

**Pharmaceutical Regulatory Information System  
(PRISM)  
Internet – CT Expedited Safety Report Module  
User Manual**

**Version 3.2 (Jul 2021)**

## **REVISION HISTORY**

<b>Version</b>	<b>Effective Date</b>	<b>Summary of Changes</b>	<b>Author</b>
1.0	March 2008	First Release	NCS PRISM Team
2.0	April 2008	Second Release	NCS PRISM Team
2.1	October 2008	Change in Screen Captures & Steps	HSA-CTB
2.2	February 2009	Additional Information	HSA-CTB
3.0	July 2009	Enhancements Added	HSA-CTB
3.1	August 2018	Change from SingPass to CorpPass	HSA-CTB
3.2	July 2021	Change in login process for Corppass	HSA-IOCTB

## Table of Contents

<b>1</b>	<b>INTRODUCTION .....</b>	<b>4</b>
	PURPOSE.....	4
	SCOPE.....	4
	OVERVIEW .....	4
<b>2</b>	<b>FUNCTION.....</b>	<b>5</b>
2.1	TO APPLY FOR SUBMISSION OF EXPEDITED SAFETY REPORT .....	5
2.1.1	<i>Login.....</i>	5
2.2	COMMON ICONS AND LINKS IN ALL SECTIONS: .....	7
2.3	APPLICATION FORM OF CLINICAL TRIAL SUBMISSION OF EXPEDITED SAFETY REPORT.....	8
2.3.1	<i>Introduction .....</i>	8
2.3.2	<i>Particulars of Clinical Trial Application.....</i>	9
2.3.3	<i>Applicant Particulars.....</i>	10
2.3.4	<i>Safety Report Summary.....</i>	11
2.3.5	<i>Supporting Attachments.....</i>	15
2.3.6	<i>Confirmation.....</i>	16
2.3.7	<i>Acknowledgment .....</i>	19

## **1 Introduction**

### **Purpose**

The purpose of this user manual is to ensure that all nominated application users will be proficient in the use of the online application system.

### **Scope**

The scope of the manual is to provide information on the use of the eService for the online application of the extended function – Submission of Expedited Safety Report

### **Overview**

This document provides brief details on the standards and guidelines that a user should adhere to in doing an online preparation and submission of an application. It divides the application procedure into sections and provides the brief guidelines for each of them.

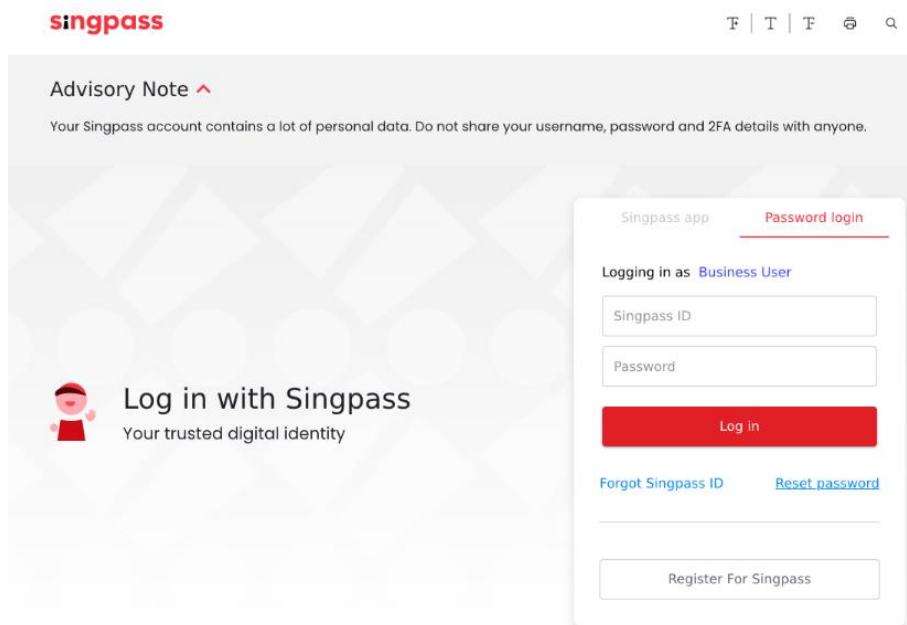
## 2 Function

### 2.1 To Apply for Submission of Expedited Safety Report

Steps:

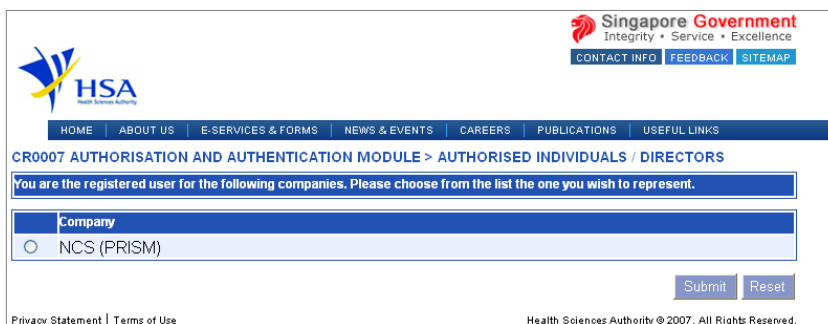
- 1) CRIS administrator grants access to eService of **CT - Submission of Expedited Safety Report**
- 2) Please access the following URL (**DO NOT** click on link, please copy the URL to address bar of browser)

<http://eservice.hsa.gov.sg/osc/portal/jsp/AA/process.jsp?eService=190>



#### 2.1.1 Login

- 1) Log in with your Singpass.
- 2) The predefined roles of the users, comprising of drafter, submitter, CRIS administrator, counter staff, will be verified against the CRIS authorisation.
- 3) Upon successful authentication, a page will be shown for the applicant to select the company.



- 4) Select the specific company and click the **Submit** button.

- 5) The Terms and Conditions page will be shown. The application user is required to read the Terms and Conditions before indicating accept or reject. If the **Accept** button is clicked, the user will be able to proceed with the eService. If the **Cancel** button is clicked, the page will be re-directed to the HSA homepage.

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**HSA**  
HEALTH SCIENCES AUTHORITY

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CR0010 AUTHORIZATION AND AUTHENTICATION MODULE > TERMS AND CONDITIONS

**Terms and Conditions of Use**  
Updated as of 19/01/2005

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2. The information/materials/contents contained in the HSA website are protected by copyright, trademark and other forms of proprietary rights. All rights, title and interest in the same are owned by, licensed to or controlled by HSA.
3. You shall therefore not reproduce, transmit or distribute in any way, the information/materials/contents of the HSA website without HSA's prior written consent.
4. You may not set robots, crawlers, software agents or any other agents and/or devices to retrieve data from the HSA website or database.

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## 2.2 Common icons and links in all sections:

- Attach icon. This will allow user to go to the **Supporting Attachments** page to attach relevant documents.



- Save icon. This will allow the user to save the form information at any desired point of time.



- Application form links. This will allow the user to toggle to different sections of the application form.

- This will allow the user to proceed to the next section of the application form.

Next

- Previous button. This will allow the user to proceed to the previous section of the application form.

Previous

- Reset button. This will clear the information the user has input in the page.

Reset

- Fields with a red asterix \* are mandatory input fields. Unless it is entered, the system validation will highlight error and application submission will be disabled.

### 2.3 Application Form of Clinical Trial Submission of Expedited Safety Report

The application form consists of 6 sections:

1	Introduction
2	Particular Of Clinical Trial Application
3	Applicant Particulars
4	Safety Report Summary
5	Supporting Attachments
6	Confirmation

It is recommended for users to fill in the application form details in a systematic serial manner as the later sections could reference information in the earlier sections.

#### 2.3.1 Introduction


The screenshot displays the PRISM web interface. At the top left is the HSA logo. At the top right is the Singapore Government logo with the tagline 'Integrity • Service • Excellence' and links for 'CONTACT INFO', 'FEEDBACK', and 'SITEMAP'. Below these are navigation tabs: 'HOME', 'ABOUT US', 'E-SERVICES & FORMS', 'NEWS & EVENTS', 'CAREERS', 'PUBLICATIONS', and 'USEFUL LINKS'. The user's session information is shown: 'Logon ID : S0750213C', 'Client Name : SHISEIDO SINGAPORE COMPANY (PT) LTD', and 'Transaction No : T0802572E'. There are 'Log out' and 'CDA' buttons. The main heading is 'PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT'. A note states 'Fields marked with an asterisk \* are mandatory.' The 'Introduction' section contains the text 'CT application Submitted online via Prism'. Below this is a form with the label 'State the CTC Application No. : \*' and a dropdown menu showing '0600450G - 435345345'. A 'Retrieve' button is next to the dropdown. To the right of the dropdown, red text provides instructions: 'If this expedited safety report occurred in an on-going clinical trial conducted in Singapore, please select the actual CTC application no.' and 'If this expedited safety report occurred in a clinical trial that is not conducted in Singapore. You may select an application no. involving the use of the same study drug.' At the bottom left are links for 'Privacy Statement' and 'Terms of Use'. At the bottom right is the copyright notice 'Health Sciences Authority © 2007. All Rights Reserved.'

This section shows the list of Clinical Trial Application numbers. Select a Clinical Trial Application Number and click the **Retrieve** button to go to the **Clinical Trial Application** information section.



2.3.2 Particulars of Clinical Trial Application





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---

HOME | ABOUT US | E-SERVICES & FORMS | NEWS & EVENTS | CAREERS | PUBLICATIONS | USEFUL LINKS

Login ID : 50750213C
Client Name : SHISEIDO SINGAPORE COMPANY (PTB) LTD
Transaction No : T0802572E [Log out](#) [CDA](#)

**PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT**

**Fill in the application form** [Guideline](#) [Help](#)

**1. Particulars of Clinical Trial Application**

2. Applicant Particulars

3. Safety Report Summary

4. Supporting Attachments

5. Confirmation

Special Symbol

[Attach](#) [Save](#)

[Next](#)

Fields marked with an asterisk \* are mandatory.

**1. Particulars of Clinical Trial Application**

HSA Clinical Trial Application Number	0600450G
Title of Clinical Trial	sdfasdfsdfasd
Protocol Number	435345345
Protocol Date	28/06/2006

**List of Principal Investigator(s) & Clinical Trial Institution(s)**

Principal Investigator	Clinical Trial Institution	Date Of Approval	CTC Expiry Date	CTC Status
adasdfasd	Changi General Hospital	31/01/2007	19/03/2008	Ongoing

**CT Study Drugs**

SN	Drug Type	Drug Name	ATC Code	Class of Drug
1	STD	weaqwerasdfa	Antineoplastic and immunomodulat	Class III – Approved drug undergoing

**Trial Summary**

(a) Therapeutic Area:

(b) DSMB:  Yes  No

(e) Is:  Single-Blind  Double-Blind  Open-Label

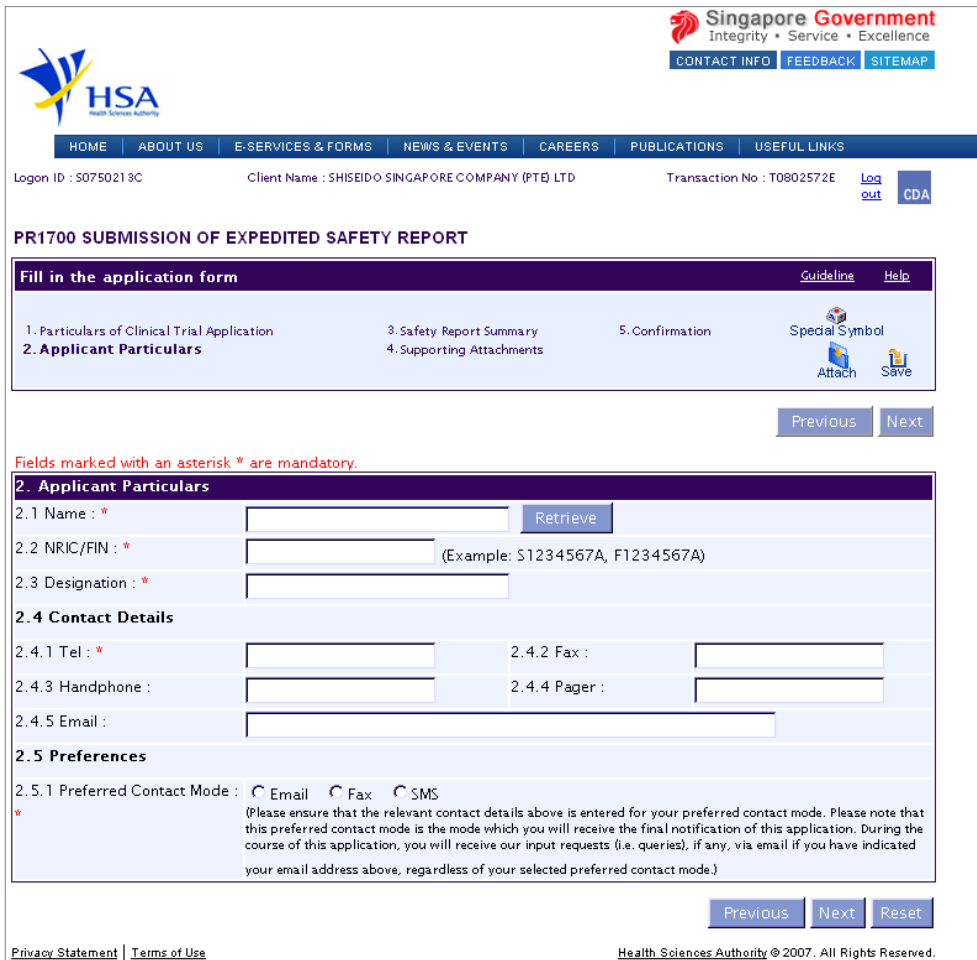
Others

[Next](#)

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This section shows the Clinical Trial Application information after a Clinical Trial Application Number is selected. The Clinical Trial Application information is auto-populated. Select a study drug and click the **Next** button to go to the **Applicant Particulars** section.

2.3.3 Applicant Particulars



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Login ID : S0750213C Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD Transaction No : T0802572E Log out CDA

PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT

Fill in the application form [Guideline](#) [Help](#)

1. Particulars of Clinical Trial Application  
2. Applicant Particulars  
3. Safety Report Summary  
4. Supporting Attachments  
5. Confirmation

Special Symbol  
Attach Save

Previous Next

Fields marked with an asterisk \* are mandatory.

2. Applicant Particulars

2.1 Name : \*

2.2 NRIC/FIN : \*  (Example: S1234567A, F1234567A)

2.3 Designation : \*

2.4 Contact Details

2.4.1 Tel : \*  2.4.2 Fax :

2.4.3 Handphone :  2.4.4 Pager :

2.4.5 Email :

2.5 Preferences

2.5.1 Preferred Contact Mode :  Email  Fax  SMS

\* (Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

Previous Next Reset

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This section allows the input of applicant particulars. Please note that drafter will not be able to see this page since they are not required to enter information for applicant.

- 1) Fill in **Name** or **NRIC**.
- 2) Click on the **Retrieve** button to populate the remaining fields.
- 3) Fill in the other details if applicable.
- 4) Click on the **Next** button to go to the **Safety Report Summary** section.

2.3.4 Safety Report Summary

The screenshot shows the 'PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT' interface. At the top, there are logos for HSA and Singapore Government, along with navigation links like HOME, ABOUT US, E-SERVICES & FORMS, etc. The user's session information is displayed: Logon ID: 50750213C, Client Name: SHISEIDO SINGAPORE COMPANY (PTB) LTD, Transaction No: T0802572E. The main heading is 'PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT'. Below this is a progress bar with steps: 1. Particulars of Clinical Trial Application, 2. Applicant Particulars, 3. Safety Report Summary (active), 4. Supporting Attachments, 5. Confirmation. There are icons for 'Special Symbol', 'Attach', and 'Save'. Navigation buttons 'Previous' and 'Next' are present. A note states: 'Fields marked with an asterisk \* are mandatory.' The '3. Safety Report Summary' section has two radio buttons: 'Initial' (selected) and 'Follow up'. Red text instructions explain the report type selection. Below are fields for 'Select Manufacturer Control No(MCN):' (a dropdown menu showing 'Please Select') and 'Enter Manufacturer Control No(MCN):' (a text box containing 'MCN1111') with an 'Add MCN' button. At the bottom, there are instructions: '1. Please click on the MCN hyperlink to enter the required safety report information. 2. Please ensure that all safety report information is filled in before proceeding to Previous or Next Page.' and 'Previous', 'Next', 'Reset' buttons.

Initial Safety Report

This screenshot is similar to the previous one but shows the 'Follow up' radio button selected. The 'Enter Manufacturer Control No(MCN):' field is empty. A new field 'Search Manufacturer Control No(MCN):' with a 'Search for MCN' link is added. Red text instructions state: 'To search for the MCN no., please click on the Search for MCN link.' The 'Previous', 'Next', and 'Reset' buttons are at the bottom. The footer includes 'Privacy Statement | Terms of Use' and 'Health Sciences Authority © 2007. All Rights Reserved.'

Follow up Safety Report

The screenshot shows the 'Search For MCN' form. It includes a header with the Singapore Government logo and HSA logo. The navigation bar contains links for HOME, ABOUT US, E-SERVICES & FORMS, NEWS & EVENTS, CAREERS, PUBLICATIONS, and USEFUL LINKS. The user's session information is displayed: Logon ID: 50750219C, Client Name: SHISEIDO SINGAPORE COMPANY (PTE) LTD, and Transaction No: T0802572E. The form title is 'PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT'. The search criteria section includes:
 

- MCN: Begins With [dropdown]
- Patient Age: [input] To [input] Please Select [dropdown]
- Submission Date: [calendar icon]
- Did the SAE occur in Singapore:  Yes  No

 Buttons for 'Reset', 'Search', and 'Cancel' are at the bottom. A footer contains 'Privacy Statement | Terms of Use' and 'Health Sciences Authority © 2007. All Rights Reserved.'

Search for Manufacturer Control Number (MCN)

The screenshot shows the 'Fill in the application form' section for '3. Safety Report Summary'. It includes a progress bar with steps: 1. Particulars of Clinical Trial Application, 2. Applicant Particulars, 3. Safety Report Summary (current), 4. Supporting Attachments, and 5. Confirmation. There are icons for 'Special Symbol', 'Attach', and 'Save'. 'Previous' and 'Next' buttons are present. Below the progress bar, a note states: 'Fields marked with an asterisk \* are mandatory.' The '3. Safety Report Summary' section has:
 

- Radio buttons for 'Initial' (selected) and 'Follow up'.
- Text: 'Please indicate the report type. If Initial, please enter a new MCN no. and click on Add MCN button. If follow up, select one existing MCN no. from dropdown list or enter a new MCN no. if MCN no. is not found in the dropdown list. Click on Add MCN button.'
- 'Select Manufacturer Control No(MCN):' dropdown menu (Please Select).
- 'Enter Manufacturer Control No(MCN):' text input (MCN001) and 'Add MCN' button.
- 'List of Saved Safety Reports:' section with a table:
 

Manufacturer Control No.	Initial / Followup	Last Modified Date
<input type="checkbox"/> MCN001	Initial	12/03/2008

 A 'Delete' button is next to the table row.

 A footer contains 'Privacy Statement | Terms of Use' and 'Health Sciences Authority © 2007. All Rights Reserved.'

Safety Report Added

To add a Safety Report

**Please note that more than 1 CIOMS report for the same drug can be submitted per application.**

- 1) Select a report type, initial or follow up report.
- 2) For initial report, enter a Manufacturer Control Number (MCN) and click **Add MCN** button.  
For follow up report, select a Manufacturer Control Number (MCN) from dropdown list and click **Add MCN** button. To search for Manufacturer Control Number (MCN), click on the **Search for MCN** link to search for MCN.  
If the Manufacturer Control Number (MCN) is not found in the dropdown list, enter a Manufacturer Control Number (MCN) and click **Add MCN** button.
- 3) After adding the safety report, the Manufacturer Control Number (MCN) will appear in the list at bottom. Click on the Manufacturer Control Number (MCN) hyperlink to enter report details.
- 4) To add another CIOMS report, please return to steps 1-3.

Safety Report Details





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Logon ID : S0750213C
Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD CHG
Transaction No : T0802572E

[Logout](#)

### PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT

Fields marked with an asterisk \* are mandatory.

#### 3.1 PARTICULARS OF PATIENT

Age: \*  Please Select Please enter age or approximate age. If age is unknown, leave blank.

Sex: \*  Male  Female  Unknown

Is this report from the same Clinical Trial protocol in Singapore?: \*  Yes  No

Protocol No:  Protocol no. is only required if the Clinical Trial is ongoing in Singapore.

For locally registered products, only SAEs that are unexpected, related and arising from the same Clinical Trial protocol (conducted in Singapore) need to be submitted.

Did this SAE occur in Singapore: \*  Yes  No

Manufacturer Control No: MCN001

Date received by Manf: \*

#### 3.2 DETAILS OF ADVERSE DRUG REACTION(S)

Date of onset(dd/mm/yyyy):

Outcome:

Time to Event(days):

SAE Description: *	SOC1: *	Causality: *
<input type="text"/> search keyword	<input type="text"/>	Please Select
<input type="text"/> search keyword	<input type="text"/>	Please Select
<input type="text"/> search keyword	<input type="text"/>	Please Select

[Add SAE Description](#)

#### 3.3 CRITERIA OF SAE

(Please tick all that apply):

Patient die due to reaction

Life Threatening

Congenital anomaly

Involved or prolonged in-patient hospitalisation

Involved persistent or significant disability or incapacity

Medically significant

Please state why it was considered medically significant(max 255 characters)

#### 3.4 SUSPECTED DRUG DETAILS(Minimum of one entry is required)

Unblinded Report:  Yes  No  Unknown

Date started(dd/mm/yyyy):  Date stopped(dd/mm/yyyy):

Indication:

#### 3.5 OTHER RELEVANT INFORMATION

E.g. Upgraded or down graded reports (max 2500 characters).

#### 3.6 Supporting Attachments

To add an attachment, type in the path or hit the browse button. Then **hit the Attach Files button to save the attachment** to the list below.

Please click [here](#) for guideline on document attachment.

Documents	
3.6.1 CIOMS / MedWatch Report :	<input type="text"/> <a href="#">Browse...</a>
3.6.2 Dear Doctor Letters :	<input type="text"/> <a href="#">Browse...</a>

Please attach at least ONE document

[Attach Files](#)

To go back MCN Report Summary Page without saving the changes, please click on the Cancel button.

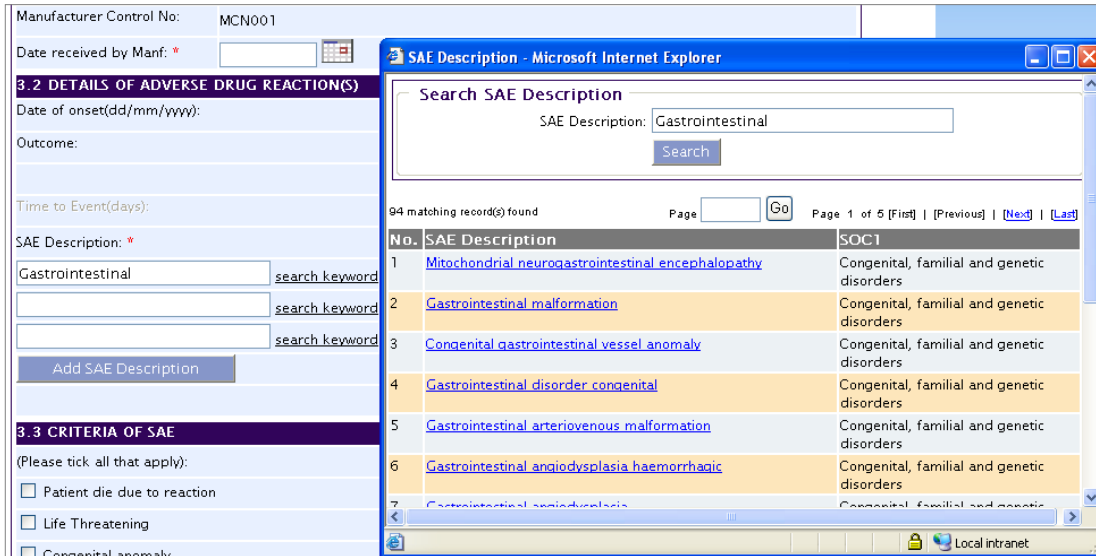
To save the changes, please click on the Save button.

To save all changes and go back MCN Report Summary Page, please click on the Back to Summary button.

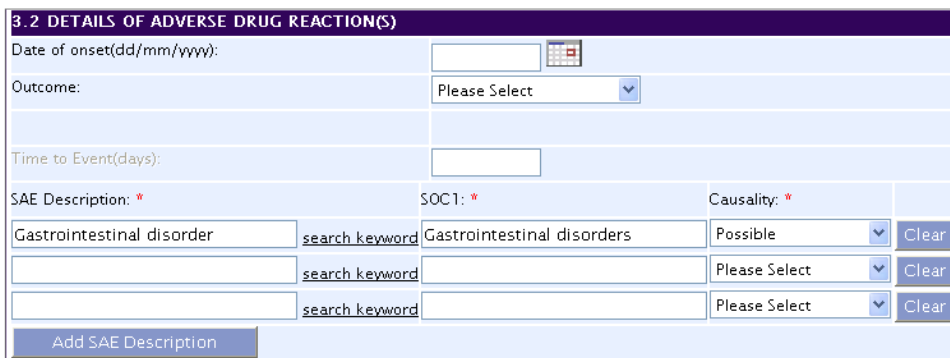
[Cancel](#)
[Save](#)
[Back to Summary](#)

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Search for SAE Description and SOC1



SAE Description and SOC1 are populated

### To enter Safety Report Details

Please note that only events that meet the 3 criteria of serious, unexpected and drug-related are to be entered. MedDRA Preferred Terms are used for SAE Description.

- 1) Enter all mandatory fields, date of onset (if available), indication, start and stop dates of drug.  
To enter SAE Description and SOC1, enter a keyword and click on **search keyword**. Select the appropriate SAE term from the search results. Both SAE Description and SOC1 fields will be populated.  
To delete SAE Description and SOC1 entry, click on **Clear** button.
- 2) Attach at least one document of any required document type and click on **Attach Files** button to upload the document.
- 3) After entering the details of safety report, click on **Back to Summary** button to save changes and go back to summary page.

### 2.3.5 Supporting Attachments

The screenshot displays the PRISM web application interface for submitting an expedited safety report. At the top, there is a navigation bar with the Singapore Government logo and the HSA logo. The main content area shows a progress bar with 5 steps: 1. Particulars of Clinical Trial Application, 2. Applicant Particulars, 3. Safety Report Summary, 4. Supporting Attachments (current step), and 5. Confirmation. Below the progress bar, there is a section titled '4. Supporting Attachments' with instructions on how to add attachments and a form with a 'Browse...' button and an 'Attach Files' button. The page also includes a Singapore Government logo, HSA logo, and various navigation links.

This section allows the attachment of the supporting documents for the application.

#### Add Attachment

- 1) Click on the **Browse** button to select the required file for attachment.
- 2) Select the required file.
- 3) Click on the **Ok** button.
- 4) Click on the **Attach File** button for the file to be attached to this application.
- 5) Fill up remarks with regards to the attachment if required.

#### Remove Attachment

- 1) Click on the checkbox beside the attachment or attachments from the **List of Attachments** table.
- 2) To delete all attachments, click on the checkbox beside S/n.
- 3) Click on the **Remove** button.

The file extensions, which are acceptable and supported, are:

- tif
- jpg
- pdf
- doc
- xls
- ppt
- avi (audio visual, if required)
- mpeg(audio visual, if required)

2.3.6 Confirmation

This section shows all the information the user has entered into the different sections of the application form. It allows the user to manually verify all the information fields.

Logon ID : S0750219C Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD Transaction No : T0802572E [Log out](#) [CDA](#)

**PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT**

Fill in the application form [Guidelines](#) [Help](#)

1. Particulars of Clinical Trial Application 3. Safety Report Summary **5. Confirmation** [Special Symbol](#)  
 2. Applicant Particulars 4. Supporting Attachments [Attach](#) [Save](#)

[Previous](#)

Fields marked with an asterisk \* are mandatory.

**1. Particulars of Clinical Trial Application**

HSA Clinical Trial Application Number	0600450G
Title of Clinical Trial	sdfasdfsdfasd
Protocol Number	435345345
Protocol Date	28/06/2006

**List of Principal Investigator(s) & Clinical Trial Institution(s)**

Principal Investigator	Clinical Trial Institution	Date Of Approval	CTC Expiry Date	CTC Status
adasdfasd	Changi General Hospital	31/01/2007	19/03/2008	Ongoing

**Study Drug Information**

Drug Type:	STD
Drug Name:	weaqwerasdfa
ATC Code:	Antineoplastic and immunomodulating agents (Endocrine therapy)
Class of Drug:	Class III – Approved drug undergoing clinical trial for new indications, method of administration and/or dosages, etc

**Trial Summary**

Therapeutic Area:	Dentistry
DSMB:	Yes
Is:	Single-Blind

**2. Applicant Particulars**

2.1 Name : \*

2.2 NRIC/FIN : \*

2.3 Designation : \*

**2.4 Address**

2.4.1 Address Type : \* Local

2.4.2 Postal Code : \*

2.4.3 Block / House No : 2.4.4 Level – Unit : # -

2.4.5 Street Name :

2.4.6 Building Name :

2.4.7 Country : Singapore

**2.5 Contact Details**

2.5.1 Tel : \* 2.5.2 Fax :

2.5.3 Handphone : 2.5.4 Pager :

2.5.5 Email :

**2.6 Preferences**

2.6.1 Preferred Contact Mode : \*

(Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

**3. Safety Report Summary**

**List of Saved Safety Reports:**  
 Click on the Manufacturer Control No. hyperlink to view details of safety report

SN	Manufacturer Control No.	Initial / Followup	Last Modified Date
1	<a href="#">MCN001</a>	Initial	12/03/2008

**4. Supporting Attachments**

Sn	Attachment Name	Attachment Type	Size (kb)	Remarks
----	-----------------	-----------------	-----------	---------

[Previous](#) [Validate](#) [Notify](#) [Reset](#)

Confirmation Page for Drafter

Notify

The drafter would need to click on the **Notify** button to inform the applicant the application of Clinical Trial Submission of Expedited Safety Report. The notification email will be sent to the email of the latest submitter of Clinical Trial Extended eService. The applicant will fill in the applicant details and submit the application.





  
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Logon ID : 50750213C
Client Name : SHISEDO SINGAPORE COMPANY (PTD) LTD
Transaction No : T0802572E
Log out 

---

**PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT**

[Guideline](#) [Help](#)

1. Particulars of Clinical Trial Application      3. Safety Report Summary      **5. Confirmation**

2. Applicant Particulars                              4. Supporting Attachments

Special Symbol

[Previous](#)

Fields marked with an asterisk \* are mandatory.

**1. Particulars of Clinical Trial Application**

HSA Clinical Trial Application Number	0600450G
Title of Clinical Trial	sdfasdfsdfasd
Protocol Number	435345345
Protocol Date	28/06/2006

**List of Principal Investigator(s) & Clinical Trial Institution(s)**

Principal Investigator	Clinical Trial Institution	Date Of Approval	CTC Expiry Date	CTC Status
adasdfasd	Changi General Hospital	31/01/2007	19/03/2008	Ongoing

**Study Drug Information**

Drug Type:	STD
Drug Name:	weaqwersdfa
ATC Code:	Antineoplastic and immunomodulating agents (Endocrine therapy)
Class of Drug:	Class III – Approved drug undergoing clinical trial for new indications, method of administration and/or dosages, etc.

**Trial Summary**

Therapeutic Area:	Dentistry
DSMB:	Yes
Is:	Single-Blind

**2. Applicant Particulars**

2.1 Name : \*

2.2 NRIC/FIN : \*

2.3 Designation : \*

**2.4 Address**

2.4.1 Address Type : \*      Local

2.4.2 Postal Code : \*

2.4.3 Block / House No :      2.4.4 Level – Unit :      # –

2.4.5 Street Name :

2.4.6 Building Name :

2.4.7 Country :      Singapore

**2.5 Contact Details**

2.5.1 Tel : \*      2.5.2 Fax :

2.5.3 Handphone :      2.5.4 Pager :

2.5.5 Email :

**2.6 Preferences**

2.6.1 Preferred Contact Mode : \*

\* Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)

**3. Safety Report Summary**

**List of Saved Safety Reports:**

Click on the Manufacturer Control No. hyperlink to view details of safety report

SN	Manufacturer Control No.	Initial / Followup	Last Modified Date
1	<a href="#">MCN001</a>	Initial	12/03/2008

**4. Supporting Attachments**

Sn	Attachment Name	Attachment Type	Size (kb)	Remarks

[Previous](#)   [Validate](#)   [Submit](#)   [Reset](#)

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**Confirmation Page for Submitter**

To proceed with the system verification of the information on the application form,

- 1) Click on the **Validate** button.
- 2) If there is any missing mandatory information or details, which do not meet the application requirements, a pop up screen will appear with the details of the validation error. (Please disable any popup blockers to allow the notification to show.)
- 3) If there is no validation error, click on the **Submit** button to submit the application.

Logon ID : S0750213C	Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD	Transaction No : T0802572E	CDA
<b>PZ0101 VALIDATION ERROR REPORT</b>			
<b>2. Applicant Particulars</b>			
2.1	Name for applicant is mandatory		
2.2	NRIC/FIN for applicant is mandatory		
2.3	Designation for applicant is mandatory		
2.4.2	Postal code for applicant's local address is mandatory		
2.5.1	Telephone number in applicant is mandatory		
2.6.1	Preferred contact mode for applicant is mandatory		
<b>3. Safety Report Summary</b>			
3	Please ensure all the mandatory fields in report are entered		
3	Please ensure that there is a CIOMS report / Dear Doctor Letter attached for each report: MCN001		
Close			

This will allow the user to take note of the relevant changes to be made and return back to the application form and amend accordingly.

### 2.3.7 Acknowledgment

The screenshot shows the HSA website interface. At the top right, there is the Singapore Government logo with the tagline 'Integrity • Service • Excellence' and links for 'CONTACT INFO', 'FEEDBACK', and 'SITEMAP'. Below this is a navigation bar with links for 'HOME', 'ABOUT US', 'E-SERVICES & FORMS', 'NEWS & EVENTS', 'CAREERS', 'PUBLICATIONS', and 'USEFUL LINKS'. The user's session information is displayed: 'Logon ID : 50750213C', 'Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD', 'Application No : 0800986Q', and 'Date of Submission: 12/03/2008'. There are also links for 'Log out' and 'CDA'. The main heading is 'PR1700 SUBMISSION OF EXPEDITED SAFETY REPORT'. Below this is a purple box titled 'Acknowledgement' containing the text: 'Your application have been successfully submitted' and 'Please note that your application number is 0800986Q'. At the bottom of the page, there are three links circled in red: 'Click Here To Start A New ESR Application', 'Back to HSA Home Page', and 'Show Printer-Friendly version'. The footer contains 'Privacy statement | Terms of Use' and 'Health Sciences Authority © 2007. All Rights Reserved.'

This section acknowledges that the application has been submitted to HSA for processing. An application number will be generated for the application.

#### Links

- 1) **Show Printer Friendly version**  
This allows the applicant to print or view the application.
- 2) **Click here to start a new ESR application**  
This allows the applicant to start a new ESR application.
- 3) **Back to HSA Home**  
This allows the applicant to go back to HSA home page.