



L'Institut de recherche  
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The Research Institute  
of the McGill University Health Centre

## Optimizing Use of the eReviews Online Submission Tool

February 6<sup>th</sup>, 2014

# eReviews Software

- ❖ Internet-based study review management software
- ❖ Launched at the MUHC on April 1, 2011
- ❖ System manages:
  - ❖ Science review
  - ❖ Ethics review
  - ❖ Site-specific assessments (pharmacy, resources utilization, contracts, access to medical records)
- ❖ Currently over 1000 users and 2000 ongoing studies in the system



# System Access

- ❖ Only PIs can create account
- ❖ Access to system is controlled manually. Allows for verification of:
  - ❖ MUHC or McGill staff appointment
  - ❖ Valid research privileges
- ❖ All other users (students, research staff, residents, fellows) must be delegated a study to access the system



# System Access

## ❖ User account permissions:

### ❖ Principle Investigator (PI):

- create studies
- delegate individuals to studies
- complete forms
- sign off on forms
- submit Confidentiality Disclosure Agreements (CDAs) for review

### ❖ Delegate:

- complete forms for delegated studies
- submit (CDAs) for review on behalf of PI



# System Access

- ❖ Each user is assigned their own username and password
  - MUHC policy and good security practices: **DO NOT SHARE YOUR USERNAME AND PASSWORDS**
- ❖ Each user is responsible for the use of their username, password and the activities conducted in their account.



# Password Management

- ❖ Password reset function is available on the login screen:



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eREVIEWS

## Welcome

This site allows MUHC personnel to submit the information for review (initial and ongoing) of any research activity that requires:

- An intervention with a human subject, or
- The collection of information on a human subject, whether prospectively or retrospectively, or
- The use of human biological material

to be conducted at the MUHC (Montreal General Hospital, Royal Victoria Hospital -including the Allen Memorial Institute, Montreal Children's Hospital, Montreal Neurological Hospital, and the Montreal Chest Institute).

## Sign In

Username

Password

**Sign In**




[Forgot my password?](#)  
[Forgot my username?](#)  
[Create account](#)



# Password Management

- ❖ Passwords can be changed once logged in by accessing profile information

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What do you want to do?

▶ [Submit CDA](#)

## Study Management

**Notifications pending! Please consult your studies list to see which one(s) require(s) your attention**

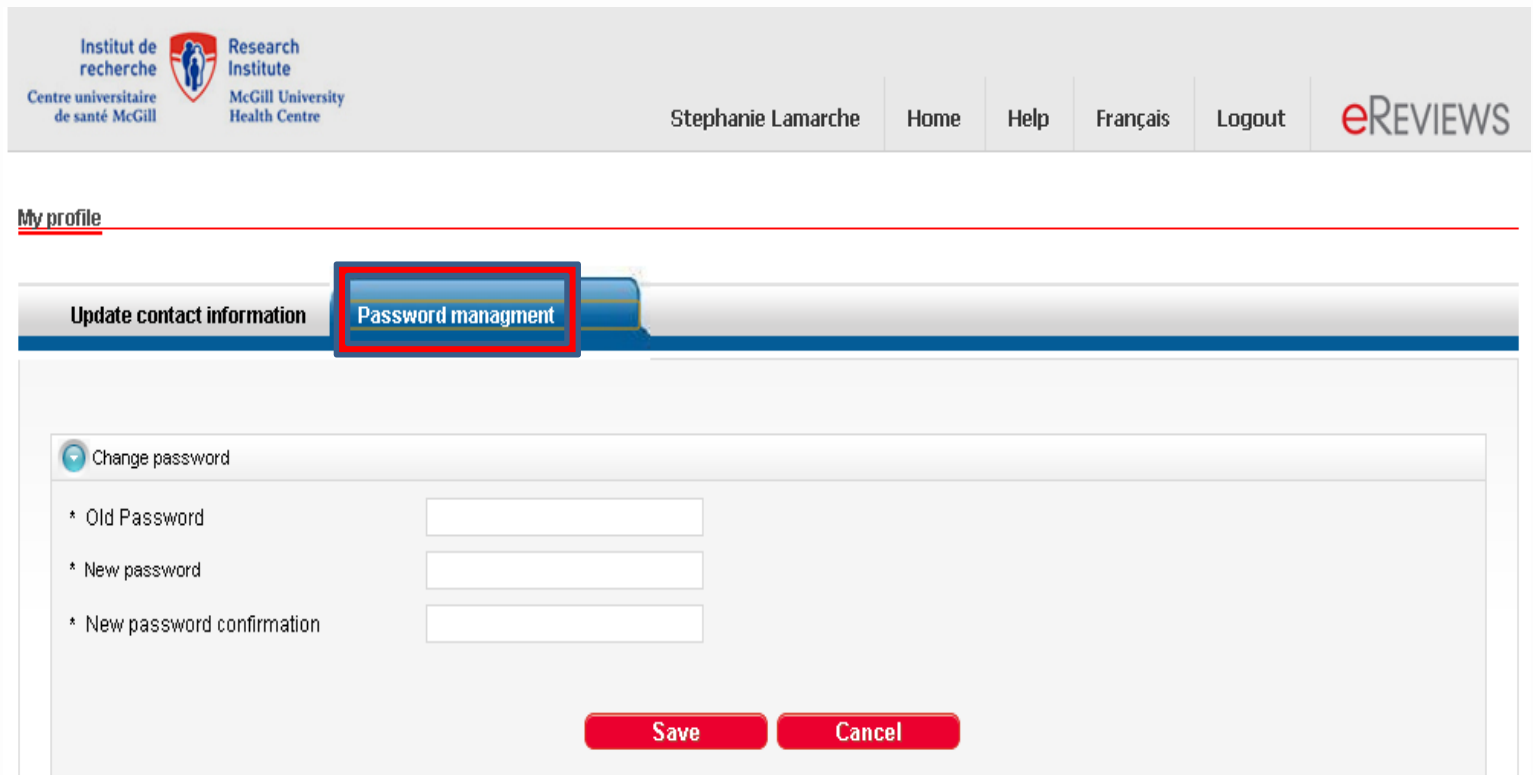
Pending Authorization								
Authorized (Ongoing)								
Archived								
MUHC Study Code:	ID	Study short title	Principal Investigator	Status	Edit	Submit / Track	Notifications	
	1657	TEST 1	Stephanie Lamarche	Not submitted			0	
	2776	IM101240	Rosie Scuccimarri	Approval in progress			0	
	3630		Jacques Genest	Not submitted			0	

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# Password Management

❖ Use the Password management tab



The screenshot displays the eREVIEWS user interface. At the top, the header includes the logos for the Institut de recherche Centre universitaire de santé McGill and the Research Institute McGill University Health Centre. To the right of the logos, the user's name 'Stephanie Lamarche' is shown, followed by navigation links for 'Home', 'Help', 'Français', and 'Logout'. The 'eREVIEWS' logo is positioned on the far right of the header.

Below the header, the 'My profile' section is visible. It contains two tabs: 'Update contact information' and 'Password managment'. The 'Password managment' tab is selected and highlighted with a red rectangular box.

Under the 'Password managment' tab, there is a 'Change password' section. This section contains three input fields, each preceded by an asterisk (\*): 'Old Password', 'New password', and 'New password confirmation'. At the bottom of this section, there are two red buttons: 'Save' and 'Cancel'.





# Delegate Management

## What do you want to do?


[Submit CDA](#)

[Create a new study](#)

[Manage delegates](#)



## Study Management

Pending Authorization				Authorized (Ongoing)		Archived			
MUHC Study Code: ◆	ID ◆	Study short title ◆	Principal Investigator ◆	Status ◆	Edit	Submit / Track	Manage Delegates	Notifications	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>					
	1657	TEST 1	Stephanie Lamarche	Not submitted				0	
	1695	TEST 2	Stephanie Lamarche	Not submitted				0	
	1712		Stephanie Lamarche	Not submitted				0	
	1823	TEST 3	Stephanie Lamarche	Not submitted				0	
	1858		Stephanie Lamarche	Not submitted				0	
	1889		Stephanie Lamarche	Not submitted				0	
	2039		Stephanie Lamarche	Not submitted				0	
	2064		Stephanie Lamarche	Not submitted				0	
	2113	TEST	Stephanie Lamarche	Not submitted				0	
	2155		Stephanie Lamarche	Not submitted				0	



# New Study Creation

- ❖ Studies can only be created by PI
- ❖ A series of initial questions determine which forms the investigator will need to complete.
- ❖ The investigator can delegate the role of form completion to a member of his team only once the study has been created.



# New Study Creation

## What do you want to do?

[Submit CDA](#)

[→ Create a new study](#)

[Manage delegates](#)

## Initial Questions

Please answer the following questions that will guide you to the forms required for "initial review". At each question, place your cursor over the question mark symbol under help to get additional information on the question. You may always go back one question by clicking the 'back one' button or begin again with the first question by clicking 'start over'. Once you have answered all the questions, click on 'finish' to receive your study record number and the specific forms required to submit for the study.

Help	Question *	Answer *	Required Form *
	Will the human subject information required for the study be collected from existing medical records only for which no subjects will be contacted?	No	Resource
?	Does your study involve testing a drug or natural health product (whether marketed or not)?	Yes	Pharmacy, Regulatory compliance
?	Does your study involve testing a medical device (whether marketed or not)?	No	--
?	Does your study involve a contract or legal agreement to be reviewed by the Office of Clinical Contracts (OCC)?	Yes	Budget/contract
?	Does your study involve minors (children under 18 years of age)?	No	Adults science/ethics review
?	Will you require access to MUHC records prior to obtaining written informed consent from the subjects whose data you seek?	Yes	Medical record access
?	Does your study involve use of information or human material from an existing data or tissue bank or creating a new data or tissue bank?	Yes	Data or tissue bank
?	Will your study be registered in a public registry, as required by the MUHC for all randomised clinical research?	Yes	Clinical trial registration

[Start over](#)

[Finish](#)

[Cancel operation](#)



# New Study Creation

- ❖ **Question:** Will the human subject information required for the study be collected from existing medical records only for which no subjects will be contacted?
- ❖ “Medical Records” not limited to paper charts – includes any information which is part of a patient’s medical history
- ❖ Answering Yes generates both the Health Records Research form and the DPS Medical Records Access form.



# New Study Creation

## ❖ Laws governing access to information

- Article 19.1 of *La loi sur les services de santé et les services sociaux*
  - Requirement to obtain informed consent for use of health record information
- Article 125 of *La loi sur l'accès aux documents des organismes publics et sur la protection des renseignements personnels*
  - The requirement for consent may be waived if:
    - The projected use of the data is not frivolous
    - The personal information will be used in a manner which respects its confidential nature



# New Study Creation

- ❖ In institutions of the health and social services network, the Director of Professional Services (DPS) can authorize use of information for research if conditions outlined in Article 125 are met
- ❖ Approval of either the DPS or the REB alone is not sufficient to conduct health records research



# New Study Creation

- ❖ **Question:** Will you require access to MUHC records prior to obtaining written informed consent from the subjects whose data you seek?
  - Answering Yes will generate the DPS Access to Medical Records form
  - Using medical records to screen for potential participants prior to contacting them
  - No need to answer Yes if only accessing records after participant consent (provisions should be in consent form)



# New Study Creation


- ❖ **Question:** Does your study involve a contract or legal agreement to be reviewed by the Office of Clinical Contracts (OCC)?
  - Answering Yes will generate the Contract Review Application
  - When is a contract or agreement required?
    - When both parties stand to benefit from a collaboration (benefit can be money, publication rights, data, etc.)
  - Agreements include: Clinical study agreements, inter-institutional agreements, material transfer and data transfer/sharing agreements, etc.





# Form Navigation and Validation

❖ The study forms are listed in the left hand menu



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eREVIEWS

Study Forms Section

Common questions

Children science/ethics review

Scientific review and study design

Recruitment and enrollment

Informed consent

Confidentiality of data

Regulatory compliance

Financial issues

Clinical trial registration

Resource

Pharmacy

Budget/contract

PI's declaration

Study management

Submit Study/Track Review Progress

Modify Initial Questions

Print/Preview

Common questions

Study ID

3087

Study title

Study short title

Study summary with study objectives (100 words or less)

Append study protocol, principal investigator's CV and the investigator brochure (if applicable)  
Append M-Eval form in case of a study falling under the MSSS Multicentric Mechanism

id*	Filename*	Size*	New version	History	Delete
Empty					

Add attachment\*

Is the research an "extension" or "companion" to an existing study?

☐ Yes ☒ No

Projected MUHC study start date

Projected MUHC study end date

Save



# Form Navigation and Validation

- ❖ Navigation tabs at the bottom of the screen guide the investigator through the study application

Indicate the study sponsor (if organization) \*

Organization name	Start date	End Date	Edit	Delete
Empty				

New row



Indicate the study sponsor (if person) \*

Person name*	Start date	End Date	Edit	Delete
Empty				

New row

Indicate the source of funding for the study \*

☐ Internal/Departmental Funding

Organization name	Organization Type	Start date	End Date	Edit	Delete
Eli Lilly Canada Inc.	Compa corporations CAN.PRIV	2013-04-22	2014-03-31		

New row

Indicate any other site (than MUHC) involved in the study \*

Organization name	Organization Location	Start date	End Date	Edit	Delete
Empty					

New row

Previous

Save


Validate

Next



# Form Navigation and Validation

- ❖ The « Validate » function allows the investigator to verify what information is required to submit the study



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Study Forms Section

→ Common questions

Children science/ethics review

Scientific review and study design

Recruitment and enrollment

Informed consent

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Study management

Submit Study/Track Review Progress

Modify Initial Questions

You must correct the following error(s) before proceeding:

- Study title is required.
- Study short title is required.
- Study summary with study objectives is required.
- Initial review date is required.
- Close out date is required.
- Study protocol is required

Print/Preview

Common questions

▼ Study ID

3087

▼ Study title

▼ Study short title



▼ Study summary with study objectives (100 words or less)

▼ Append study protocol, principal investigator's CV and the investigator brochure (if applicable)  
Append M Eval form in case of a study falling under the MSSC Multicentric Mechanism



# Study Submission

❖ When ready to submit the study for review, click on Submit



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Study Forms Section

▶ Common questions

▶ Children science/ethics review

▶ Scientific review and study design

▶ Recruitment and enrollment

▶ Informed consent

▶ Confidentiality of data

▶ Regulatory compliance

▶ Financial issues

▶ Clinical trial registration

▶ Resource

▶ Pharmacy

▶ Budget/contract

▶ PI's declaration

Study management

→ Submit Study/Track Review Progress

▶ Modify Initial Questions

**Submit / Track [ Study # 3087, ]**

Use the Submit buttons to submit your study application for review. Please note that you may submit your contract/budget for review at a later time than your science/ethics/site-specific assessments. You may not start your study until all required approvals are obtained and the RI MUHC issues the MUHC Authorization Letter

Review	Start date	End Date	Sections	Status	Submit
Central intake			➡	Not submitted	➡
Science review			➡	Not submitted	
Ethics review			➡	Not submitted	
DPS review			➡	Not submitted	
Resource review			➡		
Pharmacy review			➡	Not submitted	
Budget/Contract review			➡	Not submitted	➡

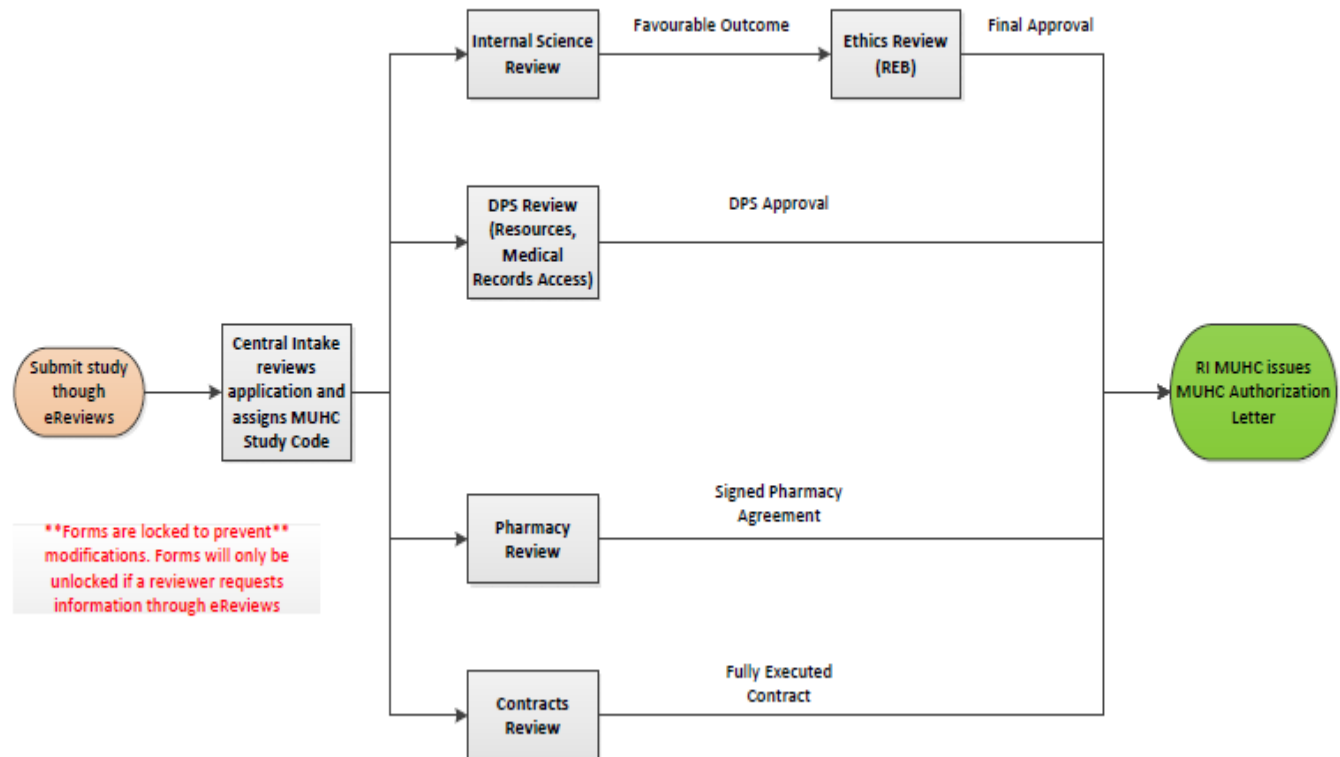
**Notifications/Requests for Information : [ Study # 3087, ]**

If a reviewer requires more information/additional documentation to process your application you will see a notification here. Make the requested changes to the appropriate study forms then come back to this page and click on Submit Changes. You may provide a comment to the reviewer by entering text in the "Comments" box below.

Process	Comments	Investigator comment	Submit changes
Empty			

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# Review Process Overview




# Review Process Tracking

- ❖ Clicking on Submit locks the forms to prevent further modification
- ❖ To modify forms a reviewer (REB coordinator, contract reviewer, pharmacy manager) has to request information



# Review Process Tracking



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## Study Forms Section

- Common questions
- Adults science/ethics review
  - Scientific review and study design
  - Recruitment and enrollment
  - Informed consent
  - Confidentiality of data
  - Regulatory compliance
  - Financial issues
- Clinical trial registration
- Resource
- Pharmacy
- Budget/contract
- PI's declaration

## Study management

- Submit Study/Track Review Progress
- Modify Initial Questionnaire

## Submit / Track [ Study # 13-123-BMA, DECLARE-TIMI 58 ]

Use the Submit buttons to submit your study application for review. Please note that you may submit your contract/budget for review at a later time than your science/ethics/site-specific assessments. You may not start your study until all required approvals are obtained and the RI MUHC issues the MUHC Authorization Letter

Review	Start date	End Date	Sections	Status	Submit
Central intake	2013-06-17	2013-06-17	➡	Completed	
Science review	2013-06-17	2013-06-27	➡	Approved	
Ethics review	2013-06-27		➡	Review in progress	
DPS review	2013-06-17		➡	Review in progress	
Resource review	2013-06-17		➡		
Pharmacy review	2013-06-17	2013-06-20	➡	Completed	
Budget/Contract review	2013-07-11		➡	Review in progress	

## Notifications/Requests for Information : [ Study # 13-123-BMA, DECLARE-TIMI 58 ]


If a reviewer requires more information/additional documentation to process your application you will see a notification here. Make the requested changes to the appropriate study forms then come back to this page and click on Submit Changes. You may provide a comment to the reviewer by entering text in the "Comments" box below.

Process	Comments	Investigator comment	Submit changes
Empty			



# Review Process Tracking

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What do you want to do?  
[Submit CDA](#)

### Study Management

**Notifications pending! Please consult your studies list to see which one(s) require(s) your attention**

Pending Authorization		Authorized (Ongoing)			Archived		
MUHC Study Code:	ID	Study short title	Principal Investigator	Status	Edit	Submit / Track	Notifications
<input type="text" value="13-147"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>			
13-147-BMA	3243	EYEGUARD™-C STUDY	Jean Deschenes	Approval in progress			1



1 - 1 / 1 (22) 40

❖ PI and delegates will receive copy of notification email





# Review Process Tracking

## Study Forms Section

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- ▶ [Adults science/ethics review](#)
  - ▶ [Scientific review and study design](#)
  - ▶ [Recruitment and enrollment](#)
  - ▶ [Informed consent](#)
  - ▶ [Confidentiality of data](#)
  - ▶ [Regulatory compliance](#)
  - ▶ [Financial issues](#)
- ▶ [Clinical trial registration](#)
- ▶ [Resource](#)
- ▶ [Medical record access](#)
- ▶ [Pharmacy](#)
- ▶ [Budget/contract](#)
- ▶ [PI's declaration](#)

## Study management

- ➔ [Submit Study/Track Review Progress](#)
- ▶ [Modify Initial Questions](#)

## Submit / Track [ Study # 13-147-BMA, EYEGUARD™-C STUDY ]

Use the Submit buttons to submit your study application for review. Please note that you may submit your contract/budget for review at a later time than your science/ethics/site-specific assessments. You may not start your study until all required approvals are obtained and the RI MUHC issues the MUHC Authorization Letter

Review	Start date	End Date	Sections	Status	Submit
Central intake	2013-07-05	2013-07-08	➡	Completed	
Science review	2013-07-08	2013-07-15	➡	Approved	
Ethics review	2013-07-15		➡	Modification requested	
DPS review	2013-07-08		➡	Review in progress	
Medical Record Access	2013-07-08		➡		
Resource review	2013-07-08		➡		
Pharmacy review	2013-07-08		➡	Review in progress	
Budget/Contract review	2013-07-19		➡	Review in progress	


## Notifications/Requests for Information : [ Study # 13-147-BMA, EYEGUARD™-C STUDY ]

If a reviewer requires more information/additional documentation to process your application you will see a notification here. Make the requested changes to the appropriate study forms then come back to this page and click on Submit Changes. You may provide a comment to the reviewer by entering text in the "Comments" box below.

Process	Comments	Investigator comment	Submit changes
Ethics review	<p>Dear Dr. Deschenes:</p> <p>Please submit 1 signed original and 9 copies of collated study documents that require ethics review to my attention at S11.08.</p> <p>Please confirm in the eReview comment field that you will do the submission.</p> <p>Thank you!</p> <p>James Ellasus Research Ethics Office-Intake RVH S11.08 x34323</p>	<div> <input type="text"/> </div>	➡




# Ongoing Report Management



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Reports list

























Study ID: 486

PI: Yale, Jean-Francois

Study ref number: 09-297-BMB

Study title: A Randomized, Double-blind, Placebo-controlled, 3-arm, Parallel-group, 26-week, Multicenter Study with a 26-week Extension, to Evaluate the Efficacy, Safety and Tolerability of Canagliflozin in the Treatment of Subjects with Type 2

Add Report

Report ID	Report Name	SAE-Type	Subject identifier	Creation date	Submission Date	Decision Date	Status	Edit/ Submit Report	Print/ Preview	Del
	All Report									
<a href="#">2970</a>	Continuing Review	NA	NA	04/13/2012	04/19/2012		Review in progress			
<a href="#">321</a>	Continuing Review	NA	NA	04/14/2011	04/18/2011		Approved			
<a href="#">601</a>	Contract/Budget Amendment	NA	NA	11/15/2011	11/16/2011		Approved			
<a href="#">303</a>	Protocol Violation Report	NA	NA	05/27/2011	01/16/2012		Review in progress			
<a href="#">304</a>	Protocol Violation Report	NA	NA	05/27/2011	01/16/2012		Review in progress			
<a href="#">473</a>	Protocol Violation Report	NA	NA	10/17/2011	11/02/2011		Review in progress			
<a href="#">474</a>	Protocol Violation Report	NA	NA	10/17/2011	11/02/2011		Review in progress			
<a href="#">1562</a>	Revision To An Approved Study	NA	NA	07/15/2011	07/18/2011		Review in progress			





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# Thank you

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