Australian Government
Department of Health
Therapeutic Goods Administration

Online Clinical Trial Notification (CTN)

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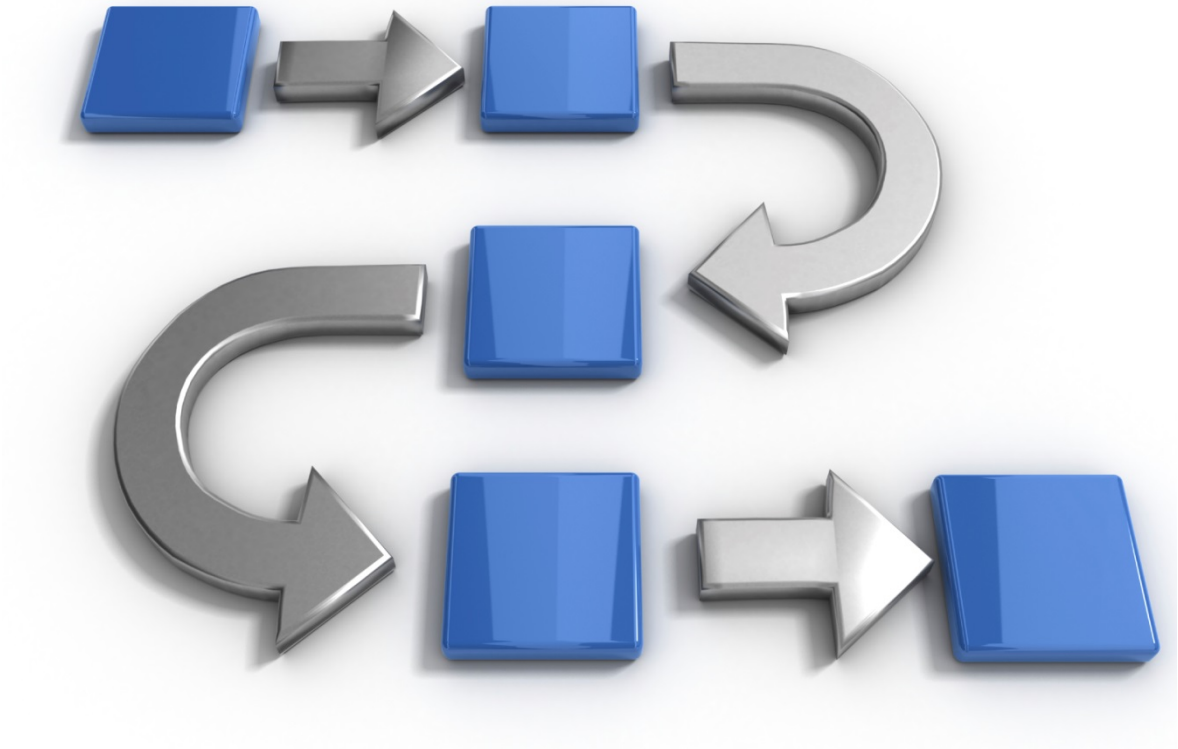
Pharmacovigilance & Special Access Branch
Medicines Regulation Division, TGA

24 November 2016

TGA Health Safety Regulation

Overview

- Background
- How to Access the Online Form
- Guidance on using the new Online CTN form
- Clinical trials FAQs



Background - TGA's role differs from other regulators

- Exemption provided for unapproved therapeutic goods rather than end-to-end regulation of trials
  - CTN – Section 18(1) of the Therapeutic Goods Act 1989
  - CTX – Section 19(1)(b) of the Therapeutic Goods Act 1989

- Biologicals
  - CTN – Section 32CA(2) of the Act, Regulation 12(2) – Schedule 5A, Item 3
  - CTX – Section 32CK(1), 32CL of the Act, Regulation 12AA, 12AB, 12AC, 32AD

- **CTN or CTX required** for supply of any unapproved good in a clinical trial

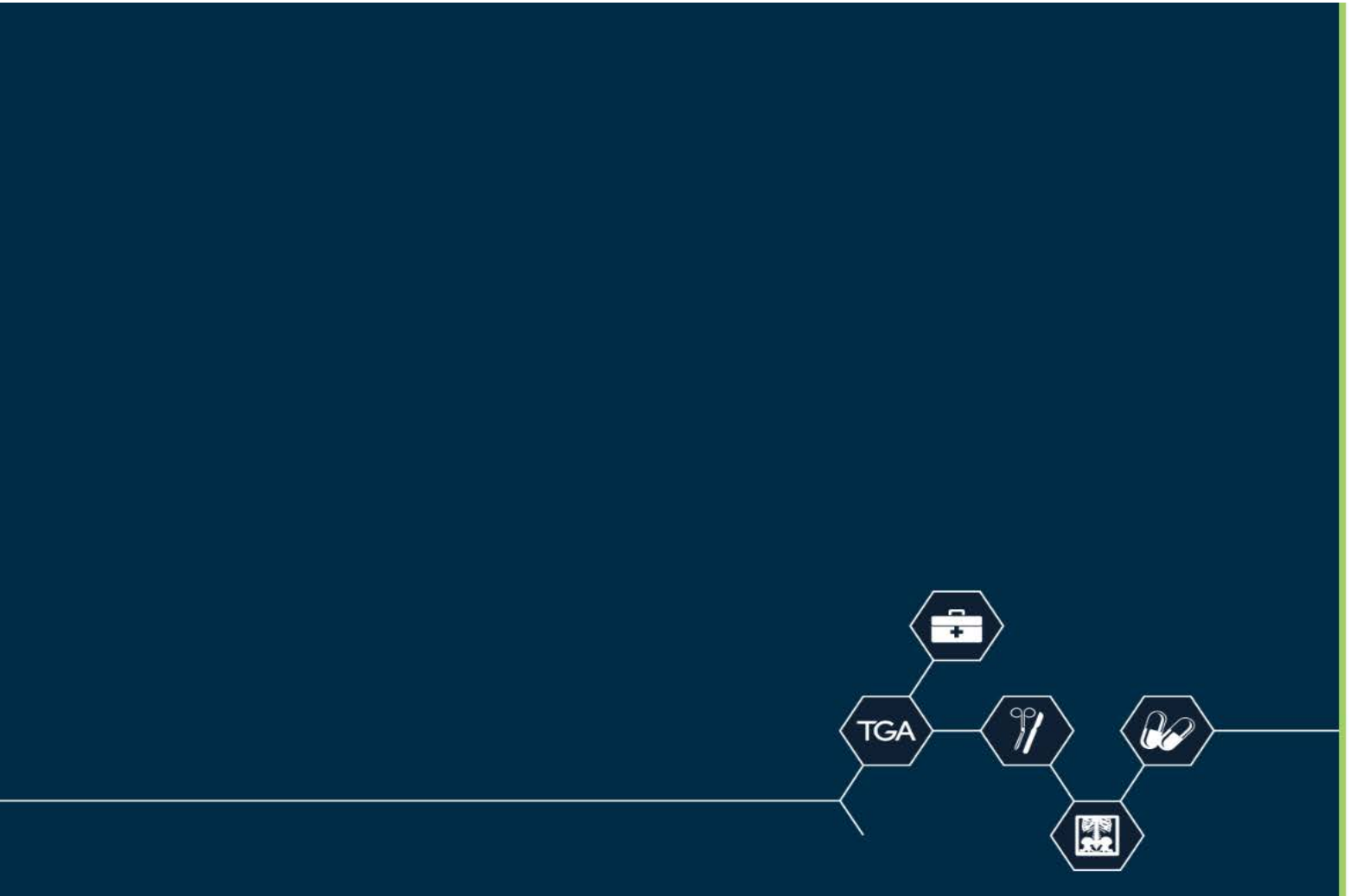
Online vs Paper based CTN – Sponsor Requirements

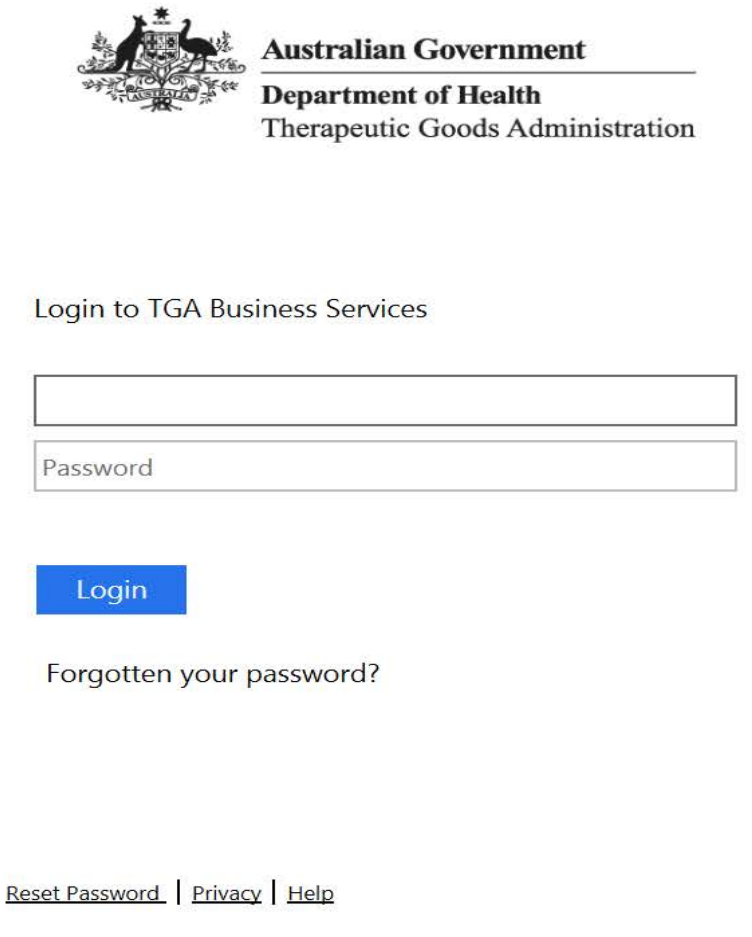
Online	Paper based
Online sponsor declaration - no signatures required	Four signatures required (HREC, Principal Investigator, Approving Authority, Sponsor)
Manage and track CTN's via the TGA Business Services (TBS) dashboard	Track CTNs via paper files
Vary trials electronically, change relevant element	Variations required submission of all information again on paper with relevant signatures
Online invoices for initial CTN. Online payment portal. ***No invoice for variations	No invoice generated prior to payment. Online Payment portal

Where are we up to in the implementation.

- Data from clinical trials will be moved into the relevant fields in TBS
  - From 7 December 2015
    - Sponsors to review CTN information/Confirm Migration/Active or Closed
  - By 29 September 2016
    - 77.6% of trials Migrated and 335 closed

Submission of notification via Online Form





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Welcome Jamie Chang

What would you like to do today?

Boston Scientific Pty Ltd (23932)

ABN:45071676063
ACN:071676063

View my organisation

My work

Work on drafts
View submissions

News panel — View more news

Listed medicines with blood glucose and cholesterol indications 12/07/2016
The TGA will be initiating targeted compliance reviews for Listed medicines that have indications relating to blood glucose or cholesterol biomarkers....

Medical Device Mandatory Audit Timeframes 03/06/2016
Planning ARTG inclusion for your Class III or AIMD medical device? Note that mandatory audits for these medical devices are currently delayed due to a...

Update to ingredient names - OTC and Registered complementary 05/05/2016

Work in progress — View all drafts

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Department of Health

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

Application | Trial Details | Change to Trial Details | Completion | Validation messages

* Always Required * Required under certain conditions

Contact Name * — eg: Joan Johnson

Contact Phone Number * — eg: 0987654321

Contact Email * — email.address@domain.com.au

Confirm Email — email.address@domain.com.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

Brief Description of Trial

This Trial *

- [ ] Involves Animal excipients
- [x] Involves the use of a Medicine
- [ ] Involves the use of a Therapeutic Device
- [x] Is placebo controlled
- [ ] Involves a Genetically Modified Organism
- [ ] Is a multicentre trial in Australia
- [ ] Is being conducted in other countries
- [x] Involves the use of a Biological
- [x] Involves the use of a Medical Device
- [ ] Is comparator controlled
- [ ] Involves gene therapy
- [ ] Has relevant preceding trials

Total number of participants to be enrolled in the Trial

Therapeutic Area

Biological Details

* Always Required * Required under certain conditions

Trade/Product/Code Name *: Please enter a Product Name

Is this a combination product? *: Yes / No

Type of container *:

Dosage Form *: Select a Dosage Form

Route of Administration *: Select the Route of Administration

Add ingredients | Remove Selected Ingredient (s)

Ingredients

Name	Quantity	Unit	Country of origin	Open
Biolgical Ingredients Details.				

Save & Close | Close

Biological Ingredient Details

* Always Required * Required under certain conditions

Ingredient Name *:

Quantity *: Please enter

Unit *:

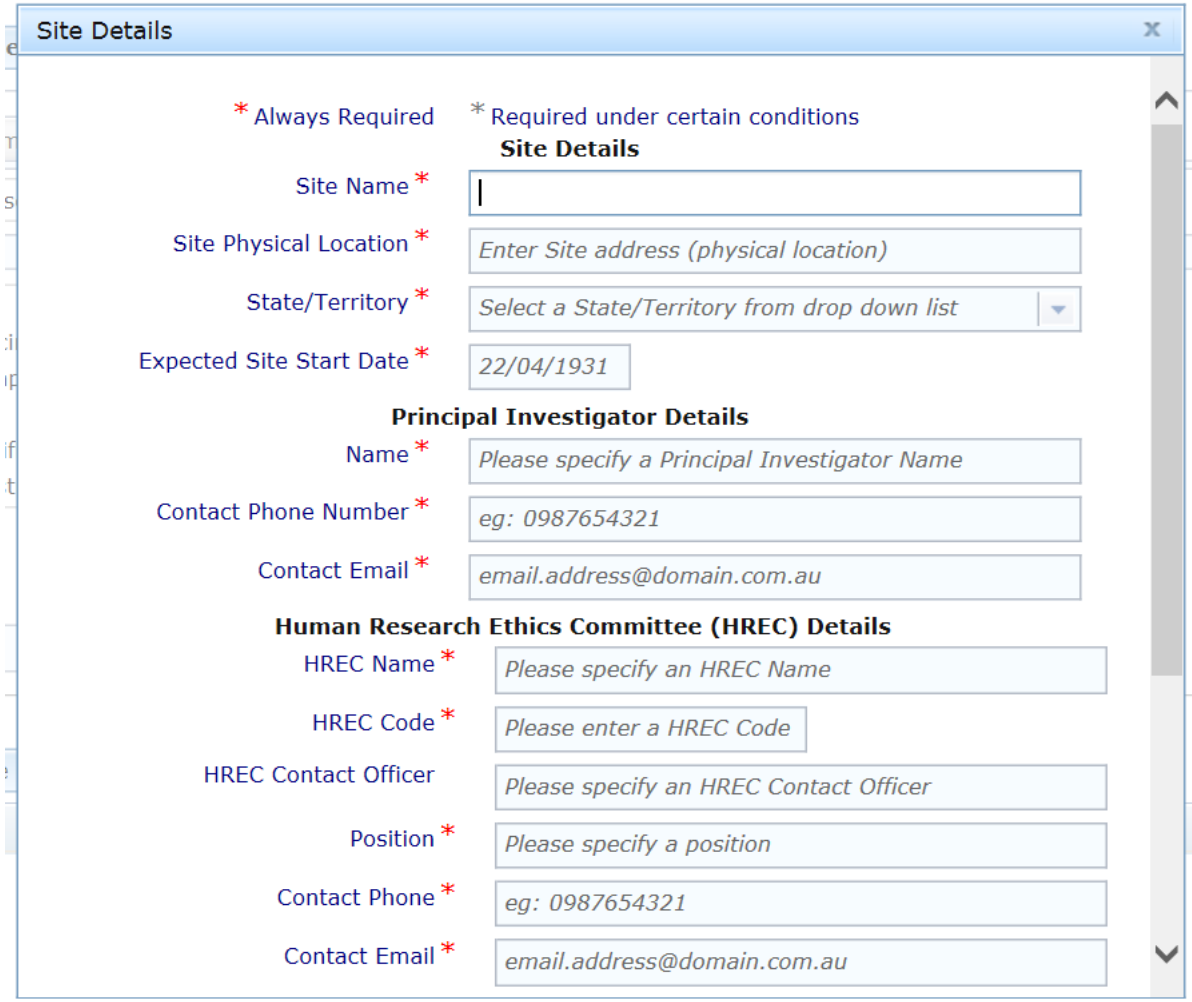
Country of Origin: Select Country then Click Add

Add Country | Remove Country(ies)

Countries Selected

Save & Close | Close

Notification



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TGA eBusiness Services Clinical Trial Notification

Application ID: CT-2016-CTN-03117-1 v1
Status: Draft Not Valid

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

Client Reference: *Reference for Client use only*

Application | Trial Details | Change to Trial Details | Completion | Validation messages

Validation Messages

(Title of Study) is mandatory in Trial Details: CT-2016-CTN-03117-1
(Contact Phone) is mandatory in Trial Details: CT-2016-CTN-03117-1
(Expected Trial Start Date) is mandatory in Trial Details: CT-2016-CTN-03117-1
(The contact email is not a valid address) in Trial Details: CT-2016-CTN-03117-1
(Potential Use of Restricted Good) is mandatory in Trial Details: CT-2016-CTN-03117-1
(Expected Completion Date) is mandatory in Trial Details: CT-2016-CTN-03117-1
Placebo information is mandatory in Trial Details : CT-2016-CTN-03117-1
MedicineIngredient information is mandatory in Trial Details : CT-2016-CTN-03117-1
Site information is mandatory in Trial Details : CT-2016-CTN-03117-1
Medicine information is mandatory in Trial Details : CT-2016-CTN-03117-1
(Trial Type) is mandatory in Trial Details: CT-2016-CTN-03117-1
(Contact Name) is mandatory in Trial Details: CT-2016-CTN-03117-1
(Please provide details of the Protocol Number.) in Trial Details: CT-2016-CTN-03117-1

TGA eBusiness Services

Clinical Trials Submissions

Close | Submit

Client Name:

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	hreayerawyh	Notificatic			$0
	CT-2015-CTN-00057-1	study title	Notificatic			$0
	CT-2015-CTN-00066-1		Notificatic			$0

Application Re-Validation Errors:

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TGA eBusiness Services

Clinical Trials Submissions

Sponsor Declaration

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:

- 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 (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 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.

Sponsor Declaration

- Online sponsor declaration states in regards to ethics approvals:
- 1. 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
- 2. the sponsor has not received advice from the ethics committee that is inconsistent with the continuation of the trial
- 3. 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

Portal -
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

Approval Area: Clinica
Sponsor: All Spo
Filter on: Receiv

Received	
2015-04-08	CT C
2015-04-08	CT C
2015-04-07	CT C
2015-04-02	CT C
2015-04-02	CT C
2015-04-02	CT C
2015-04-02	CT C

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ABN: 40 939 406 804

Tax Invoice

Tax Invoice	ONL100478
Date of Issue	02/04/2015
Invoice Total	$0.00

Client ID	Enquiries	Phone	Fax	Contact Email Address
18	TGA Accounts Receivable	(02) 6232 8228	(02) 6232 8222	accountsrec@tga.gov.au

Identifier	Description	Unit Price	GST	Total
CT-2015-CTN-00067-1~1	asdhjakld.12.23.10293	$0.00	$0.00	$0.00

Application fees are exempt from GST under Division 81 of A New Tax System (Goods & Services Tax) Act 1999

Subtotal	$0.00
GST	$0.00
Total	**$0.00**

PAYMENT OPTIONS

Please always quote your Client ID and the Payment Reference Number.

On-Line Payment: Payment can be made with credit card or direct debit via:
http://www.tga.gov.au/about/fees-payments-options.htm
or use the Online Invoice Payment link on our eBS portal

Cheques payable to: Therapeutic Goods Administration, PO Box 100, Woden ACT 2606

EFT Payments: Therapeutic Goods Administration BSB: 032-747 Account No: 156-050

NOTE: Applications will be withdrawn automatically if payment is not remitted in full within 14 days. Additionally, failure to remit payment by the due date for annual charges relating to a listing, registration or inclusion on the ARTG or for a manufacturing licence may result in the cancellation of the product or licence.

Client ID. 18 Payment Reference No. 1004787

A Receipt will only be issued on request

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

Biller Code: 1001822 - Payment of Invoice (Demo Merchant 428)

Client Identification Number:

Invoice Number:

Email Address for Tax Receipt:

Amount: $

Select your payment option: MasterCard VISA

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9.0 Acceptance

- Portal - Jamie Chang
  - View Drafts
  - View Lodged Submissions
- Create Applications & Submissions
  - Annual Charge Exemption
  - Biologicals
  - Listed Medicine
  - Clinical Trials
    - Clinical Trial Notification
    - Submission
  - Export Only Medicine
  - Manufacturers
  - Medical Device
  - Medicine Shortages
  - Non-Prescription Medicines
  - Prescription Medicine
  - Regulatory Actions
- Lodge Supporting Documentation
- Your TGA Information
  - Current ARTG Entries
  - Clinical Trials Repository
  - Consumer Medicine and Product Information

Clinical Trials Repository

Export | Print | Refresh | First | 1 | 2 | Final

Viewing 30 of 30 entries: Page 1 of 2 (in 1490 ms)

Sponsor: All Sponsors

Filter on: Date for [ ] Go Reset

Date	Identifier	Client Reference	Stage	Information	Sponsor
2016-07-29	CT-2016-CTN-01321-1-v2		Trial Details	(S2060) EVOLVE: "A prospective randomized multicenter single-blind non-inferiority trial to assess the safet...	Boston Scientific Pty Ltd
	2016-CTN-03-1-v3		Trial Details	(test) Test for dup issue and variation code fix	Boston Scientific Pty Ltd
	2015-CTN-29-1-v1		Completion	(91003730) (LEVER) Low Energy Therapy Application to Convert Ventricular Tachycardias	Boston Scientific Pty Ltd
	2015-CTN-13-1-v4		Variation	(S2332) REPRISE NG DS: REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantatio...	Boston Scientific Pty Ltd
2016-06-06	CT-2016-CTN-01654-1-v1		Completion	(S2060) EVOLVE: "A prospective randomized multicenter single-blind non-inferiority trial to assess the safet...	Boston Scientific Pty Ltd
2016-05-12	CT-2015-CTN-00987-1-v5		Variation	The Fully Absorbable Scaffold Study (FAST Feasibility Study) is an assessment of safety and performa...	Boston Scientific Pty Ltd
2016-03-24	CT-2015-CTN-00259-1-v5		Variation	REPRISE III: REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation o...	Boston Scientific Pty Ltd
2016-01-05	CT-2014-CTN-00145-0-v1	00145 - Migrated CT Trial	Trial Details	MAJESTIC: Stenting of the Superficial Femoral and/or Proximal Popliteal Artery Project with Boston S...	Boston Scientific Pty Ltd
2016-01-05	CT-2015-CTN-00169-0-v1	00169 - Migrated CT Trial	Trial Details	Zero-AF: Clinical evaluation of the Blazer Open-Irrigated Ablation Catheter for treatment of Paroxys...	Boston Scientific Pty Ltd
2016-01-05	CT-2015-CTN-00115-0-v1	00115 - Migrated CT Trial	Trial Details	EVOLVE II: A Prospective Multicentre Trial to Assess the Safety and Effectiveness of the SYNERGY(TM)...	Boston Scientific Pty Ltd
2016-01-05	CT-2015-CTN-00114-0-v1	00114 - Migrated CT Trial	Trial Details	EVOLVE II QCA: A prospective, multicentre trial to assess the SYNERGY(TM) Everolimus-Eluting Platinu...	Boston Scientific Pty Ltd
2014-09-12	CT-2014-CTN-01118-1-v1	240/2013 - 2013/018516	Trial Details	The SAMURAI Study is a prospective, open-label, two-group randomised clinical study with parallel gr	Boston Scientific Pty Ltd

- Next Stage
- Vary
- Complete
- Print Preview

Close Print

Clinical Trial CT-2016-CTN-03103-1 v3 Repository

Submission Date: 29/07/2016
Acknowledged by TGA

Application

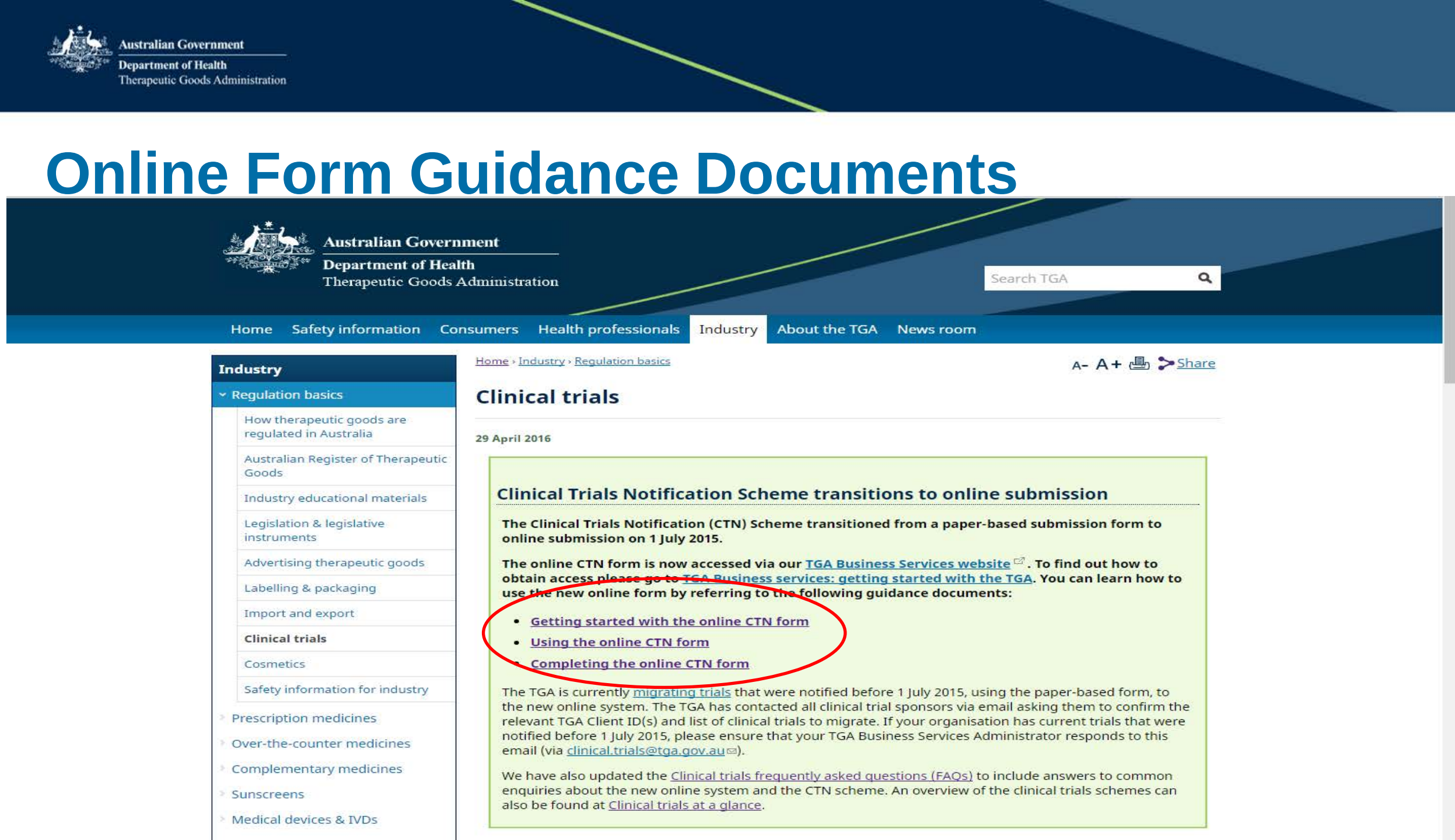
Sponsor Name	Boston Scientific Pty Ltd
Sponsor Address	PO Box 332 BOTANY NSW 1455
Notification Fee	$0

Trial Details

Contact Name	Jess
Contact Phone Number	0200000000
Contact Email	j@m.com
Protocol Number	test
Expected Trial Start Date	29/07/2016
Expected Completion Date	06/08/2016
Potential Use of Restricted Goods	No
Title of Study	Test for dup issue and variation code fix
Trial Type	Phase 1
This Trial	Is placebo controlled Involves gene therapy

Placebos

Online Form Guidance Documents



Clinical trial FAQs

How is the CTN process interlinked with Human Research Ethics Committee (HREC) approval?

- As defined in the Regulations, the clinical trial sponsor must acknowledge that the goods only remain exempt so long as:
  - appropriate advice has been received from HREC
  - the trial is conducted in accordance with the:
    - Guidelines for Good Clinical Practice
    - National Statement on the Ethical Conduct in Research involving Humans (published by the National Health and Medical Research Council).
- This is also stated in the online sponsor declaration accepted prior to submitting the CTN.
- TGA has amended the print preview function to allow documents to be printed at the draft submission or finalised notification stage.

Any comments or questions?

Enquiries: clinical.trials@tga.gov.au

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