

From: s22 [redacted] on behalf of [Clinical Trials](#)
To: s47G [redacted]
Subject: CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v1 - Acknowledgement letter [SEC=UNCLASSIFIED]
Date: Tuesday, 11 October 2016 6:26:34 PM
Attachments: [image001.emz](#)
[image003.png](#)
[image004.png](#)
[CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v1 - Acknowledgement letter.pdf](#)

Dear Regulatory Affairs

Thank you for your Clinical Trial Notification (CTN), Application ID: CT-2016-CTN-02896-1 v1. Please see your CTN acknowledgement letter attached. Your CTN has been processed by the TGA and can now be viewed via the '[Clinical Trials Repository](#)' section of your [online TBS Portal menu](#).

Please review the attached correspondence and ensure that all the details are presented correctly as per the online notification submitted. If you believe any corrections are required please contact the Clinical Trials team as soon as possible.

I trust this information is of assistance. Please contact the clinical trials team at clinical.trials@tga.gov.au for any further information or clarification.

Kind regards,

s22 [redacted]
Clinical Trials Administration
Experimental Products Section
Pharmacovigilance and Special Product Access Branch

Phone: s22 [redacted]
Fax: s22 [redacted]
Email: clinical.trials@tga.gov.au

Therapeutic Goods Administration
Australian Government Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.



Australian Government
Department of Health
 Therapeutic Goods Administration

Regulatory Affairs

s47G

CTN SCHEME: ACKNOWLEDGEMENT OF CLINICAL TRIAL NOTIFICATION

Your notification to conduct a clinical trial under the Clinical Trial Notification (CTN) Scheme, pursuant to Schedule 5A of the *Therapeutics Goods Regulations 1990* and/or Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* has been received by the Therapeutic Goods Administration (TGA).

Study Sponsor: s47G
 Protocol Number: VX15-770-124
 Application ID: CT-2016-CTN-02896-1 v1

Details of Therapeutic Goods Notified:

- **Medicine(s):**

Trade / Product / Code Name	Ingredient Name(s) Quantity Unit	Dosage Form	Type of Container
Ivacaftor	Ivacaftor 25 Milligram	Granules	Sachet (Foil-laminated)
Ivacaftor	Ivacaftor 50 Milligram	Granules	Sachet (Foil-laminated)
Ivacaftor	Ivacaftor 75 Milligram	Granules	Sachet (Foil-laminated)

- **Device(s):**

Device Name	Manufacturer	GMDN Code
Procedure Pack	ICON Central Laboratories, Inc.	

Device Name	Manufacturer	GMDN Code
Electrocardiograph Eli 150c	s47G	
Macroduct Sweat Collection System	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA	

Details of Site(s) Notified:

Site Name	State	Site Expected Start Date
The Sydney Children's Hospitals Network - Westmead	NSW	24/10/2016

In notifying this clinical trial the sponsor of the trial has acknowledged 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 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.

Please note that:

- i. the Therapeutic Goods Administration has not carried out an assessment of the quality, safety or efficacy of any therapeutic good in relation to this notification.
- ii. in the event that the Secretary of the Commonwealth Department of Health becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, the Secretary has the authority to direct that use of the therapeutic good(s) for this clinical trial must cease.
- iii. the clinical trial sponsor is still required to comply with any relevant state and territory legislation that might apply in relation to the supply of the therapeutic product(s).

If there are any changes to the trial details notified to the TGA, it would be necessary for the sponsor to update the relevant fields on the online CTN form.

Kind Regards

[s22](#)

Clinical Trials Administration
Experimental Products Section

11 October 2016

From: S22 on behalf of [Clinical Trials](#)
To: S47G
Subject: CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v2 - Acknowledgement letter [SEC=UNCLASSIFIED]
Date: Thursday, 22 December 2016 2:25:50 PM
Attachments: [CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v2 - Acknowledgement letter.pdf](#)
[image003.png](#)
[image001.wmz](#)
[image002.png](#)

Dear Regulatory Affairs,

Thank you for your Clinical Trials Notification (CTN), Application ID: CT-2016-CTN-02896-1 v2. Please see your CTN acknowledgement letter attached. Your CTN has been processed by the TGA and can now be viewed via the '[Clinical Trials Repository](#)' section of your [online TBS Portal menu](#).

Please review the attached correspondence and ensure that all the details are presented correctly as per the online notification submitted. If you believe any corrections are required please contact the Clinical Trials team as soon as possible.

I trust this information is of assistance. Please contact the clinical trials team at clinical.trials@tga.gov.au for any further information or clarification.

Kind regards,

Clinical Trials Administration
Pharmacovigilance and Special Access Branch
Phone: 02 6232 8106
Email: clinical.trials@tga.gov.au

Therapeutic Goods Administration
Australian Government Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au



Please note that the TGA will be closed from 3pm, Friday the 23rd to December due to the holiday period. We will resume normal business on Tuesday, 3rd of January 2017. All phone messages and enquiries sent during this shut down period will be responded to on our return. Thank you.



Australian Government

Department of Health
Therapeutic Goods Administration

Regulatory Affairs

s22

CTN SCHEME: ACKNOWLEDGEMENT OF CLINICAL TRIAL NOTIFICATION

Your notification to conduct a clinical trial under the Clinical Trial Notification (CTN) Scheme, pursuant to Schedule 5A of the *Therapeutics Goods Regulations 1990* and/or Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* has been received by the Therapeutic Goods Administration (TGA).

Study Sponsor: s47G
Protocol Number: VX15-770-124
Application ID: CT-2016-CTN-02896-1 v2

Details of Therapeutic Goods Notified:

- Medicine(s):

Trade / Product / Code Name	Ingredient Name(s) Quantity Unit	Dosage Form	Type of Container
Ivacaftor	Ivacaftor 25 Milligram	Granules	Sachet (Foil-laminated)
Ivacaftor	Ivacaftor 50 Milligram	Granules	Sachet (Foil-laminated)
Ivacaftor	Ivacaftor 75 Milligram	Granules	Sachet (Foil-laminated)

- **Device(s):**

Device Name	Manufacturer	GMDN Code
Laboratory packages for the collection of blood, urine and stool samples	ICON Central Laboratories, Inc.	
Electrocardiograph Eli 150c	s47G	
Macroduct Sweat Collection System	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA	

Details of Site(s) Notified:

Site Name	State	Site Expected Start Date
The Sydney Children's Hospitals Network - Westmead	NSW	24/10/2016
Lady Cilento Children's Hospital	Qld	22/12/2016

In notifying this clinical trial the sponsor of the trial has acknowledged 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.

Please note that:

- i. the Therapeutic Goods Administration has not carried out an assessment of the quality, safety or efficacy of any therapeutic good in relation to this notification.
- ii. in the event that the Secretary of the Commonwealth Department of Health becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, the Secretary has the authority to direct that use of the therapeutic good(s) for this clinical trial must cease.
- iii. the clinical trial sponsor is still required to comply with any relevant state and territory legislation that might apply in relation to the supply of the therapeutic product(s).

If there are any changes to the trial details notified to the TGA, it would be necessary for the sponsor to update the relevant fields on the online CTN form.

Kind Regards

Clinical Trials Administration
Experimental Products Section

22 December 2016

From: s22 [REDACTED] on behalf of [Clinical Trials](#)
To: s47G [REDACTED]
Subject: CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v3 - Acknowledgement letter
 [SEC=UNCLASSIFIED]
Date: Monday, 23 January 2017 4:59:37 PM
Attachments: [image001.png](#)
[CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v3 - Acknowledgement letter.pdf](#)

Dear Regulatory Affairs

Thank you for your Clinical Trial Notification (CTN), Application ID: CT-2016-CTN-02896-1 v3. Please see your CTN acknowledgement letter attached. Your CTN has been processed by the TGA and can now be viewed via the '[Clinical Trials Repository](#)' section of your [online TBS Portal menu](#).

Please review the attached correspondence and ensure that all the details are presented correctly as per the online notification submitted. If you believe any corrections are required please contact the Clinical Trials team as soon as possible.

Variations to Previously Notified Clinical Trials:

Any future variations to the details notified via the online CTN form should be updated and submitted to the TGA. Please refer to the '[Varying trial details](#)' section of the document [Using the online CTN form](#) for guidance on how to vary your online CTN.

The new online form does not currently generate an invoice for variations to notified clinical trials. The following variations to a previously notified trial will incur a fee:

- Addition of new site(s) to a previously notified trial. (The fee for notification of a multi-site trial is the same as that for a single site trial providing the sites involved in the multi-site trial are declared simultaneously)
- Change to previously notified therapeutic goods that creates [separate and distinct](#) goods
- Addition of a new therapeutic good to a previously notified trial

A CTN fee is not incurred for subsequent notification of a change of address to a clinical trial site on a CTN form where there are no changes to the clinical trial protocol, Human Research Ethics Committee (HREC) and Approving Authority.

If you are making a variation that incurs a fee, please submit the relevant payment to TGA Accounts Receivable as per TGA [Payment options](#). Credit card details or account details should not be sent to the clinical trials team. Once payment has been made, please forward proof of payment to clinical.trials@tga.gov.au.

I trust this information is of assistance. Please contact the clinical trials team at clinical.trials@tga.gov.au for any further information or clarification.

Kind regards,

Clinical Trials Administration
 Experimental Products Section
 Pharmacovigilance and Special Product Access Branch

Phone: s22 [REDACTED]
 Fax: (02) 6232 8112
 Email: clinical.trials@tga.gov.au

Therapeutic Goods Administration
 Australian Government Department of Health

PO Box 100
Woden ACT 2606
www.tga.gov.au



The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.



Australian Government

Department of Health
Therapeutic Goods Administration

Regulatory Affairs

s47G

CTN SCHEME: ACKNOWLEDGEMENT OF CLINICAL TRIAL NOTIFICATION

Your notification to conduct a clinical trial under the Clinical Trial Notification (CTN) Scheme, pursuant to Schedule 5A of the *Therapeutics Goods Regulations 1990* and/or Schedule 4 of the *Therapeutic Goods (Medical Devices) Regulations 2002* has been received by the Therapeutic Goods Administration (TGA).

Study Sponsor: s47G
Protocol Number: VX15-770-124
Application ID: CT-2016-CTN-02896-1 v3

Details of Therapeutic Goods Notified:

- **Medicine(s):**

Trade / Product / Code Name	Ingredient Name(s) Quantity Unit	Dosage Form	Type of Container
Ivacaftor	Ivacaftor 25 Milligram	Granules	Sachet (Foil-laminated)
Ivacaftor	Ivacaftor 50 Milligram	Granules	Sachet (Foil-laminated)
Ivacaftor	Ivacaftor 75 Milligram	Granules	Sachet (Foil-laminated)

- **Device(s):**

Device Name	Manufacturer	GMDN Code
Laboratory packages for the collection of blood, urine and stool samples	ICON Central Laboratories, Inc.	
Electrocardiograph Eli 150c	s47G	
Macroduct Sweat Collection System	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA	

Details of Site(s) Notified:

Site Name	State	Site Expected Start Date
The Sydney Children's Hospitals Network - Westmead	NSW	24/10/2016
Lady Cilento Children's Hospital	Qld	22/12/2016
The Royal Children's Hospital	VIC	17/02/2017

In notifying this clinical trial the sponsor of the trial has acknowledged 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 or medical practitioners or pharmacists in the relevant State or Territory
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- 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.

Please note that:

- i. the Therapeutic Goods Administration has not carried out an assessment of the quality, safety or efficacy of any therapeutic good in relation to this notification.
- ii. in the event that the Secretary of the Commonwealth Department of Health becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, the Secretary has the authority to direct that use of the therapeutic good(s) for this clinical trial must cease.
- iii. the clinical trial sponsor is still required to comply with any relevant state and territory legislation that might apply in relation to the supply of the therapeutic product(s).

If there are any changes to the trial details notified to the TGA, it would be necessary for the sponsor to update the relevant fields on the online CTN form.

Kind Regards

Clinical Trials Administration
Experimental Products Section

23 January 2016

Clinical Trial CT-2016-CTN-02896-1 v1 Repository

		Submission Date:	07/10/2016
		Acknowledged by TGA	Processed Date: 11/10/2016

Application

Sponsor Name	s22
Sponsor Address	
Submitted by	
Notification Fee	\$345

Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s22
Contact Email	
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential Use of Restricted Goods	No
Title of Study and Description	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are Less Than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial in Australia Has relevant preceding trials
Trial Type	Phase 3
Total Number of Participants to be Enrolled in the Trial	1-20
Therapeutic Area	Other

Sites	
Site Name	The Sydney Children's Hospitals Network - Westmead
Site Physical Location	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145

State / Territory	New South Wales
Expected Site Start Date	24/10/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Sydney Children’s Hospitals research Governance Office
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Medicines			
Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	50	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		

GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	75	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (Foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	25	Milligram
Manufacturer			

Indication	Cystic Fibrosis with GFTR Gating Mutation
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.
Intended Use	Investigational Medicinal Product
Is the medicine manufactured in Australia	No
Manufacturer Name	s47G
GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Medical Devices	
Product Name	Electrocardiograph Eli 150c
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper
Intended Purpose for Trial	Other
Intended Purpose Other Description	To monitor safety of Clinical Trial participants
Manufacturer Name	s47G
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Macroduct Sweat Collection System
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits

Intended Purpose for Trial	Other
Intended Purpose Other Description	Inducing sweat from a study participants arm so sweat can be collected and analysed
Manufacturer Name	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Laboratory packages for the collection of blood, urine and stool samples
Is this a	Procedure Pack
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.
Intended Purpose for Trial	Standard Care Therapy
Manufacturer Name	ICON Central Laboratories, Inc.
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Trial Conducted in Countries	
Country Name	Australia Canada Germany United Kingdom United States Of America

Preceding Trials
CA257BE300003038CA257FDA004DBC7A

Clinical Trial CT-2016-CTN-02896-1 v2 Repository

		Submission Date:	21/12/2016
		Acknowledged by TGA	Processed Date: 22/12/2016

Application

Sponsor Name	s47G
Sponsor Address	
Submitted by	
Notification Fee	\$0

Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G
Contact Email	
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential Use of Restricted Goods	No
Title of Study and Description	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are Less Than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial in Australia Has relevant preceding trials
Trial Type	Phase 3
Total Number of Participants to be Enrolled in the Trial	1-20
Therapeutic Area	Other

Sites	
Site Name	The Sydney Children's Hospitals Network - Westmead
Site Physical Location	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145

State / Territory	New South Wales
Expected Site Start Date	24/10/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children’s Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Sydney Children’s Hospitals research Governance Office
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Medicines									
Trade/Product/Code Name	Ivacaftor								
Is this a combination product	No								
Is this a cannabis product									
Type of Container	Sachet (foil-laminated)								
Type of Container Other Description									
Dosage Form	Granules								
Route of Administration	Oral								
Formulation	<table><tr><td>Ingredient Name</td><td>Quantity</td><td>Unit</td></tr><tr><td>Ivacaftor</td><td>50</td><td>Milligram</td></tr></table>			Ingredient Name	Quantity	Unit	Ivacaftor	50	Milligram
Ingredient Name	Quantity	Unit							
Ivacaftor	50	Milligram							
Manufacturer									
Indication	Cystic Fibrosis with CFTR Gating Mutation								
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.								
Intended Use	Investigational Medicinal Product								
Is the medicine manufactured in Australia	No								
Manufacturer Name	s47G								

GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	75	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (Foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	25	Milligram
Manufacturer			

Indication	Cystic Fibrosis with GFTR Gating Mutation
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.
Intended Use	Investigational Medicinal Product
Is the medicine manufactured in Australia	No
Manufacturer Name	s47G
GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Medical Devices	
Product Name	Electrocardiograph Eli 150c
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper
Intended Purpose for Trial	Other
Intended Purpose Other Description	To monitor safety of Clinical Trial participants
Manufacturer Name	s47G
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Macroduct Sweat Collection System
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits

Intended Purpose for Trial	Other
Intended Purpose Other Description	Inducing sweat from a study participants arm so sweat can be collected and analysed
Manufacturer Name	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Laboratory packages for the collection of blood, urine and stool samples
Is this a	Procedure Pack
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.
Intended Purpose for Trial	Standard Care Therapy
Manufacturer Name	ICON Central Laboratories, Inc.
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Trial Conducted in Countries	
Country Name	Australia Canada Germany United Kingdom United States Of America

Preceding Trials
CA257BE300003038CA257FDA004DBC7A

Change to Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G
Contact Email	
Protocol Number	VX15-770-124

04/06/2026, 13:13Clinical Trial 'CT-2016-CTN-02896-1'FOI 26-3184 - Document 5

Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential use of restricted goods	No
Title of Study and Description	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are Less Than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial in Australia Has relevant preceding trials
Trial Type	Phase 3
Total number of participants to be enrolled in the Trial	1-20
Therapeutic Area	Other

Sites	
Site Name	The Sydney Children's Hospitals Network - Westmead
Site Physical Location	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145
State / Territory	New South Wales
Expected Site Start Date	24/10/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Sydney Children's Hospitals research Governance Office
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Site Name	Lady Cilento Children's Hospital
Site Physical Location	501 Stanley Street, South Brisbane 4101

State / Territory	Queensland
Expected Site Start Date	22/12/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	Children's Health Queensland Hospital and Health Service
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Medicines			
Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	50	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		

GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	75	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (Foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	25	Milligram
Manufacturer			

Indication	Cystic Fibrosis with GFTR Gating Mutation
Dosage and Frequency	Part A: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects <7 kg on Day 1), 50-mg (for subjects 7 to <14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.
Intended Use	Investigational Medicinal Product
Is the medicine manufactured in Australia	No
Manufacturer Name	s47G
GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Medical Devices	
Product Name	Electrocardiograph Eli 150c
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper
Intended Purpose for Trial	Other
Intended Purpose Other Description	To monitor safety of Clinical Trial participants
Manufacturer Name	s47G
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Macroduct Sweat Collection System
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits

Intended Purpose for Trial	Other
Intended Purpose Other Description	Inducing sweat from a study participants arm so sweat can be collected and analysed
Manufacturer Name	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Laboratory packages for the collection of blood, urine and stool samples
Is this a	Procedure Pack
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.
Intended Purpose for Trial	Standard Care Therapy
Manufacturer Name	ICON Central Laboratories, Inc.
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Trial Conducted in Countries	
Country Name	Australia Canada Germany United Kingdom United States Of America

Preceding Trials
CA257BE300003038CA257FDA004DBC7A

Clinical Trial CT-2016-CTN-02896-1 v3 Repository

		Submission Date:	18/01/2017
		Acknowledged by TGA	Processed Date: 23/01/2017

Application

Sponsor Name	s47G
Sponsor Address	
Submitted by	
Notification Fee	\$0

Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G
Contact Email	
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential Use of Restricted Goods	No
Title of Study and Description	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are less than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial in Australia Has relevant preceding trials
Trial Type	Phase 3
Total Number of Participants to be Enrolled in the Trial	1-20
Therapeutic Area	Other

Sites	
Site Name	The Sydney Children's Hospitals Network - Westmead
Site Physical Location	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145
State / Territory	New South Wales
Expected Site Start Date	24/10/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Sydney Children's Hospitals research Governance Office
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Site Name	Lady Cilento Children's Hospital
Site Physical Location	501 Stanley Street, South Brisbane 4101
State / Territory	Queensland
Expected Site Start Date	22/12/2016

Principal Investigator Name	s22	
Principal Investigator Contact Phone		
Principal Investigator Contact Email		
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]	
HREC Contact Officer	s22	
HREC Contact Position		
HREC Contact Phone		
HREC Contact Email		
Name of Approving Authority	Children's Health Queensland Hospital and Health Service	
Approving Authority Contact Officer	s22	
Approving Authority Contact Position		
Approving Authority Contact Phone		
Approving Authority Contact Email		

Medicines			
Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation	Ingredient Name	Quantity	Unit
	Ivacaftor	50	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation	Ingredient Name	Quantity	Unit
	Ivacaftor	75	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		

GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (Foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation	Ingredient Name	Quantity	Unit
	Ivacaftor	25	Milligram
Manufacturer			
Indication	Cystic Fibrosis with GFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ̥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ̥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Medical Devices	
Product Name	Electrocardiograph Eli 150c
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper
Intended Purpose for Trial	Other
Intended Purpose Other Description	To monitor safety of Clinical Trial participants
Manufacturer Name	s47G
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Macroduct Sweat Collection System
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits
Intended Purpose for Trial	Other
Intended Purpose Other Description	Inducing sweat from a study participants arm so sweat can be collected and analysed
Manufacturer Name	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA
Manufacturer Address	

Investigator's Brochure or equivalent documentation	
Product Name	Laboratory packages for the collection of blood, urine and stool samples
Is this a	Procedure Pack
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.
Intended Purpose for Trial	Standard Care Therapy
Manufacturer Name	ICON Central Laboratories, Inc.
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Trial Conducted in Countries	
Country Name	Australia Canada Germany United Kingdom United States Of America

Preceding Trials
CA257BE300003038CA257FDA004DBC7A

Change to Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G
Contact Email	
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential use of restricted goods	No
Title of Study and Description	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are less than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial in Australia Has relevant preceding trials
Trial Type	Phase 3
Total number of participants to be enrolled in the Trial	1-20
Therapeutic Area	Other

Sites	
Site Name	The Sydney Children's Hospitals Network - Westmead
Site Physical Location	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145
State / Territory	New South Wales
Expected Site Start Date	24/10/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22

HREC Contact Position	s22	
HREC Contact Phone		
HREC Contact Email		
Name of Approving Authority	The Sydney Children's Hospitals research Governance Office	
Approving Authority Contact Officer	s22	
Approving Authority Contact Position		
Approving Authority Contact Phone		
Approving Authority Contact Email		

Site Name	Lady Cilento Children's Hospital	
Site Physical Location	501 Stanley Street, South Brisbane 4101	
State / Territory	Queensland	
Expected Site Start Date	22/12/2016	
Principal Investigator Name	s22	
Principal Investigator Contact Phone		
Principal Investigator Contact Email		
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]	
HREC Contact Officer	s22	
HREC Contact Position		
HREC Contact Phone		
HREC Contact Email		
Name of Approving Authority	Children's Health Queensland Hospital and Health Service	
Approving Authority Contact Officer	s22	
Approving Authority Contact Position		
Approving Authority Contact Phone		
Approving Authority Contact Email		

Site Name	The Royal Children's Hospital	
Site Physical Location	Flemington Road, Parkville 3052	
State / Territory	Victoria	
Expected Site Start Date	17/02/2017	
Principal Investigator Name	s22	
Principal Investigator Contact Phone		
Principal Investigator Contact Email		
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]	
HREC Contact Officer	s22	
HREC Contact Position		
HREC Contact Phone		
HREC Contact Email		
Name of Approving Authority	The Royal Children's Hospital Melbourne Research Ethics and Governance	
Approving Authority Contact Officer	s22	
Approving Authority Contact Position		
Approving Authority Contact Phone		
Approving Authority Contact Email		

Medicines	
Trade/Product/Code Name	Ivacaftor
Is this a combination product	No
Is this a cannabis product	
Type of Container	Sachet (foil-laminated)
Type of Container Other Description	
Dosage Form	Granules
Route of Administration	Oral

Formulation	Ingredient Name	Quantity	Unit
	Ivacaftor	50	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation			
	Ingredient Name	Quantity	Unit
	Ivacaftor	75	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Trade/Product/Code Name	Ivacaftor								
Is this a combination product	No								
Is this a cannabis product									
Type of Container	Sachet (Foil-laminated)								
Type of Container Other Description									
Dosage Form	Granules								
Route of Administration	Oral								
Formulation	<table><tr><th>Ingredient Name</th><th>Quantity</th><th>Unit</th></tr><tr><td>Ivacaftor</td><td>25</td><td>Milligram</td></tr></table>			Ingredient Name	Quantity	Unit	Ivacaftor	25	Milligram
	Ingredient Name	Quantity	Unit						
Ivacaftor	25	Milligram							
Manufacturer									
Indication	Cystic Fibrosis with GFTR Gating Mutation								
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.								
Intended Use	Investigational Medicinal Product								
Is the medicine manufactured in Australia	No								
Manufacturer Name	s47G								
GMP licence/clearance number or relevant exemption									

Investigator's Brochure or equivalent documentation	
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Medical Devices	
Product Name	Electrocardiograph Eli 150c
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper
Intended Purpose for Trial	Other
Intended Purpose Other Description	To monitor safety of Clinical Trial participants
Manufacturer Name	s47G
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Macroduct Sweat Collection System
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits
Intended Purpose for Trial	Other
Intended Purpose Other Description	Inducing sweat from a study participants arm so sweat can be collected and analysed
Manufacturer Name	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Laboratory packages for the collection of blood, urine and stool samples
Is this a	Procedure Pack
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.
Intended Purpose for Trial	Standard Care Therapy
Manufacturer Name	ICON Central Laboratories, Inc.
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Trial Conducted in Countries	
Country Name	Australia Canada Germany United Kingdom United States Of America

Preceding Trials
CA257BE300003038CA257FDA004DBC7A

Clinical Trial CT-2016-CTN-02896-1 v3 Repository

		Submission Date:	02/02/2023
		Acknowledged by TGA	Processed Date: 03/02/2023

Application

Sponsor Name	s47G
Sponsor Address	
Submitted by	
Notification Fee	\$0

Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G
Contact Email	
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential Use of Restricted Goods	No
Title of Study and Description	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are less than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
This Trial	Involves the use of a Medicine Involves the use of a Medical Device Has relevant preceding trials Is a multicentre trial in Australia Is being conducted in other countries
Trial Type	Phase 3
Total Number of Participants to be Enrolled in the Trial	1-20
Therapeutic Area	Other

Sites	
Site Name	The Sydney Children's Hospitals Network - Westmead
Site Physical Location	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145

State / Territory	New South Wales
Expected Site Start Date	24/10/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Sydney Children's Hospitals research Governance Office
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Site Name	Lady Cilento Children's Hospital
Site Physical Location	501 Stanley Street, South Brisbane 4101
State / Territory	Queensland
Expected Site Start Date	22/12/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	Children's Health Queensland Hospital and Health Service
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Site Name	The Royal Children's Hospital
Site Physical Location	Flemington Road, Parkville 3052
State / Territory	Victoria
Expected Site Start Date	17/02/2017
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Royal Children's Hospital Melbourne Research Ethics and Governance
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Medicines								
Trade/Product/Code Name	Ivacaftor							
Is this a combination product	No							
Is this a cannabis product								
Type of Container	Sachet (foil-laminated)							
Type of Container Other Description								
Dosage Form	Granules							
Route of Administration	Oral							
Formulation	<table><tr><th>Ingredient Name</th><th>Quantity</th><th>Unit</th></tr><tr><td>Ivacaftor</td><td>50</td><td>Milligram</td></tr></table>		Ingredient Name	Quantity	Unit	Ivacaftor	50	Milligram
Ingredient Name	Quantity	Unit						
Ivacaftor	50	Milligram						
Manufacturer								
Indication	Cystic Fibrosis with CFTR Gating Mutation							
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.							

Intended Use	Investigational Medicinal Product
Is the medicine manufactured in Australia	No
Manufacturer Name	s47G
GMP licence/clearance number or relevant exemption	
Investigator's Brochure or equivalent documentation	

Trade/Product/Code Name	Ivacaftor		
Is this a combination product	No		
Is this a cannabis product			
Type of Container	Sachet (foil-laminated)		
Type of Container Other Description			
Dosage Form	Granules		
Route of Administration	Oral		
Formulation	Ingredient Name	Quantity	Unit
	Ivacaftor	75	Milligram
Manufacturer			
Indication	Cystic Fibrosis with CFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Trade/Product/Code Name	Ivacaftor
Is this a combination product	No
Is this a cannabis product	
Type of Container	Sachet (Foil-laminated)
Type of Container Other Description	
Dosage Form	Granules

Route of Administration	Oral		
Formulation	Ingredient Name	Quantity	Unit
	Ivacaftor	25	Milligram
Manufacturer			
Indication	Cystic Fibrosis with GFTR Gating Mutation		
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.		
Intended Use	Investigational Medicinal Product		
Is the medicine manufactured in Australia	No		
Manufacturer Name	s47G		
GMP licence/clearance number or relevant exemption			
Investigator's Brochure or equivalent documentation			

Medical Devices	
Product Name	Electrocardiograph Eli 150c
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper
Intended Purpose for Trial	Other
Intended Purpose Other Description	To monitor safety of Clinical Trial participants
Manufacturer Name	s47G
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Macroduct Sweat Collection System
Is this a	Single Device
Classification	

Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits
Intended Purpose for Trial	Other
Intended Purpose Other Description	Inducing sweat from a study participants arm so sweat can be collected and analysed
Manufacturer Name	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Laboratory packages for the collection of blood, urine and stool samples
Is this a	Procedure Pack
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.
Intended Purpose for Trial	Standard Care Therapy
Manufacturer Name	ICON Central Laboratories, Inc.
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Trial Conducted in Countries	
Country Name	Australia Canada Germany United Kingdom United States Of America

Change to Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G

Contact Email	s47G
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential use of restricted goods	No
Title of Study and Description	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are less than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
This Trial	Involves the use of a Medicine Involves the use of a Medical Device Has relevant preceding trials Is a multicentre trial in Australia Is being conducted in other countries
Trial Type	Phase 3
Total number of participants to be enrolled in the Trial	1-20
Therapeutic Area	Other

Sites	
Site Name	The Sydney Children's Hospitals Network - Westmead
Site Physical Location	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145
State / Territory	New South Wales
Expected Site Start Date	24/10/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Sydney Children's Hospitals research Governance Office
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Site Name	The Royal Children's Hospital
Site Physical Location	Flemington Road, Parkville 3052
State / Territory	Victoria
Expected Site Start Date	17/02/2017
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	The Royal Children's Hospital Melbourne Research Ethics and Governance
Approving Authority Contact Officer	s22
Approving Authority Contact Position	
Approving Authority Contact Phone	
Approving Authority Contact Email	

Site Name	Queensland Children's Hospital
Site Physical Location	501 Stanley Street, South Brisbane 4101
State / Territory	Queensland
Expected Site Start Date	22/12/2016
Principal Investigator Name	s22
Principal Investigator Contact Phone	
Principal Investigator Contact Email	
HREC Name and Code	Sydney Children's Hospitals Network HREC [EC00130]
HREC Contact Officer	s22
HREC Contact Position	
HREC Contact Phone	
HREC Contact Email	
Name of Approving Authority	Children's Health Queensland Hospital and Health Service
Approving Authority Contact Officer	s22
Approving Authority Contact Position	

Medicines									
Trade/Product/Code Name	Ivacaftor								
Is this a combination product	No								
Is this a cannabis product									
Type of Container	Sachet (foil-laminated)								
Type of Container Other Description									
Dosage Form	Granules								
Route of Administration	Oral								
Formulation	<table><tr><td>Ingredient Name</td><td>Quantity</td><td>Unit</td></tr><tr><td>Ivacaftor</td><td>50</td><td>Milligram</td></tr></table>			Ingredient Name	Quantity	Unit	Ivacaftor	50	Milligram
	Ingredient Name	Quantity	Unit						
Ivacaftor	50	Milligram							
Manufacturer									
Indication	Cystic Fibrosis with CFTR Gating Mutation								
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.								
Intended Use	Investigational Medicinal Product								
Is the medicine manufactured in Australia	No								
Manufacturer Name	s47G								
GMP licence/clearance number or relevant exemption									
Investigator's Brochure or equivalent documentation									

Trade/Product/Code Name	Ivacaftor								
Is this a combination product	No								
Is this a cannabis product									
Type of Container	Sachet (foil-laminated)								
Type of Container Other Description									
Dosage Form	Granules								
Route of Administration	Oral								
Formulation	<table><tr><td>Ingredient Name</td><td>Quantity</td><td>Unit</td></tr><tr><td>Ivacaftor</td><td>75</td><td>Milligram</td></tr></table>			Ingredient Name	Quantity	Unit	Ivacaftor	75	Milligram
	Ingredient Name	Quantity	Unit						
Ivacaftor	75	Milligram							

04/06/2026, 13:18Clinical Trial 'CT-2016-CTN-02896-1'		FOI 26-3184 - Document 7
Manufacturer		
Indication	Cystic Fibrosis with CFTR Gating Mutation	
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.	
Intended Use	Investigational Medicinal Product	
Is the medicine manufactured in Australia	No	
Manufacturer Name	s47G	
GMP licence/clearance number or relevant exemption		
Investigator's Brochure or equivalent documentation		

Trade/Product/Code Name	Ivacaftor								
Is this a combination product	No								
Is this a cannabis product									
Type of Container	Sachet (Foil-laminated)								
Type of Container Other Description									
Dosage Form	Granules								
Route of Administration	Oral								
Formulation	<table><tr><th>Ingredient Name</th><th>Quantity</th><th>Unit</th></tr><tr><td>Ivacaftor</td><td>25</td><td>Milligram</td></tr></table>			Ingredient Name	Quantity	Unit	Ivacaftor	25	Milligram
	Ingredient Name	Quantity	Unit						
Ivacaftor	25	Milligram							
Manufacturer									
Indication	Cystic Fibrosis with GFTR Gating Mutation								
Dosage and Frequency	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.								
Intended Use	Investigational Medicinal Product								
Is the medicine manufactured in Australia	No								
Manufacturer Name	s47G								
GMP licence/clearance number or relevant exemption									
Investigator's Brochure or equivalent documentation									

Medical Devices	
Product Name	Electrocardiograph Eli 150c

Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper
Intended Purpose for Trial	Other
Intended Purpose Other Description	To monitor safety of Clinical Trial participants
Manufacturer Name	s47G
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Macroduct Sweat Collection System
Is this a	Single Device
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	
Is it an implantable device?	
Description and Intended Purpose for Medical Device	Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits
Intended Purpose for Trial	Other
Intended Purpose Other Description	Inducing sweat from a study participants arm so sweat can be collected and analysed
Manufacturer Name	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Product Name	Laboratory packages for the collection of blood, urine and stool samples
Is this a	Procedure Pack
Classification	
Is this device software or does it incorporate software (this may include firmware)?	
Is it an invasive device?	

Is it an implantable device?	
Description and Intended Purpose for Medical Device	Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.
Intended Purpose for Trial	Standard Care Therapy
Manufacturer Name	ICON Central Laboratories, Inc.
Manufacturer Address	
Investigator's Brochure or equivalent documentation	

Trial Conducted in Countries	
Country Name	Australia Canada Germany United Kingdom United States Of America

Completion

Contact Name	s22
Contact Phone Number	
Contact Email	
Date Trial Completed	16/01/2023
Completion Reason	Concluded Normally

From: s22 on behalf of [PSAB Systems](#)
To: [Clinical Trials](#)
Subject: RE: CTN - Missing details on PDF - CT-2016-CTN-02896-1 v3 - s22 - 19/01/2017 - s22 86193
 [SEC=UNCLASSIFIED]
Date: Friday, 20 January 2017 1:55:54 PM
Attachments: [image001.png](#)
[image002.png](#)
[CT-2016-CTN-02896-1 v3.pdf](#)

Hi s22

IT have corrected the special characters that were causing this issue so the sponsor should now be able to see all details in their preview (see preview generated by IT in the test environment attached).

Warm regards,

s22

s22

Technical and Safety Improvement Section
 Pharmacovigilance and Special Access Branch
 Medicines Regulation Division

Phone: s22
 Fax: s22
 Email s22 @health.gov.au

-

Therapeutic Goods Administration
 Department of Health
 PO BOX 100
 Woden ACT 2606
 Website: www.tga.gov.au



The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 **On Behalf Of** PSAB Systems
Sent: Thursday, 19 January 2017 9:35 AM
To: Clinical Trials
Subject: RE: CTN - Missing details on PDF - CT-2016-CTN-02896-1 v3 - s22 - 19/01/2017 - s22 86193 [SEC=UNCLASSIFIED]

Hi s22

I have asked IT to investigate and will let you know when the issue should be resolved.

Warm regards,

s22

s22

Technical and Safety Improvement Section
 Pharmacovigilance and Special Access Branch
 Medicines Regulation Division

Phone: s22
 Fax: s22
 Email: s22@health.gov.au

-
 Therapeutic Goods Administration
 Department of Health
 PO BOX 100
 Woden ACT 2606
 Website: www.tga.gov.au

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 **On Behalf Of** Clinical Trials
Sent: Thursday, 19 January 2017 7:22 AM
To: PSAB Systems
Subject: CTN - Missing details on PDF - CT-2016-CTN-02896-1 v3 - s22 - 19/01/2017
 [SEC=UNCLASSIFIED]

Hi s22

Would you please ask IT to investigate – another missing details when printing

Warm regards

s22

From: s22 [<mailto:s22@s47G>]
Sent: Wednesday, 18 January 2017 4:32 PM
To: Clinical Trials
Subject: CTN - Missing details on PDF - CT-2016-CTN-02896-1 v3 - s22 - 19/01/2017

Dear Clinical Trial Team,

I have encountered the “missing information on pdf” issue again (see attached pdf). I was advised by your team to clear search history and allow pop-up and it has not worked. Could you please address this with your IT so I can print all information on the CTN.

I look forward to hearing from you.

Kind Regards,
 s22

From: s22
Sent: Wednesday, 21 December 2016 1:49 PM
To: 'Clinical Trials' <clinical.trials@tga.gov.au>
Subject: CID20399 - VX15-770-124 - CT-2016-02896-1 v2 - missing details on pdf

Dear Clinical Trials Team,

I have submitted the above-mention eCTN (proof of submission and payment attached) and I tried to print preview the CTN for a lot of the information was missing e.g. Medicine details, site details etc...

Can you please assist me in retrieving the missing information? Thank you.

Kind Regards,

s22

s22

s47G

s22

s47G

***** IMPORTANT--PLEASE READ

***** This electronic message, including its attachments, is CONFIDENTIAL and may contain PROPRIETARY or LEGALLY PRIVILEGED or PROTECTED information and is intended for the authorized recipient of the sender. If you are not the intended recipient, you are hereby notified that any use, disclosure, copying, or distribution of this message or any of the information included in it is unauthorized and strictly prohibited. If you have received this message in error, please immediately notify the sender by reply e-mail and permanently delete this message and its attachments, along with any copies thereof, from all locations received (e.g., computer, mobile device, etc.). Thank you.

Clinical Trial CT-2016-CTN-02896-1 v3 Under Review

Submission Date: 18/01/2017

Application

Sponsor Name	s47G
Sponsor Address	
Notification Fee	\$0

Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G
Contact Email	
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential Use of Restricted Goods	No
Title of Study	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are less than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
Trial Type	Phase 3
Total Number of Patients to be Enrolled in Trial	1-20
Therapeutic Area	Other
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial Has relevant preceding trials

Medicines

Trade/Product/ Code Name	Combination product?	Type of Container	Dosage Form	Route of Administration	Indication	Dosage Frequency	Intended Use	Medicine Manufacture in Australia	Manufacturer Details	Formulation						
Ivacaftor	No	Sachet (foil-laminated)	Granules	Oral	Cystic Fibrosis with CFTR Gating Mutation	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.	Investigational Medicinal Product	No	s47G	<table><tr><th>Ingredient Name</th><th>Quantity</th><th>Unit</th></tr><tr><td>Ivacaftor</td><td>50</td><td>mg</td></tr></table>	Ingredient Name	Quantity	Unit	Ivacaftor	50	mg
Ingredient Name	Quantity	Unit														
Ivacaftor	50	mg														
Ivacaftor	No	Sachet (foil-laminated)	Granules	Oral	Cystic Fibrosis with CFTR Gating Mutation	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.	Investigational Medicinal Product	No		<table><tr><th>Ingredient Name</th><th>Quantity</th><th>Unit</th></tr><tr><td>Ivacaftor</td><td>75</td><td>mg</td></tr></table>	Ingredient Name	Quantity	Unit	Ivacaftor	75	mg
Ingredient Name	Quantity	Unit														
Ivacaftor	75	mg														
Ivacaftor	No	Sachet (Foil-laminated)	Granules	Oral	Cystic Fibrosis with GFTR Gating Mutation	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.	Investigational Medicinal Product	No	<table><tr><th>Ingredient Name</th><th>Quantity</th><th>Unit</th></tr><tr><td>Ivacaftor</td><td>25</td><td>mg</td></tr></table>	Ingredient Name	Quantity	Unit	Ivacaftor	25	mg	
Ingredient Name	Quantity	Unit														
Ivacaftor	25	mg														

Devices

Product Name	Is this a kit?	Manufacturer	GMDN	Description	Intended Purpose	Other Description
Electrocardiograph Eli 150c	Single Device	s47G		ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper	Other	To monitor safety of Clinical Trial participants
Macroduct Sweat Collection System	Single Device	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA		Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits	Other	Inducing sweat from a study participants arm so sweat can be collected and

1/20/2017	Clinical Trial 'CT-2016-CTN-02896-1'					FOI 26-3184 - Document 8	
Laboratory packages for the collection of blood, urine and stool samples	Procedure Pack	ICON Central Laboratories, Inc.		Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.			Standard Care Therapy

Sites

Site	Site Address, Location	Expected Site Start Date	Principal Investigator Name	Principal Investigator Contact Phone Number	Principal Investigator Contact Email	HREC Name, Code	HREC Contact Officer, Position	HREC Contact Phone	HREC Contact Email	Approving Authority Name	Approving Authority Contact Officer, Position	Contact Phone	Contact Email
The Sydney Children's Hospitals Network - Westmead	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145, NSW	24/10/2016	s22			Sydney Children's Hospitals Network HREC, EC00130	s22			The Sydney Children's Hospitals research Governance Office	s22		
Lady Cilento Children's Hospital	501 Stanley Street, South Brisbane 4101, QLD	22/12/2016				Sydney Children's Hospitals Network HREC, EC00130				Children's Health Queensland Hospital and Health Service			

Trial Conducted In Countries

Country Name
Australia
Canada
Germany
United Kingdom
United States Of America

Preceding Trials

CA257BE300003038CA257FDA004DBC7A

Change to Trial Details

Contact Name	Regulatory Affairs
Contact's Phone Number	s47G
Contact's Email	
Protocol Number	VX15-770-124
Title of Study	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are less than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential Use of Restricted Goods	No
Title of Study	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are less than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
Trial Type	Phase 3
Number of Patients to be Enrolled in Trial	1-20
Therapeutic Area	Other
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial Has relevant preceding trials

Medicines

Trade/Product/ Code Name	Combination product?	Type of Container	Dosage Form	Route of Administration	Indication	Dosage Frequency	Intended Use	Medicine Manufacture in Australia	Manufacturer Details	Formulation
Ivacaftor	No	Sachet (foil-	Granules	Oral	Cystic	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for	Investigational	No	s47G	

		laminated)			Fibrosis with CFTR Gating Mutation	subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.	Medicinal Product		s47G	FOI 26-2184 Document 8		
										Ingredient Name Quantity Unit		
Ivacaftor	No	Sachet (foil-laminated)	Granules	Oral	Cystic Fibrosis with CFTR Gating Mutation	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.	Investigational Medicinal Product	No		Ingredient Name Quantity Unit		
										Ingredient Name Quantity Unit		
Ivacaftor	No	Sachet (Foil-laminated)	Granules	Oral	Cystic Fibrosis with GFTR Gating Mutation	Part A: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered every 12 hours (q12h) on Days 1 through 3 and 1 morning dose on Day 4. Part B: 25-mg (for subjects less than 7 kg on Day 1), 50-mg (for subjects 7 to less than 14 kg on Day 1), and 75-mg (for subjects ≥14 kg on Day 1) ivacaftor will be administered q12h for 24 weeks.	Investigational Medicinal Product	No		Ingredient Name Quantity Unit		
										Ingredient Name Quantity Unit		

Devices

Product Name	Is this a kit?	Manufacturer	GMDN	Description	Intended Purpose	Other Description
Electrocardiograph Eli 150c	Single Device	s47G		ELI 150c ECG, Electrocardiograph Machine including 12-leads, disposable electrodes, paper	Other	To monitor safety of Clinical Trial participants
Macroduct Sweat Collection System	Single Device	Wescor Inc 459 South Main Street, Logan, Utah 84321 in USA		Macroduct 3700-SYS Wescor Sweat Inducer and Wescor Macroduct accessories (60mL deionized water bottle, 1cc syringe w/#22 blunt needle, small/medium/large/extra large straps,nblack electrode attachment strap, red electrode attachment strap, supply kits	Other	Inducing sweat from a study participants arm so sweat can be collected and analysed
Laboratory packages for the collection of blood, urine and stool samples	Procedure Pack	ICON Central Laboratories, Inc.		Package type (names):Screen A_VX15-770-124_v01;Day 4 A_VX15-770-124_v01;Day 5 A_VX15-770-124_v01;Screen B_VX15-770-124_v01;Day 1 B_VX15-770-124_v01;Week 2 B_VX15-770-124_v01;Week 4 B_VX15-770-124_v01;Week 8 B_VX15-770-124_v01;Week 12 B_VX15-770-124_v01;Week 18 B_VX15-770-124_v01;Week 24 B_VX15-770-124_v01;ETT_VX15-770-124_v01;Follow up_VX15-770-124_v01;Unscheduled_VX15-770-124_v01;Miscellaneous supplies_VX15-770-124_v01.	Standard Care Therapy	

Sites

Site	Site Address, Location	Expected Site Start Date	Principal Investigator Name	Principal Investigator Contact Phone Number	Principal Investigator Contact Email	HREC Name, Code	HREC Contact Officer, Position	HREC Contact Phone	HREC Contact Email	Approving Authority Name	Approving Authority Contact Officer, Position	Contact Phone	Contact Email
The Sydney Children's Hospitals Network - Westmead	Corner of Hawkesbury Road and Hainsworth Street, Westmead 2145, NSW	24/10/2016	s22			Sydney Children's Hospitals Network HREC, EC00130	s22			The Sydney Children's Hospitals research Governance Office	s22		
Lady Cilento Children's Hospital	501 Stanley Street, South Brisbane 4101, QLD	22/12/2016				Sydney Children's Hospitals Network HREC, EC00130				Children's Health Queensland Hospital and Health Service			
The Royal Children's Hospital	Flemington Road, Parkville 3052, VIC	17/02/2017				Sydney Children's Hospitals Network HREC, EC00130				The Royal Children's Hospital Melbourne Research Ethics and Governance			

Trial Conducted In Countries

Country Name
Australia
Canada
Germany
United Kingdom
United States Of America

Preceding Trials

CA257BE300003038CA257FDA004DBC7A

Completion

From: s22 on behalf of [Clinical Trials](#)
To: s22 @s47G
Subject: CTN - Missing details on PDF - CT-2016-CTN-02896-1 v3 - s22 - 19/01/2017
 [SEC=UNCLASSIFIED]
Date: Thursday, 19 January 2017 7:24:18 AM
Attachments: [image001.png](#)
[image002.png](#)
[VX15-770-124 submitted eCTN CT-2016-CTN-02896-1 21Dec2016.pdf](#)
[Clinical Trial CT-2016-CTN-02896-1 v3.pdf](#)

Dear s22

Thank you for providing this information. We apologise for the issue you are currently experiencing with the online system. Please be assured that we are looking into this technical issue as a priority.

We will advise you as soon as the technical issue has been resolved.

Please do not hesitate to contact me for any further assistance or clarification.

Kind regards,

s22
 Clinical Trials Administration
 Pharmacovigilance and Special Access Branch
 Phone: s22
 Email: clinical.trials@tga.gov.au

Therapeutic Goods Administration
 Australian Government Department of Health
 PO Box 100
 Woden ACT 2606 Australia
www.tga.gov.au



The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [mailto:s22@s47G]
Sent: Wednesday, 18 January 2017 4:32 PM
To: Clinical Trials
Subject: CTN - Missing details on PDF - CT-2016-CTN-02896-1 v3 - s22 - 19/01/2017

Dear Clinical Trial Team,

I have encountered the "missing information on pdf" issue again (see attached pdf). I was advised by your team to clear search history and allow pop-up and it has not worked. Could you please address this with your IT so I can print all information on the CTN.

I look forward to hearing from you.

Kind Regards,

s22

From: s22**Sent:** Wednesday, 21 December 2016 1:49 PM**To:** 'Clinical Trials' <clinical.trials@tga.gov.au>**Subject:** CID20399 - VX15-770-124 - CT-2016-02896-1 v2 - missing details on pdf

Dear Clinical Trials Team,

I have submitted the above-mention eCTN (proof of submission and payment attached) and I tried to print preview the CTN for a lot of the information was missing e.g. Medicine details, site details etc...

Can you please assist me in retrieving the missing information? Thank you.

Kind Regards,

s22

s22

s47G

s22

s47G

***** IMPORTANT--PLEASE READ

***** This electronic message, including its attachments, is CONFIDENTIAL and may contain PROPRIETARY or LEGALLY PRIVILEGED or PROTECTED information and is intended for the authorized recipient of the sender. If you are not the intended recipient, you are hereby notified that any use, disclosure, copying, or distribution of this message or any of the information included in it is unauthorized and strictly prohibited. If you have received this message in error, please immediately notify the sender by reply e-mail and permanently delete this message and its attachments, along with any copies thereof, from all locations received (e.g., computer, mobile device, etc.). Thank you.

Clinical Trial CT-2016-CTN-02896-1 v2 Submitted

Application

Trial Details

Contact Name Regulatory Affairs
 Contact Phone Number 547G
 Contact Email
 Protocol Number VX15-770-124
 Expected Trial Start Date 24/10/2016
 Expected Completion Date 31/12/2019
 Potential Use of Restricted Goods No
 Title of Study A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are Less Than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
 Trial Type Phase 3
 Total Number of Patients to be Enrolled in Trial 1-20
 Therapeutic Area Other
 This Trial Is being conducted in other countries
 Involves the use of a Medicine
 Involves the use of a Medical Device
 Is a multicentre trial
 Has relevant preceding trials

Medicines

Trade/Product/ Code Name	Combination product?	Type of Container	Dosage Form	Route of Administration	Indication	Dosage Frequency	Intended Use	Medicine Manufacture in Australia	Manufacturer Details	Formulation			
Ivacaftor	No	Sachet (foil-laminated)	Granules	Oral	Cystic Fibrosis with CFTR Gating Mutation	Part A: 25-mg (for subjects					Ingredient Name	Quantity	Unit

Preceding Trials

CA257BE300003038CA257FDA004DBC7A

Completion

Clinical Trial CT-2016-CTN-02896-1 v3 Under Review

Application

Trial Details

Contact Name	Regulatory Affairs
Contact Phone Number	s47G
Contact Email	
Protocol Number	VX15-770-124
Expected Trial Start Date	24/10/2016
Expected Completion Date	31/12/2019
Potential Use of Restricted Goods	No
Title of Study	A Phase 3, 2-Part, Open-label Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Ivacaftor in Subjects With Cystic Fibrosis Who Are Less Than 24 Months of Age at Treatment Initiation and Have a CFTR Gating Mutation
Trial Type	Phase 3
Total Number of Patients to be Enrolled in Trial	1-20
Therapeutic Area	Other
This Trial	Is being conducted in other countries Involves the use of a Medicine Involves the use of a Medical Device Is a multicentre trial Has relevant preceding trials

Medicines

Trade/Product/ Code Name	Combination product?	Type of Container	Dosage Form	Route of Administration	Indication	Dosage Frequency	Intended Use	Medicine Manufacture in Australia	Manufacturer Details	Formulation		
Ivacaftor	No	Sachet (foil-laminated)	Granules	Oral	Cystic Fibrosis with CFTR Gating Mutation	Part A: 25-mg (for subjects					Ingredient Name	Quantity Unit

Preceding Trials

CA257BE300003038CA257FDA004DBC7A

Completion

From: s22
To: [Accounts Receivable](#)
Subject: CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v3 - Invoice Request Form [SEC=UNCLASSIFIED]
Date: Monday, 23 January 2017 5:56:30 PM
Attachments: [R14 682826 Invoice Request Form\(2\) \(2\).XLSM](#)



TGA

RBSB - AR use only

Invoice request - Please raise an invoice for the following:

Invoice No:

Date:

Client Id: 20399

Name: s47G

Address:

Email:

Phone No:

Fax No:

Notes:

When copying text from Word, you may need to copy into the Formula bar for the cell, rather than the cell itself

At the bottom of this form, are Macro buttons to facilitate emailing the form to your EL1, and then to Accounts Receivable. Once form has been emailed, close the form - the version attached to the email is the "official" form.

INVOICE WILL EITHER BE AN SAP FI INVOICE OR AN SAP SALES & DISTRIBUTION INVOICE - COMPLETE ONE SECTION ONLY

SAP FI Invoices (Item Codes not available)

Details of Goods or Services
Provided (will appear on invoice)

SAP Cost Centre	SAP Account Code	Project Code (SAP Internal Order)	Ex GST Amount	GST Amount	Total Amt
			\$0.00		\$0.00
			\$0.00		\$0.00
			\$0.00		\$0.00
SLS INVOICE TOTAL			\$0.00	\$0.00	\$0.00

Sales Invoices (Item Codes available)

Project Code for
Sales Invoice

Item Code	Item Desc	Subject to GST	Comment (will show on invoice) Max 195 characters	Qty	Unit Cost (ex GST)	GST Excl Amt	Total Amount
TG PR 7005	CTN - Variations	No	CT-2016-CTN-02896-1 v3 - Protocol VX15-770-124	1	\$345.00	\$345.00	\$345.00

SALES (SOP) INVOICE TOTAL:

\$345.00

\$345.00

Note: If costs are a reimbursement (eg freight, postage), please attach receipts.

Invoice Instructions

- ☒ Send invoice to Client
☐ Send invoice to Requestor
☐ Other - please specify - >

please apply Doc No: 1400004574 to CT-2016-CTN-02896-1 v3 - Protocol VX15-770-124

REQUESTER DETAILS

APPROVAL DETAILS (Must be EL1 level or higher)

Branch/Section:	PSAB	Name:	s22
Phone No	8105	Position:	
Requested by:	s22	Signature:	Signed by s22 on 23 Jan 2017 at 17:56

Approve

Unapprove

From: s22
To: [Accounts Receivable](#)
Subject: CTN - CID20399 - VX15-770-124 - CT-2016-CTN-02896-1 v2 - Invoice Request Form [SEC=UNCLASSIFIED]
Date: Thursday, 19 January 2017 8:05:02 PM
Attachments: [R14 682826 Invoice Request Form\(9\) \(5\).XLSM](#)



Invoice request - Please raise an invoice for the following:

Client Id:	20399		
Name:	s22		
Address:			
Email:			
Phone No:		Fax No:	

Notes:

When copying text from Word, you may need to copy into the Formula bar for the cell, rather than the cell itself

At the bottom of this form, are Macro buttons to facilitate emailing the form to your EL1, and then to Accounts Receivable. Once form has been emailed, close the form - the version attached to the email is the "official" form.

INVOICE WILL EITHER BE AN SLS INVOICE OR A SALES INVOICE - COMPLETE ONE SECTION ONLY

SLS Invoices (Item Codes not available)

Details of Goods or Services
Provided (will appear on invoice)

Cost Centre	Account Code	Project Code	Ex GST Amount	GST Amount	Total Amt
			\$0.00		\$0.00
			\$0.00		\$0.00
			\$0.00		\$0.00
SLS INVOICE TOTAL			\$0.00	\$0.00	\$0.00

Sales Invoices (Item Codes available)

Project Code for
Sales Invoice

Item Code	Item Desc	Subject to GST	Comment (will show on invoice) Max 195 characters	Qty	Unit Cost (ex GST)	GST Excl Amt	Total Amount
PR7005	CTN - Variations	No	VX15-770-124 - CT-2016-CTN-02896-1 v2	1	\$345.00	\$345.00	\$345.00
SALES (SOP) INVOICE TOTAL:						\$345.00	\$345.00

Note: If costs are a reimbursement (eg freight, postage), please attach receipts.

Invoice Instructions

- ☒ Send invoice to Client
☐ Send invoice to Requestor
☐ Other - please specify - >

Please apply 1400003280 to VX15-770-124 - CT-2016-CTN-02896-1 v2

REQUESTER DETAILS

APPROVAL DETAILS (Must be EL1 level or higher)

Branch/Section:	PSAB	Name:	s22
Phone No:	8590	Position:	
Requested by:	s22	Signature:	Signed by s22 on 19 Jan 2017 at 20:04

Approve

Unapprove