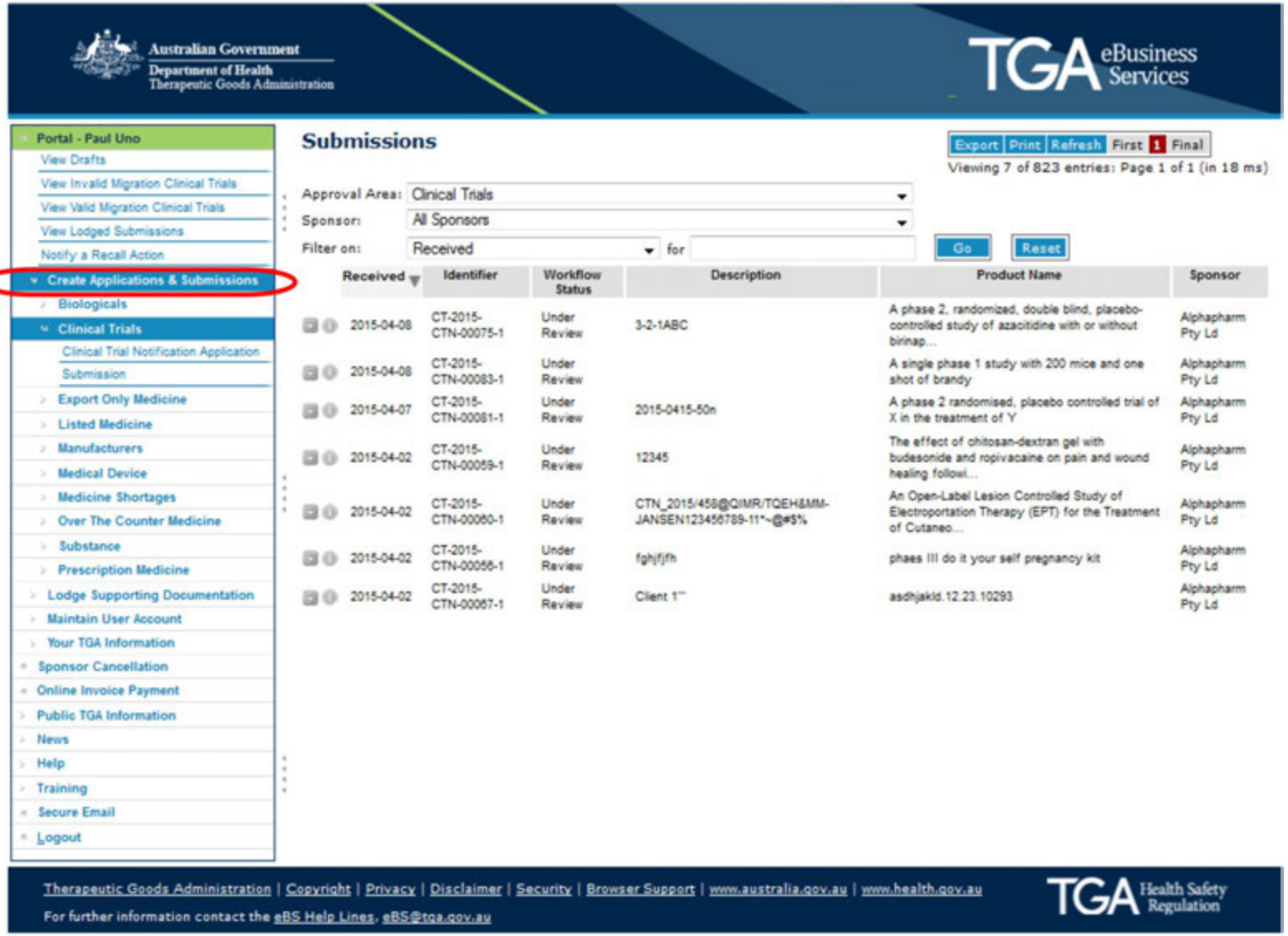
someone@example.com
Password
Login
Reset Password | Privacy | Help


Australian Government
Department of Health
Therapeutic Goods Administration
TGA eBusiness Services
Portal - Paul Uno
View Drafts
View Invalid Migration Clinical Trials
View Valid Migration Clinical Trials
View Lodged Submissions
Notify a Recall Action
Create Applications & Submissions
Biologicals
Clinical Trials
Clinical Trial Notification Application
Submission
Export Only Medicine
Listed Medicine
Manufacturers
Medical Device
Medicine Shortages
Over The Counter Medicine
Substance
Prescription Medicine
Lodge Supporting Documentation
Maintain User Account
Your TGA Information
Sponsor Cancellation
Online Invoice Payment
Public TGA Information
News
Help
Training
Secure Email
Logout
Submissions
Export Print Refresh First 1 Final
Viewing 7 of 823 entries: Page 1 of 1 (in 18 ms)
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Sponsor: All Sponsors
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Reset
Received
Identifier
Workflow Status
Description
Product Name
Sponsor
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2015-04-02 CT-2015-CTN-00056-1 Under Review fghjfjfh phaes III do it your self pregnancy kit Alphapharm Pty Ld
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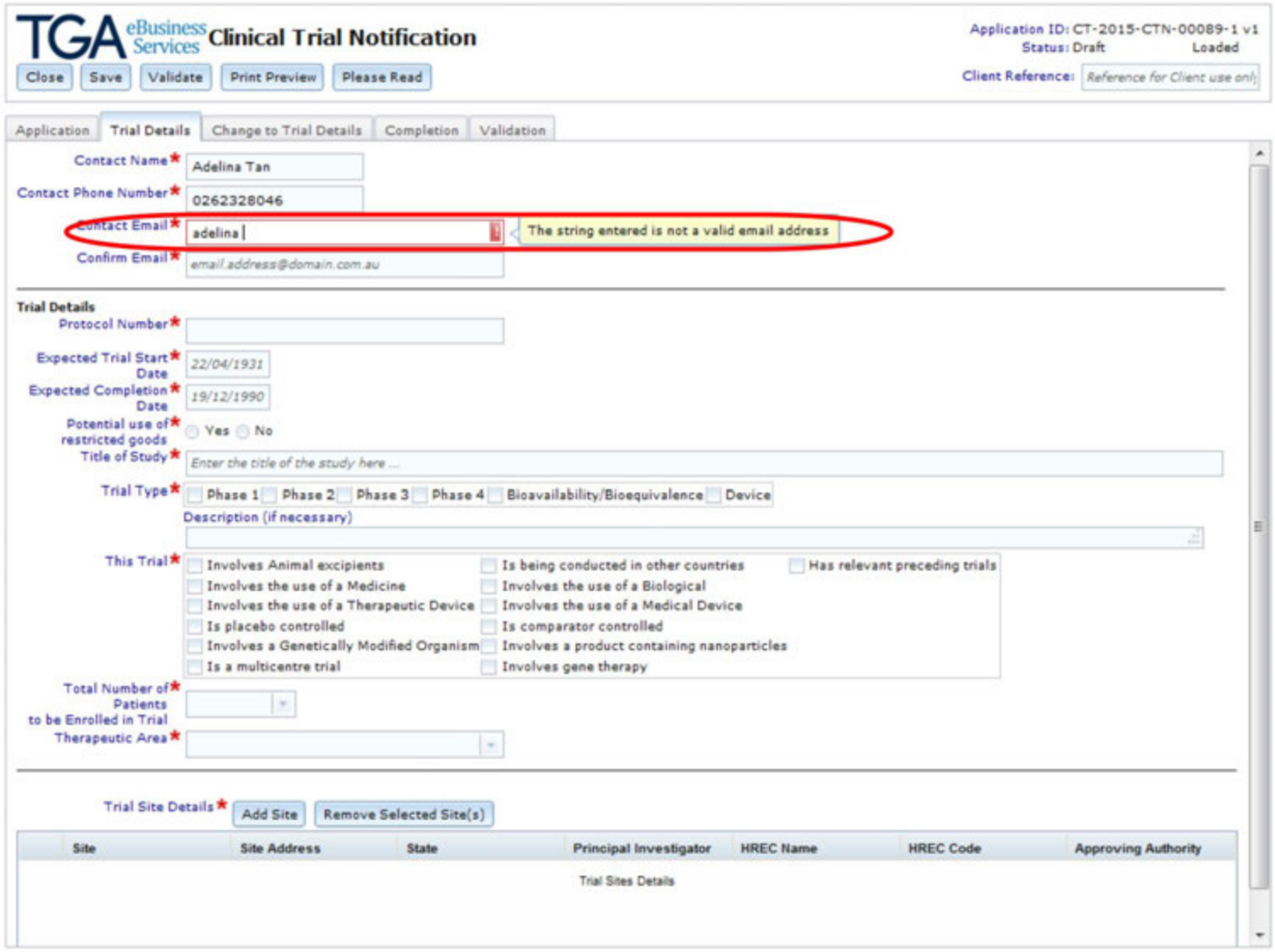
For further information contact the eBS Help Lines, eBS@tga.gov.au
TGA Health Safety Regulation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Adelina Tan
Contact Phone Number*
0262328046
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adelina
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Expected Completion Date*
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No
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Trial Type*
Phase 1
Phase 2
Phase 3
Phase 4
Bioavailability/Bioequivalence
Device
Description (if necessary)
This Trial*
Involves Animal excipients
Is being conducted in other countries
Has relevant preceding trials
Involves the use of a Medicine
Involves the use of a Biological
Involves the use of a Therapeutic Device
Involves the use of a Medical Device
Is placebo controlled
Is comparator controlled
Involves a Genetically Modified Organism
Involves a product containing nanoparticles
Is a multicentre trial
Involves gene therapy
Total Number of Patients to be Enrolled in Trial*
Therapeutic Area*
Trial Site Details*
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Remove Selected Site(s)
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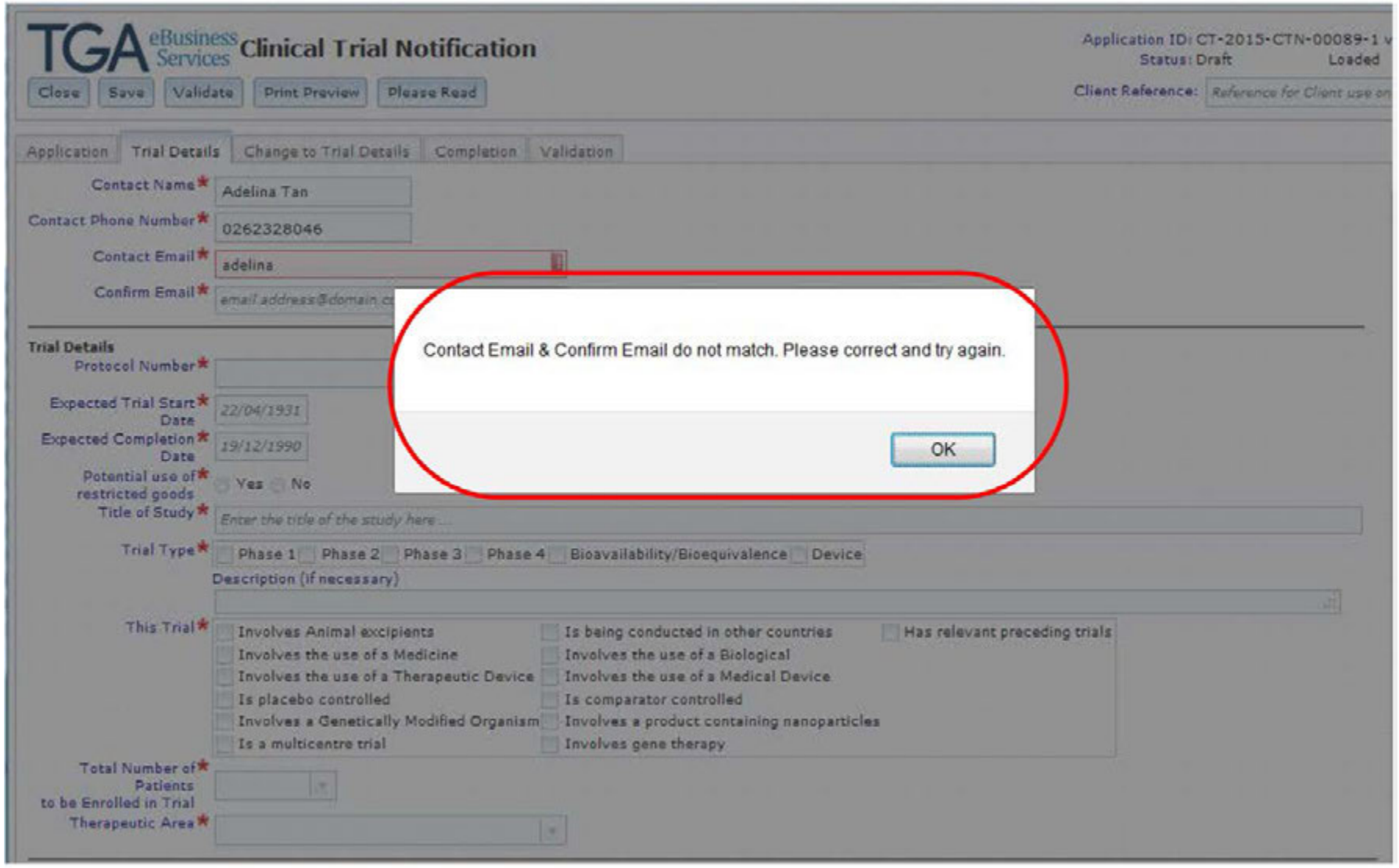
State
Principal Investigator
HREC Name
HREC Code
Approving Authority
Trial Sites Details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Adelina Tan
Contact Phone Number*
0262328046
Contact Email*
adelina
Confirm Email*
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Contact Email & Confirm Email do not match. Please correct and try again.
OK
Trial Details
Protocol Number*
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22/04/1931
Expected Completion Date*
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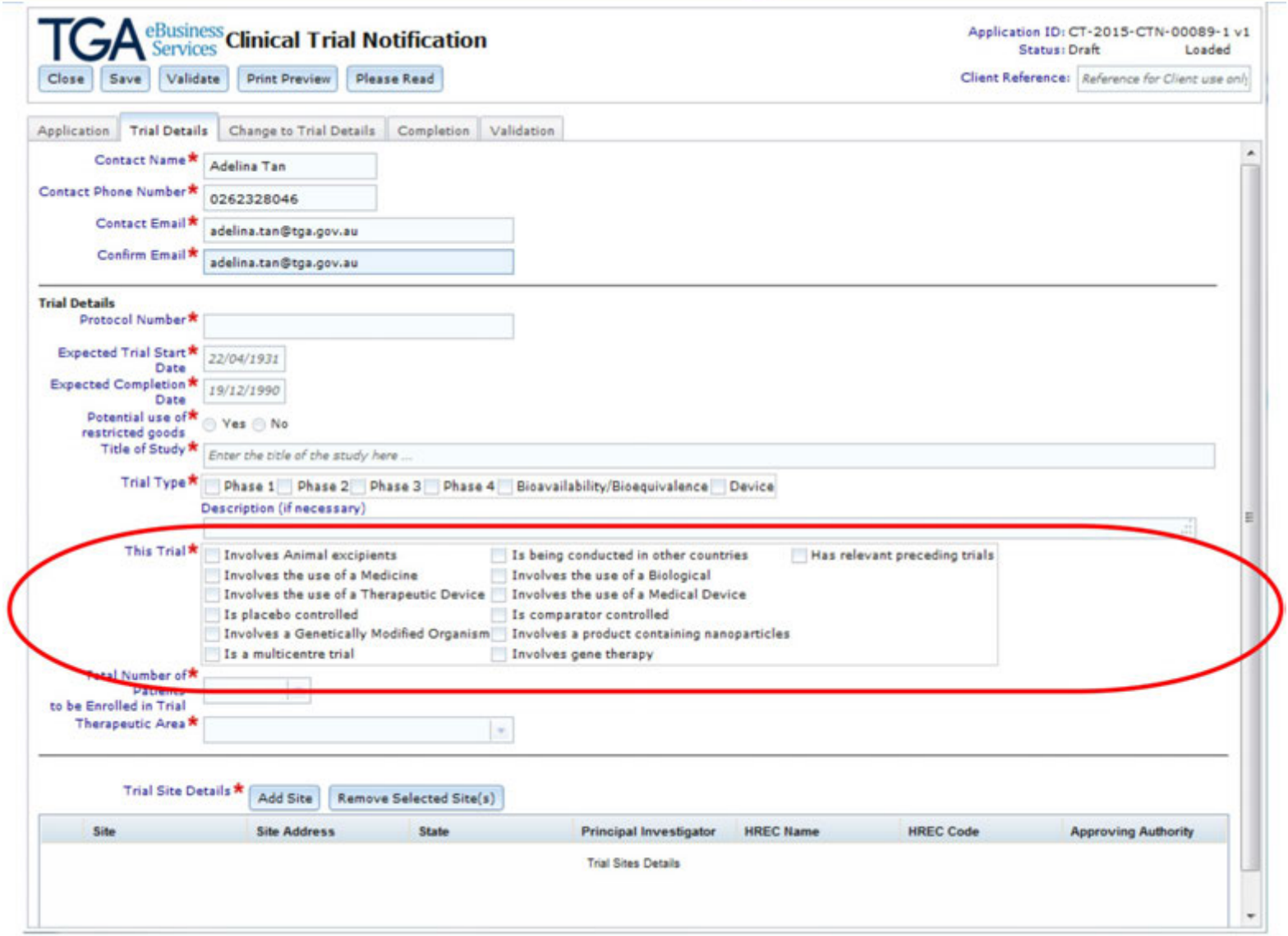
Involves gene therapy
Total Number of Patients to be Enrolled in Trial*
Therapeutic Area*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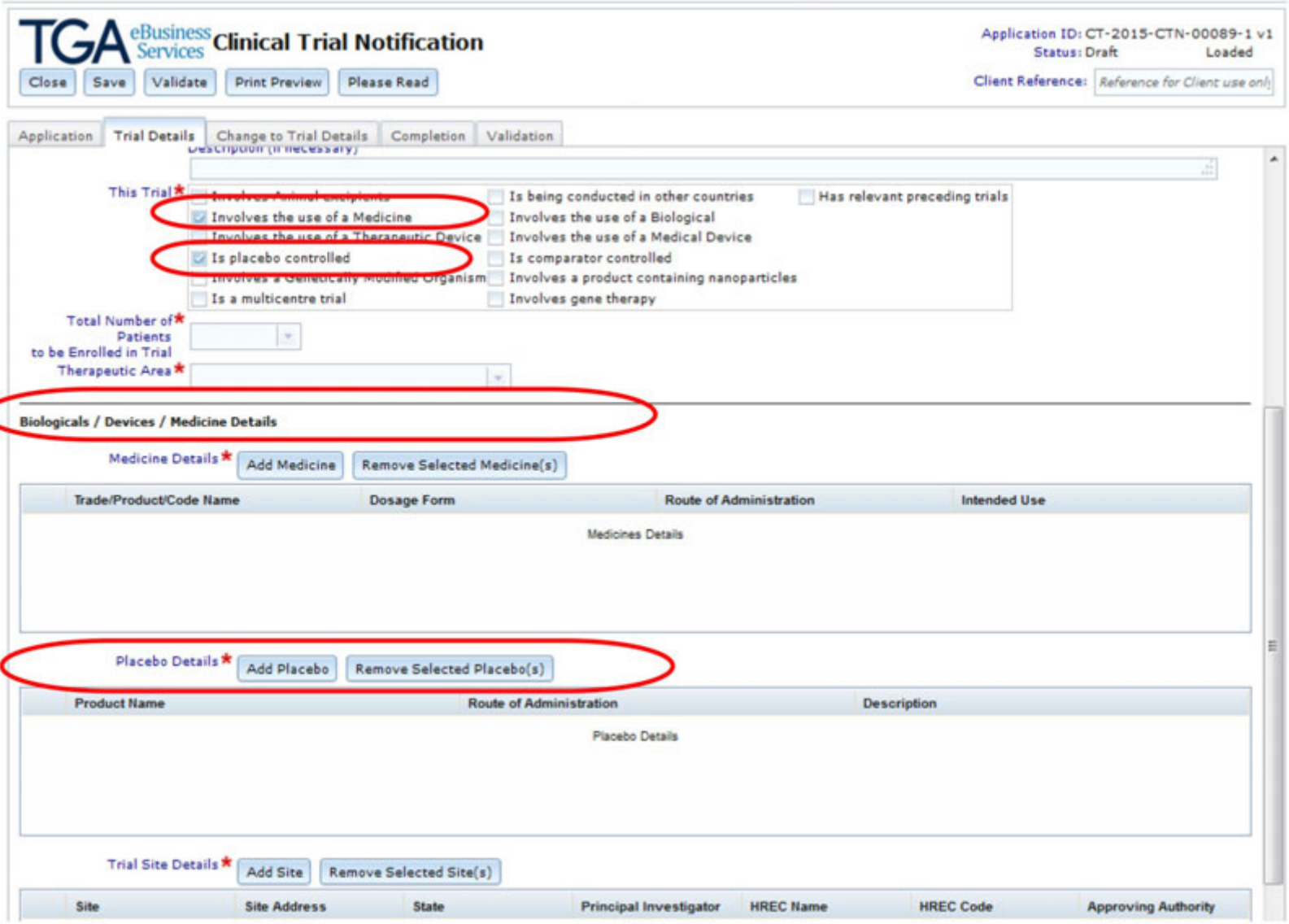
Contact Name * Adelina Tan
Contact Phone Number * 0262328046
Contact Email * adelina.tan@tga.gov.au
Confirm Email * adelina.tan@tga.gov.au
Trial Details
Protocol Number *
Expected Trial Start Date * 22/04/1931
Expected Completion Date * 19/12/1990
Potential use of restricted goods * Yes No
Title of Study * Enter the title of the study here ...
Trial Type * Phase 1 Phase 2 Phase 3 Phase 4 Bioavailability/Bioequivalence Device
Description (if necessary)
This Trial *
Involves Animal excipients
Involves the use of a Medicine
Involves the use of a Therapeutic Device
Is placebo controlled
Involves a Genetically Modified Organism
Is a multicentre trial
Is being conducted in other countries
Involves the use of a Biological
Involves the use of a Medical Device
Is comparator controlled
Involves a product containing nanoparticles
Involves gene therapy
Has relevant preceding trials
Total Number of Patients to be Enrolled in Trial *
Therapeutic Area *
Trial Site Details * Add Site Remove Selected Site(s)
Site Site Address State Principal Investigator HREC Name HREC Code Approving Authority
Trial Sites Details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Validate
Print Preview
Please Read
Application
Trial Details
Change to Trial Details
Completion
Validation
This Trial*
Involves the use of a Medicine
Is placebo controlled
Is a multicentre trial
Is being conducted in other countries
Involves the use of a Biological
Involves the use of a Medical Device
Is comparator controlled
Involves a product containing nanoparticles
Involves gene therapy
Has relevant preceding trials
Total Number of Patients to be Enrolled in Trial*
Therapeutic Area*
Biologicals / Devices / Medicine Details
Medicine Details*
Add Medicine
Remove Selected Medicine(s)
Trade/Product/Code Name
Dosage Form
Route of Administration
Intended Use
Medicines Details
Placebo Details*
Add Placebo
Remove Selected Placebo(s)
Product Name
Route of Administration
Description
Placebo Details
Trial Site Details*
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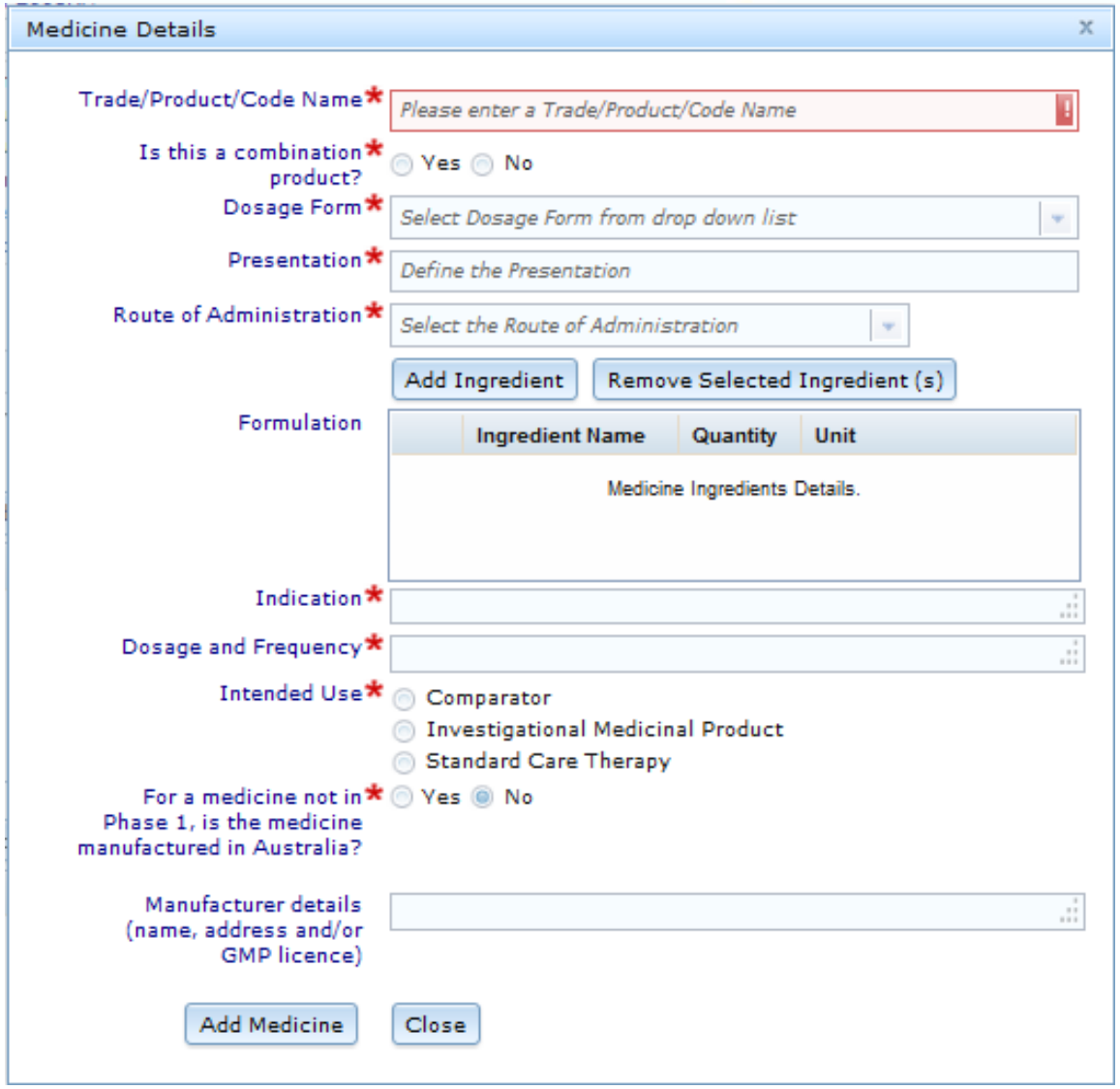
Remove Selected Site(s)
Site
Site Address
State
Principal Investigator
HREC Name
HREC Code
Approving Authority


Medicine Details
Trade/Product/Code Name*
Please enter a Trade/Product/Code Name
Is this a combination product?*
Yes
No
Dosage Form*
Select Dosage Form from drop down list
Presentation*
Define the Presentation
Route of Administration*
Select the Route of Administration
Add Ingredient
Remove Selected Ingredient (s)
Formulation
Ingredient Name
Quantity
Unit
Medicine Ingredients Details.
Indication*
Dosage and Frequency*
Intended Use*
Comparator
Investigational Medicinal Product
Standard Care Therapy
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Manufacturer details (name, address and/or GMP licence)
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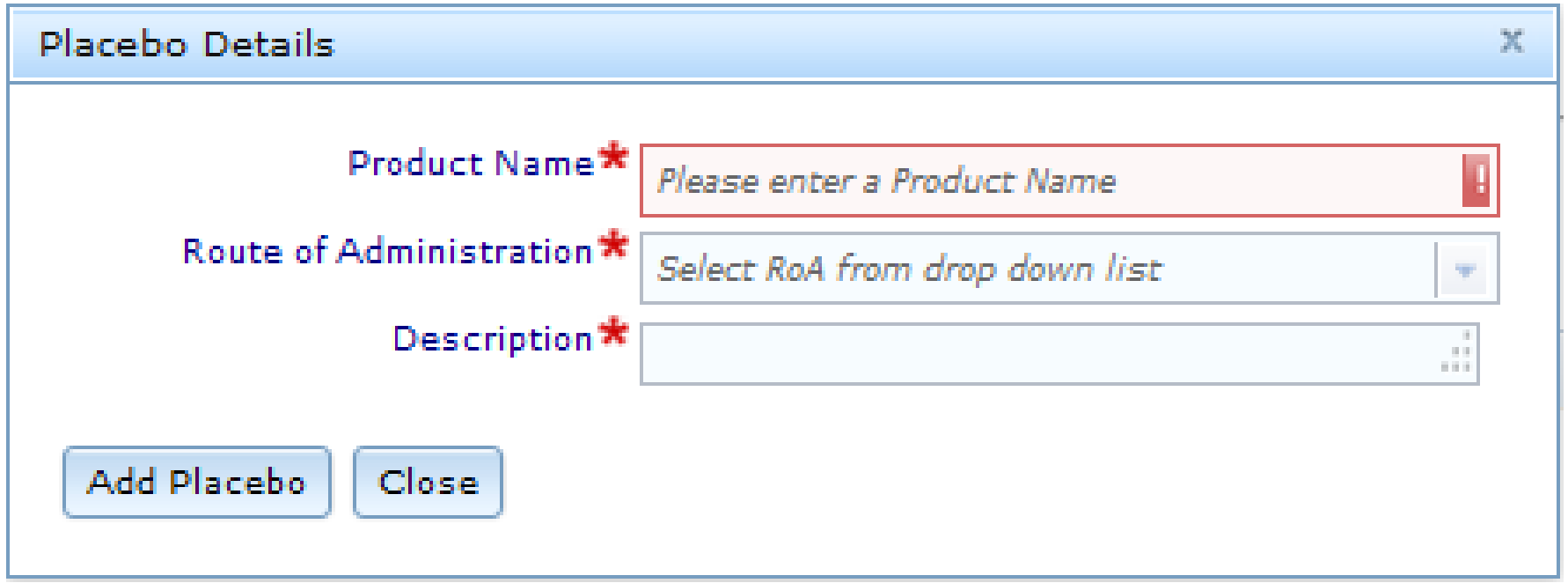
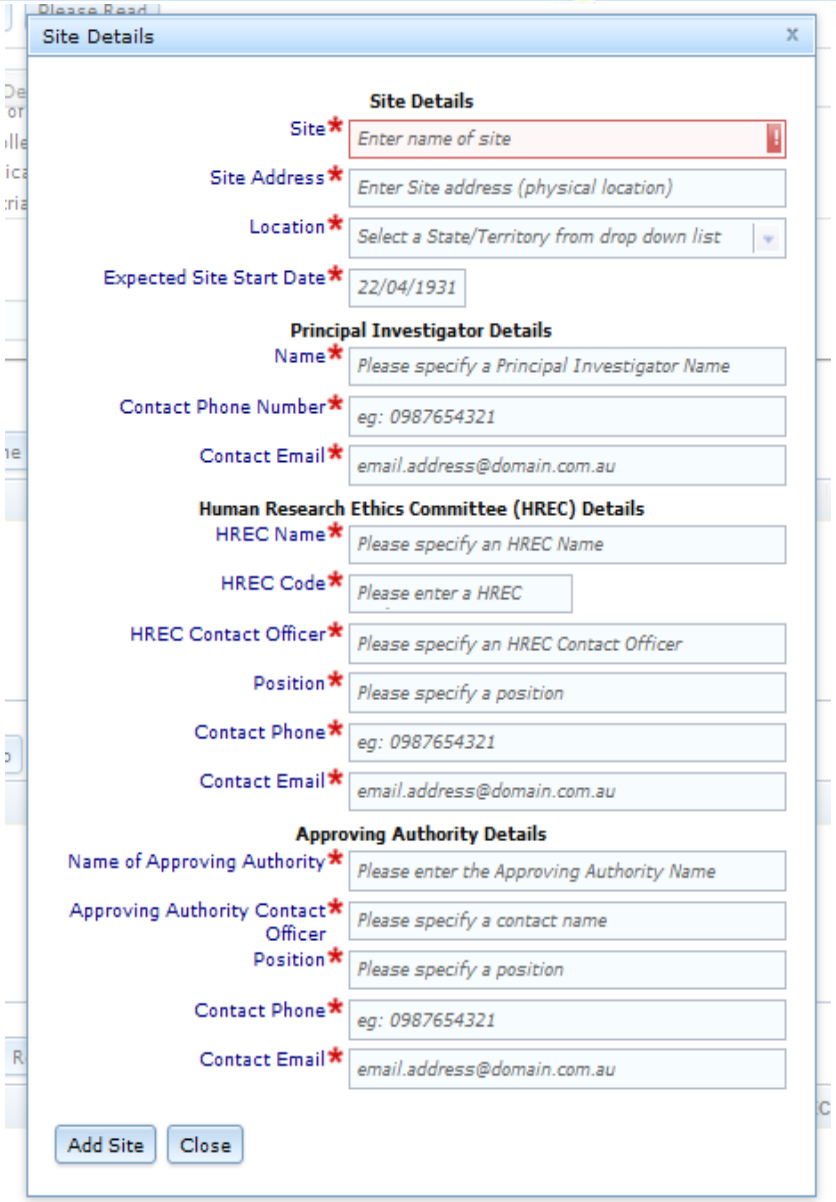


Why placebos should be entered on the CTN

Under the *Therapeutic Goods Act 1989*, therapeutic goods means goods:

(a) that are **represented in any way** to be…

(i) **for therapeutic use**; or…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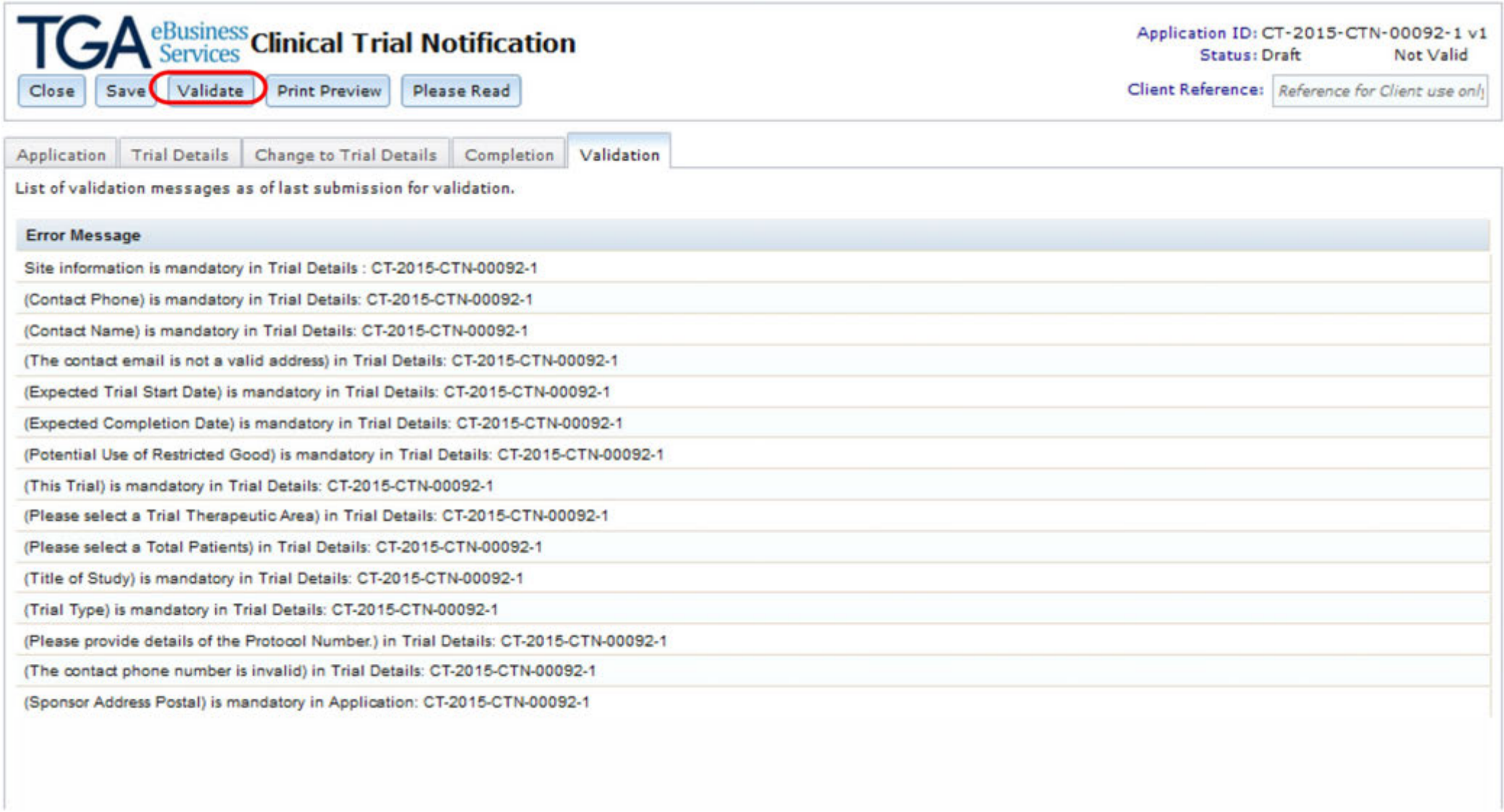
Site Address*
Enter Site address (physical location)
Location*
Select a State/Territory from drop down list
Expected Site Start Date*
22/04/1931
Principal Investigator Details
Name*
Please specify a Principal Investigator Name
Contact Phone Number*
eg: 0987654321
Contact Email*
email.address@domain.com.au
Human Research Ethics Committee (HREC) Details
HREC Name*
Please specify an HREC Name
HREC Code*
Please enter a HREC
HREC Contact Officer*
Please specify an HREC Contact Officer
Position*
Please specify a position
Contact Phone*
eg: 0987654321
Contact Email*
email.address@domain.com.au
Approving Authority Details
Name of Approving Authority*
Please enter the Approving Authority Name
Approving Authority Contact Officer*
Please specify a contact name
Position*
Please specify a position
Contact Phone*
eg: 0987654321
Contact Email*
email.address@domain.com.au
Add Site
Close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Trial Details
Change to Trial Details
Completion
Validation
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(The contact email is not a valid address) in Trial Details: CT-2015-CTN-00092-1
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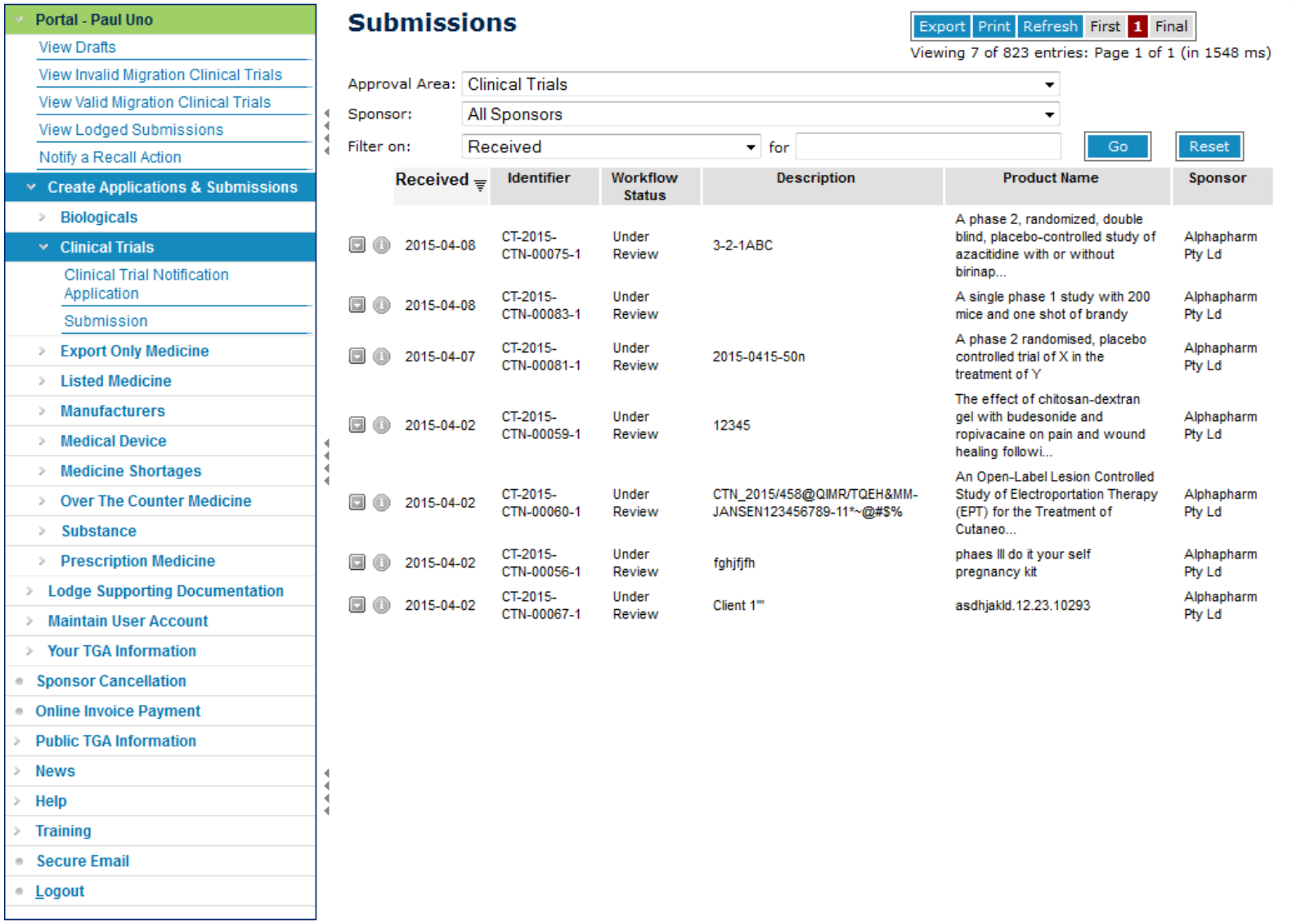
Portal - Paul Uno
View Drafts
View Invalid Migration Clinical Trials
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View Lodged Submissions
Notify a Recall Action
Create Applications & Submissions
Biologicals
Clinical Trials
Clinical Trial Notification Application
Submission
Export Only Medicine
Listed Medicine
Manufacturers
Medical Device
Medicine Shortages
Over The Counter Medicine
Substance
Prescription Medicine
Lodge Supporting Documentation
Maintain User Account
Your TGA Information
Sponsor Cancellation
Online Invoice Payment
Public TGA Information
News
Help
Training
Secure Email
Logout
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2015-04-08 CT-2015-CTN-00075-1 Under Review 3-2-1ABC A phase 2, randomized, double blind, placebo-controlled study of azacitidine with or without birinap... Alphapharm Pty Ld
2015-04-08 CT-2015-CTN-00083-1 Under Review A single phase 1 study with 200 mice and one shot of brandy Alphapharm Pty Ld
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2015-04-02 CT-2015-CTN-00059-1 Under Review 12345 The effect of chitosan-dextran gel with budesonide and ropivacaine on pain and wound healing followi... Alphapharm Pty Ld
2015-04-02 CT-2015-CTN-00060-1 Under Review CTN_2015/458@QIMR/TQEH&MM-JANSEN123456789-11*~@#$% An Open-Label Lesion Controlled Study of Electroportation Therapy (EPT) for the Treatment of Cutaneo... Alphapharm Pty Ld
2015-04-02 CT-2015-CTN-00056-1 Under Review fghjfjfh phaes III do it your self pregnancy kit Alphapharm Pty Ld
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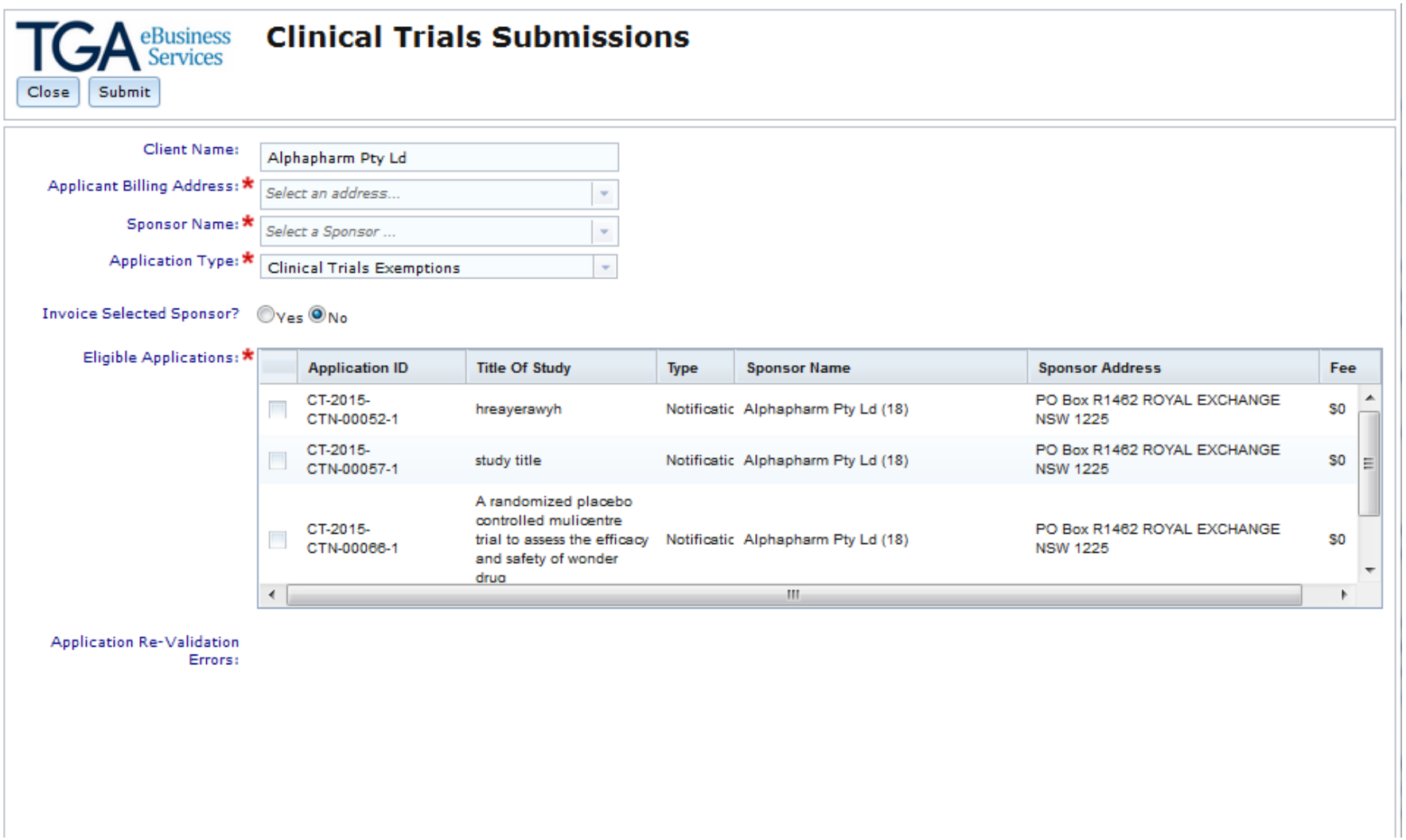
TGA eBusiness Services
Clinical Trials Submissions
Close
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Applicant Billing Address:*
Select an address...
Sponsor Name:*
Select a Sponsor ...
Application Type:*
Clinical Trials Exemptions
Invoice Selected Sponsor?
Yes
No
Eligible Applications:*
Application ID
Title Of Study
Type
Sponsor Name
Sponsor Address
Fee
CT-2015-CTN-00052-1
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Notificatic
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PO Box R1462 ROYAL EXCHANGE NSW 1225
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CT-2015-CTN-00066-1
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Notificatic
Alphapharm Pty Ld (18)
PO Box R1462 ROYAL EXCHANGE NSW 1225
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Application Re-Validation Errors:

TGA eBusiness Services

Clinical Trials Submissions

Close | Accept | Decline

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

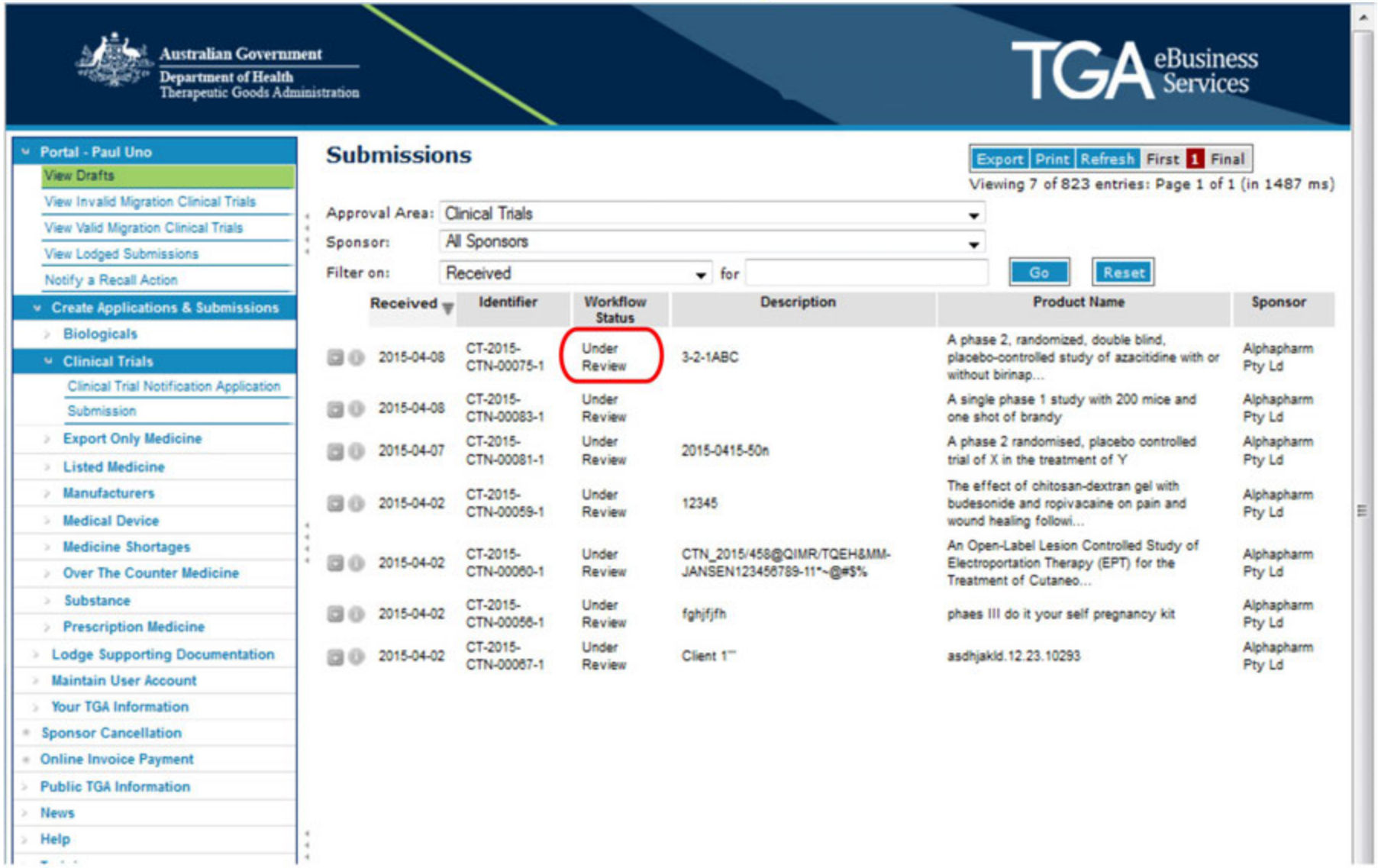
By clicking the **Accept** button:

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 responsiblity 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 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 committee that is not 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 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 or 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.


Australian Government
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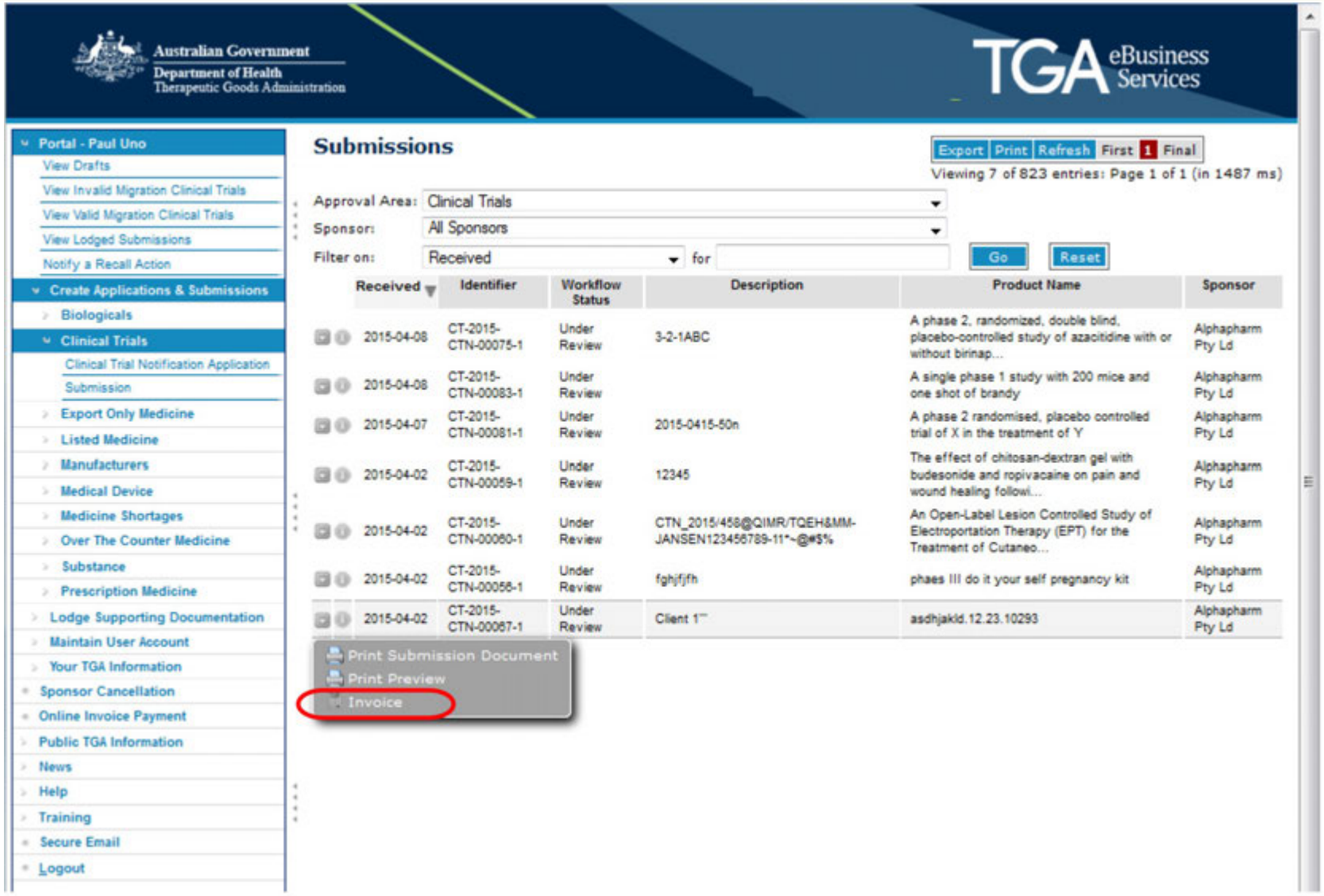
View Drafts
View Invalid Migration Clinical Trials
View Valid Migration Clinical Trials
View Lodged Submissions
Notify a Recall Action
Create Applications & Submissions
Biologicals
Clinical Trials
Clinical Trial Notification Application
Submission
Export Only Medicine
Listed Medicine
Manufacturers
Medical Device
Medicine Shortages
Over The Counter Medicine
Substance
Prescription Medicine
Lodge Supporting Documentation
Maintain User Account
Your TGA Information
Sponsor Cancellation
Online Invoice Payment
Public TGA Information
News
Help
Submissions
Export Print Refresh First 1 Final
Viewing 7 of 823 entries: Page 1 of 1 (in 1487 ms)
Approval Area: Clinical Trials
Sponsor: All Sponsors
Filter on: Received for
Go Reset
Received Identifier Workflow Status Description Product Name Sponsor
2015-04-08 CT-2015-CTN-00075-1 Under Review 3-2-1ABC A phase 2, randomized, double blind, placebo-controlled study of azacitidine with or without birinap... Alphapharm Pty Ld
2015-04-08 CT-2015-CTN-00083-1 Under Review A single phase 1 study with 200 mice and one shot of brandy Alphapharm Pty Ld
2015-04-07 CT-2015-CTN-00081-1 Under Review 2015-0415-50n A phase 2 randomised, placebo controlled trial of X in the treatment of Y Alphapharm Pty Ld
2015-04-02 CT-2015-CTN-00059-1 Under Review 12345 The effect of chitosan-dextran gel with budesonide and ropivacaine on pain and wound healing followi... Alphapharm Pty Ld
2015-04-02 CT-2015-CTN-00060-1 Under Review CTN_2015/458@QIMR/TQEH&MM-JANSEN123456789-11*~@#$% An Open-Label Lesion Controlled Study of Electroportation Therapy (EPT) for the Treatment of Cutaneo... Alphapharm Pty Ld
2015-04-02 CT-2015-CTN-00056-1 Under Review fghjfjfh phaes III do it your self pregnancy kit Alphapharm Pty Ld
2015-04-02 CT-2015-CTN-00057-1 Under Review Client 1''' asdhjakld.12.23.10293 Alphapharm Pty Ld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View Drafts
View Invalid Migration Clinical Trials
View Valid Migration Clinical Trials
View Lodged Submissions
Notify a Recall Action
Create Applications & Submissions
Biologicals
Clinical Trials
Clinical Trial Notification Application
Submission
Export Only Medicine
Listed Medicine
Manufacturers
Medical Device
Medicine Shortages
Over The Counter Medicine
Substance
Prescription Medicine
Lodge Supporting Documentation
Maintain User Account
Your TGA Information
Sponsor Cancellation
Online Invoice Payment
Public TGA Information
News
Help
Training
Secure Email
Logout
Submissions
Export Print Refresh First 1 Final
Viewing 7 of 823 entries: Page 1 of 1 (in 1487 ms)
Approval Area: Clinical Trials
Sponsor: All Sponsors
Filter on: Received for
Go Reset
Received | Identifier | Workflow Status | Description | Product Name | Sponsor
2015-04-08 | CT-2015-CTN-00075-1 | Under Review | 3-2-1ABC | A phase 2, randomized, double blind, placebo-controlled study of azacitidine with or without birinap... | Alphapharm Pty Ld
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2015-04-07 | CT-2015-CTN-00081-1 | Under Review | 2015-0415-50n | A phase 2 randomised, placebo controlled trial of X in the treatment of Y | Alphapharm Pty Ld
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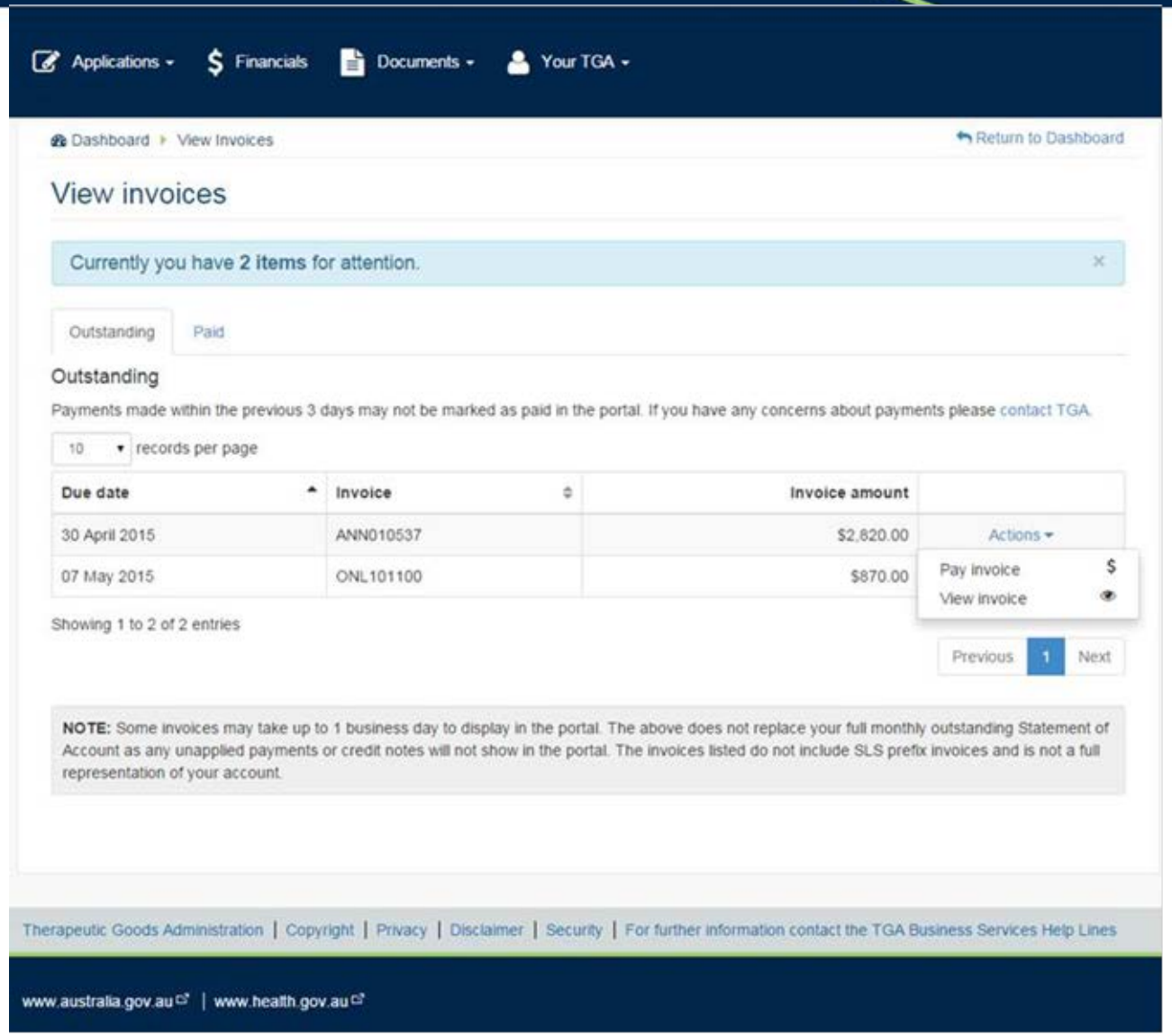
2015-04-02 | CT-2015-CTN-00056-1 | Under Review | fghjfjfh | phaes III do it your self pregnancy kit | Alphapharm Pty Ld
2015-04-02 | CT-2015-CTN-00067-1 | Under Review | Client 1"" | asdhjakld.12.23.10293 | Alphapharm Pty Ld
Print Submission Document
Print Preview
Invoice


Applications
Financials
Documents
Your TGA
Dashboard
View Invoices
Return to Dashboard
View invoices
Currently you have 2 items for attention.
Outstanding
Paid
Outstanding
Payments made within the previous 3 days may not be marked as paid in the portal. If you have any concerns about payments please contact TGA.
10
records per page
Due date
Invoice
Invoice amount
30 April 2015
ANN010537
$2,820.00
Actions
07 May 2015
ONL101100
$870.00
Pay invoice
View invoice
Showing 1 to 2 of 2 entries
Previous
1
Next
NOTE: Some invoices may take up to 1 business day to display in the portal. The above does not replace your full monthly outstanding Statement of Account as any unapplied payments or credit notes will not show in the portal. The invoices listed do not include SLS prefix invoices and is not a full representation of your account.
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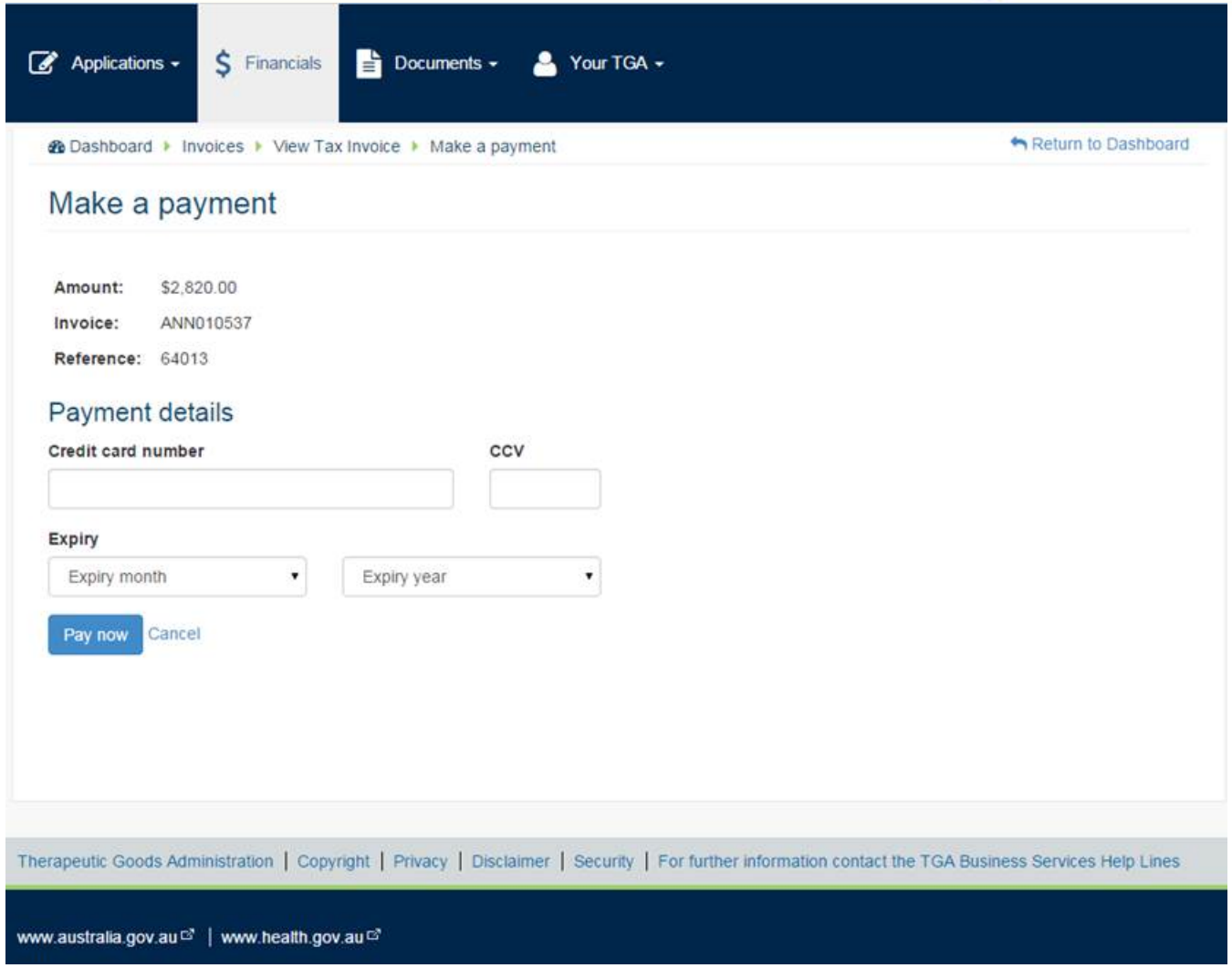
Applications
Financials
Documents
Your TGA
Dashboard
Invoices
View Tax Invoice
Make a payment
Return to Dashboard
Make a payment
Amount: $2,820.00
Invoice: ANN010537
Reference: 64013
Payment details
Credit card number
CCV
Expiry
Expiry month
Expiry year
Pay now
Cancel
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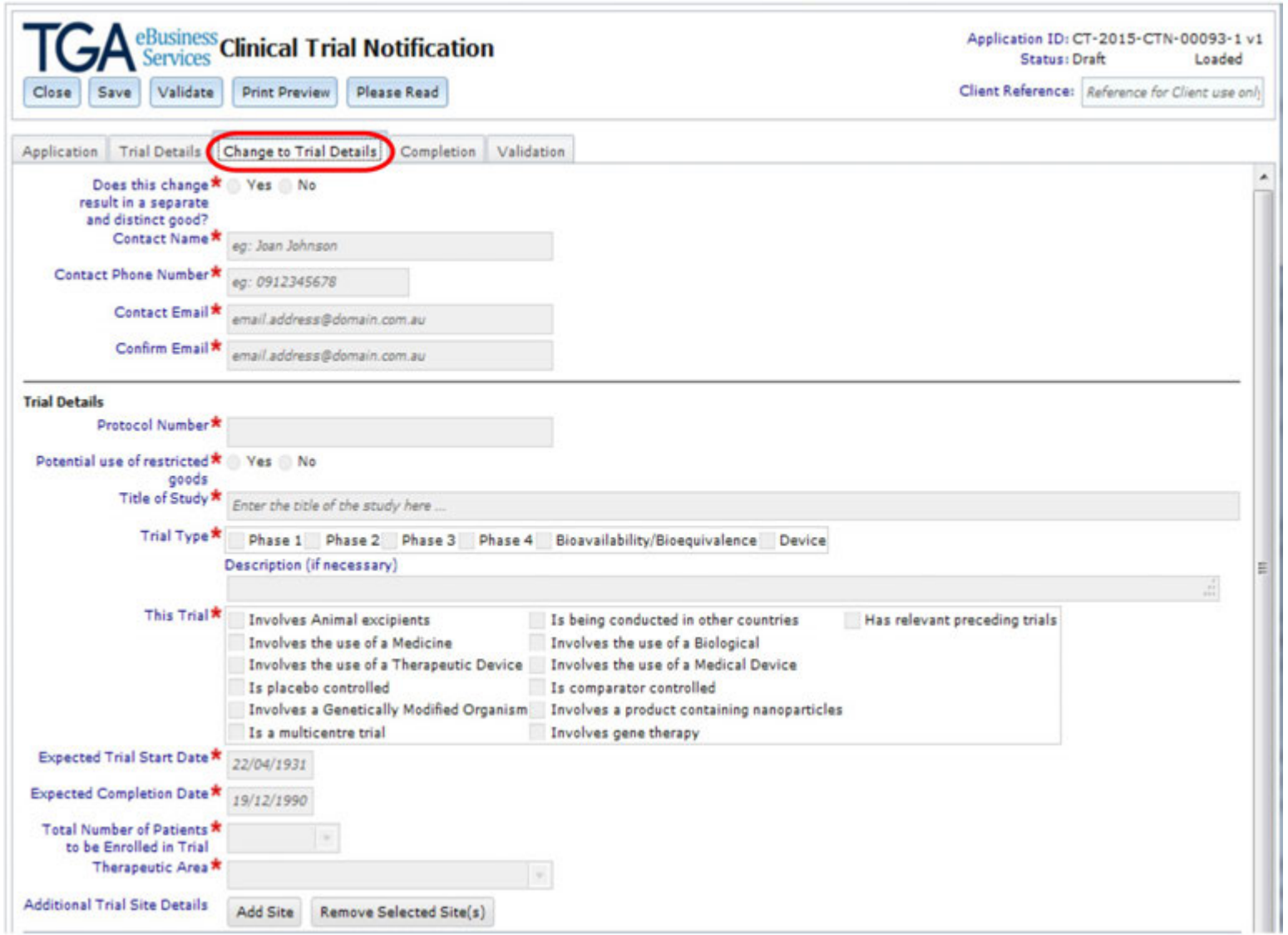
TGA eBusiness Services
Clinical Trial Notification
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Client Reference:
Reference for Client use only
Close
Save
Validate
Print Preview
Please Read
Application
Trial Details
Change to Trial Details
Completion
Validation
Does this change result in a separate and distinct good?
Yes
No
Contact Name
eg: Joan Johnson
Contact Phone Number
eg: 0912345678
Contact Email
email.address@domain.com.au
Confirm Email
email.address@domain.com.au
Trial Details
Protocol Number
Potential use of restricted goods
Yes
No
Title of Study
Enter the title of the study here ...
Trial Type
Phase 1
Phase 2
Phase 3
Phase 4
Bioavailability/Bioequivalence
Device
Description (if necessary)
This Trial
Involves Animal excipients
Is being conducted in other countries
Has relevant preceding trials
Involves the use of a Medicine
Involves the use of a Biological
Involves the use of a Therapeutic Device
Involves the use of a Medical Device
Is placebo controlled
Is comparator controlled
Involves a Genetically Modified Organism
Involves a product containing nanoparticles
Is a multicentre trial
Involves gene therapy
Expected Trial Start Date
22/04/1931
Expected Completion Date
19/12/1990
Total Number of Patients to be Enrolled in Trial
Therapeutic Area
Additional Trial Site Details
Add Site
Remove Selected Site(s)

Questions?

Enquiries: clinical.trials@tga.gov.au

Australian Government

Department of Health

Therapeutic Goods Administration