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

User Manual

Version 3.2 (Jul 2021)

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REVISION HISTORY

Version	Effective Date	Summary of Changes	Author
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

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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.

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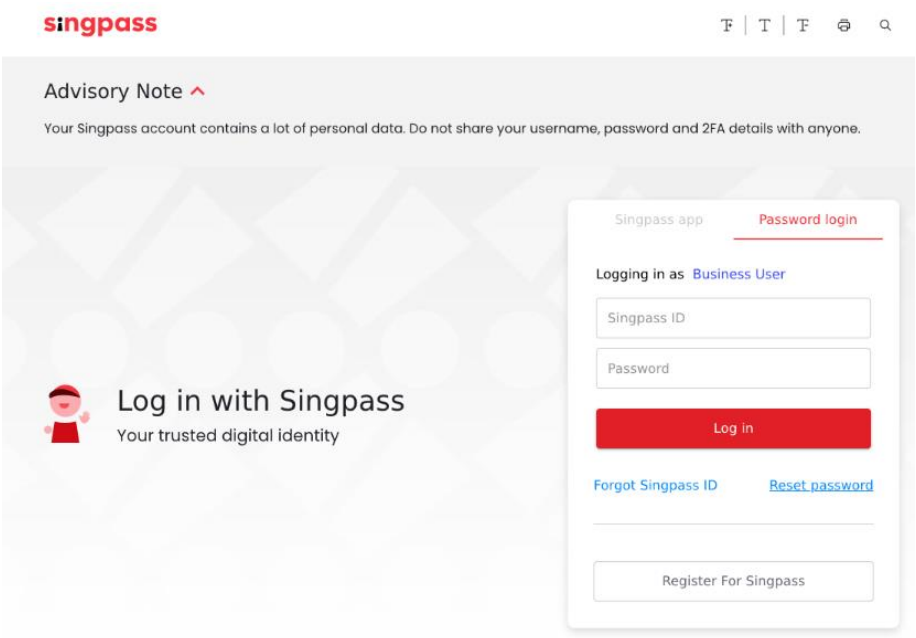
2 Function

2.1 To Apply for Submission of Expedited Safety Report

Steps:

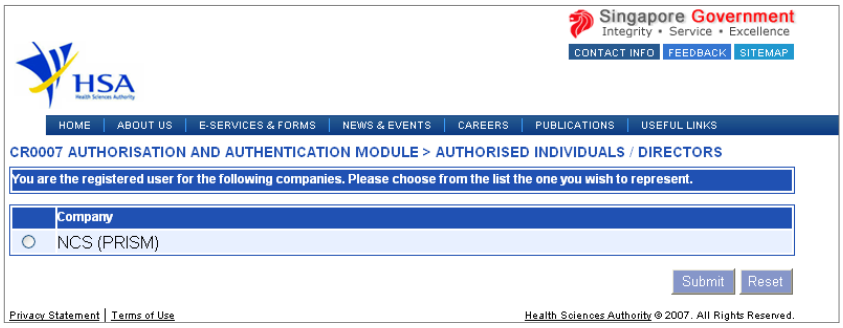
1) CRIS administrator grants access to eService of **CT - Submission of Expedited Safety Report**
2) Please access the following URL (**DO NOT** click on link, please copy the URL to address bar of browser)

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



2.1.1 Login

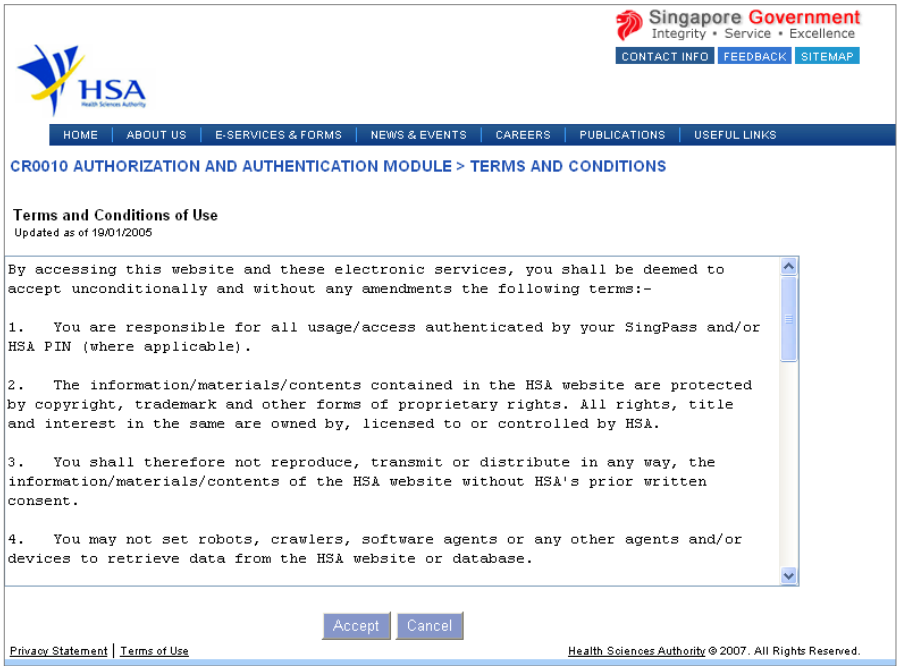
1) Log in with your Singpass.
2) The predefined roles of the users, comprising of drafter, submitter, CRIS administrator, counter staff, will be verified against the CRIS authorisation.
3) Upon successful authentication, a page will be shown for the applicant to select the company.



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

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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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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.



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



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



- 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.

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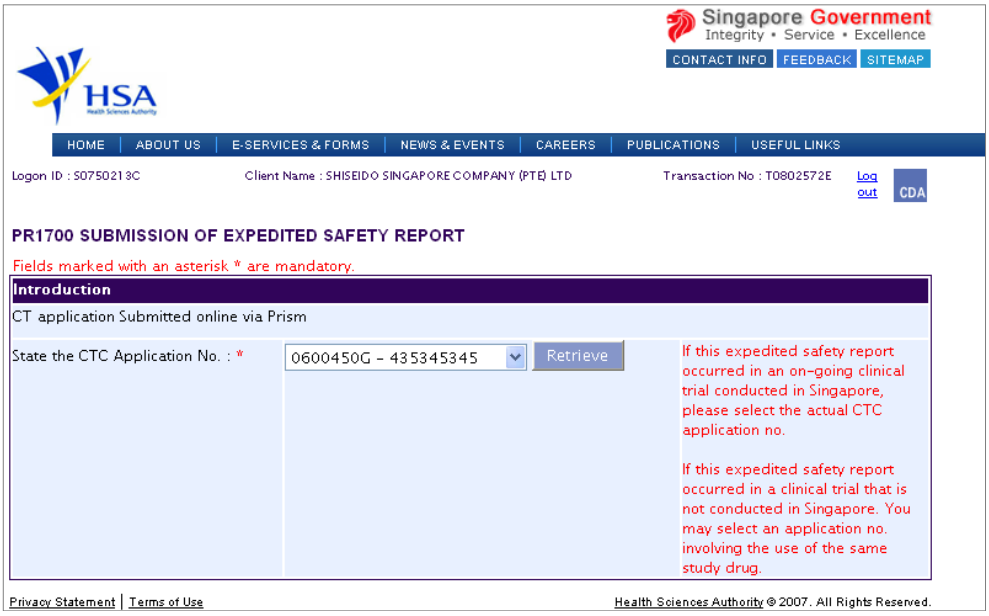
2.3 Application Form of Clinical Trial Submission of Expedited Safety Report

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.

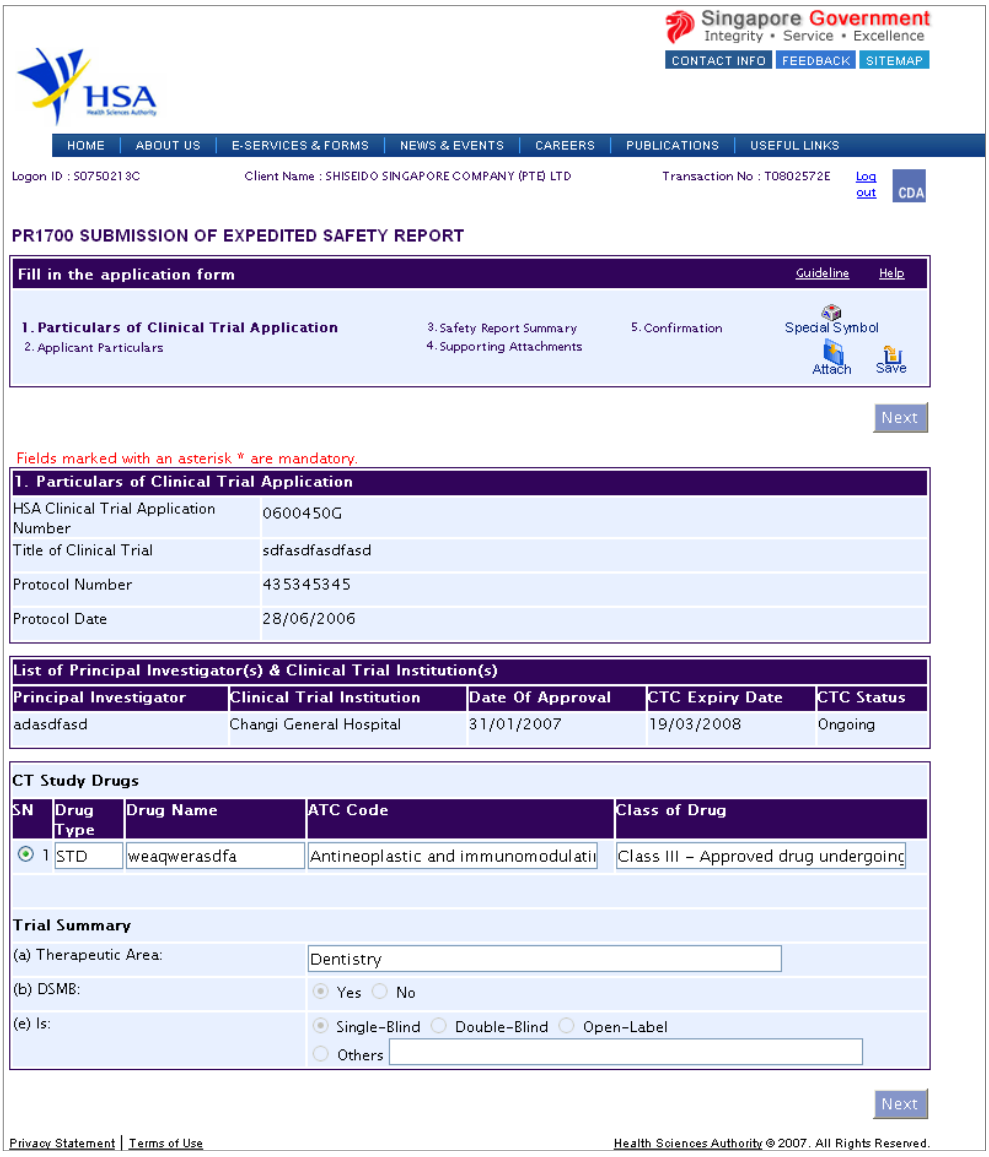
2.3.1 Introduction



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.

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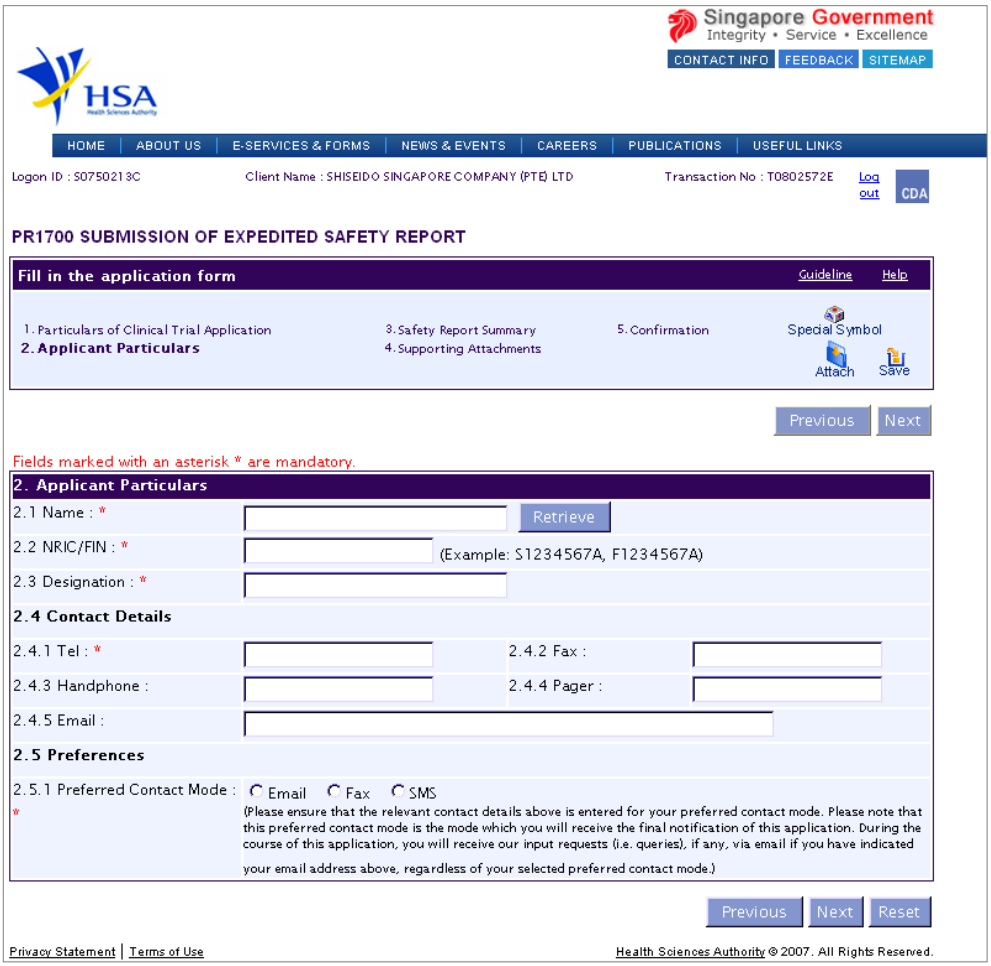
2.3.2 Particulars of Clinical Trial Application



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.

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2.3.3 Applicant Particulars

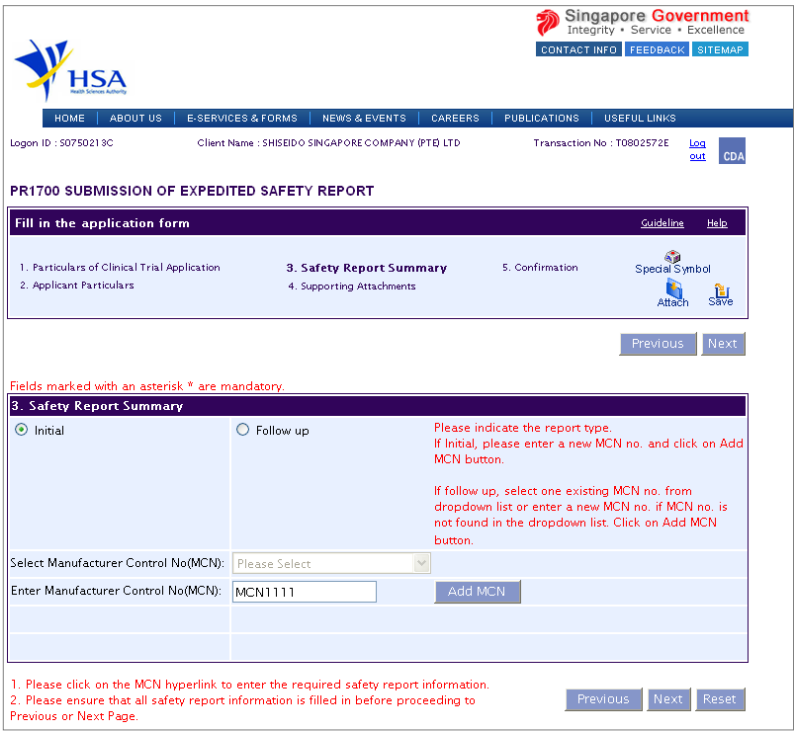


This section allows the input of applicant particulars. Please note that drafter will not be able to see this page since they are not required to enter information for applicant.

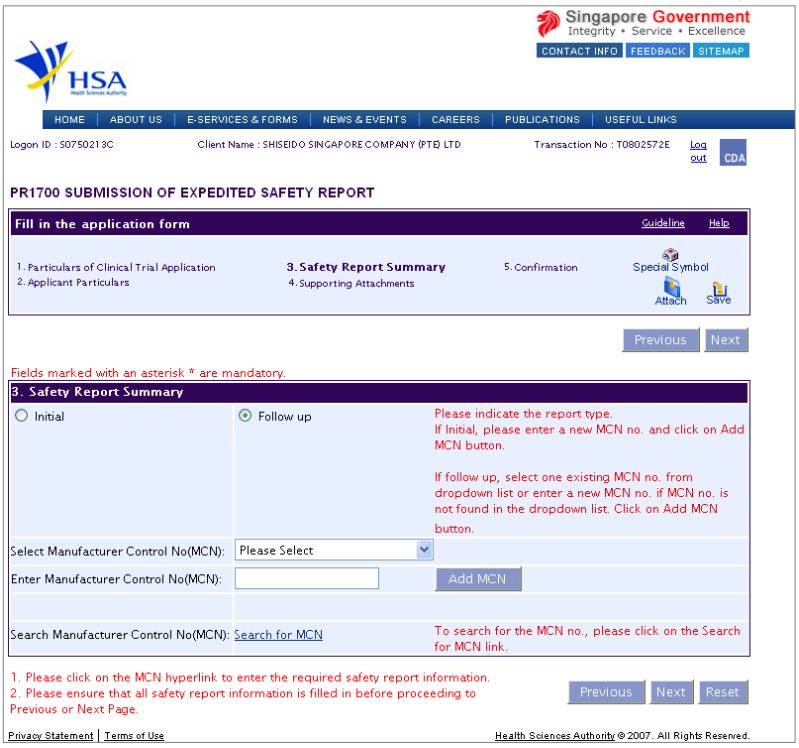
1) Fill in **Name** or **NRIC.**
2) Click on the **Retrieve** button to populate the remaining fields.
3) Fill in the other details if applicable.
4) Click on the **Next** button to go to the **Safety Report Summary** section.

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2.3.4 Safety Report Summary

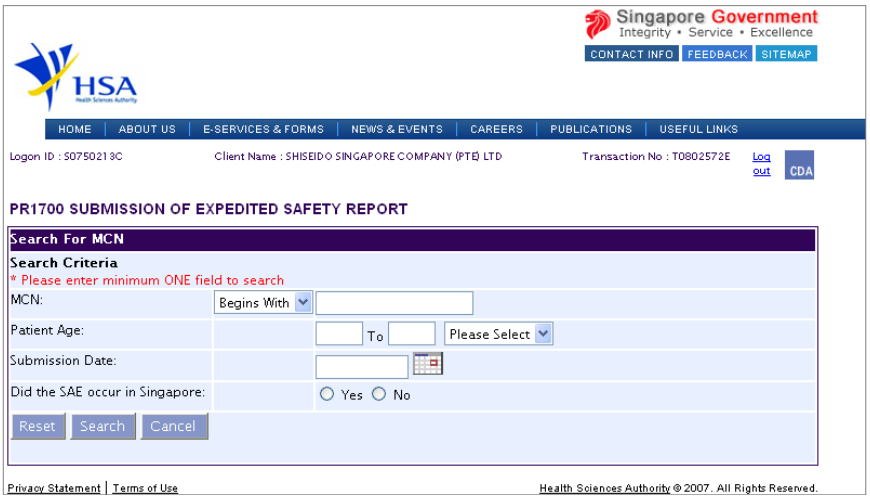


Initial Safety Report

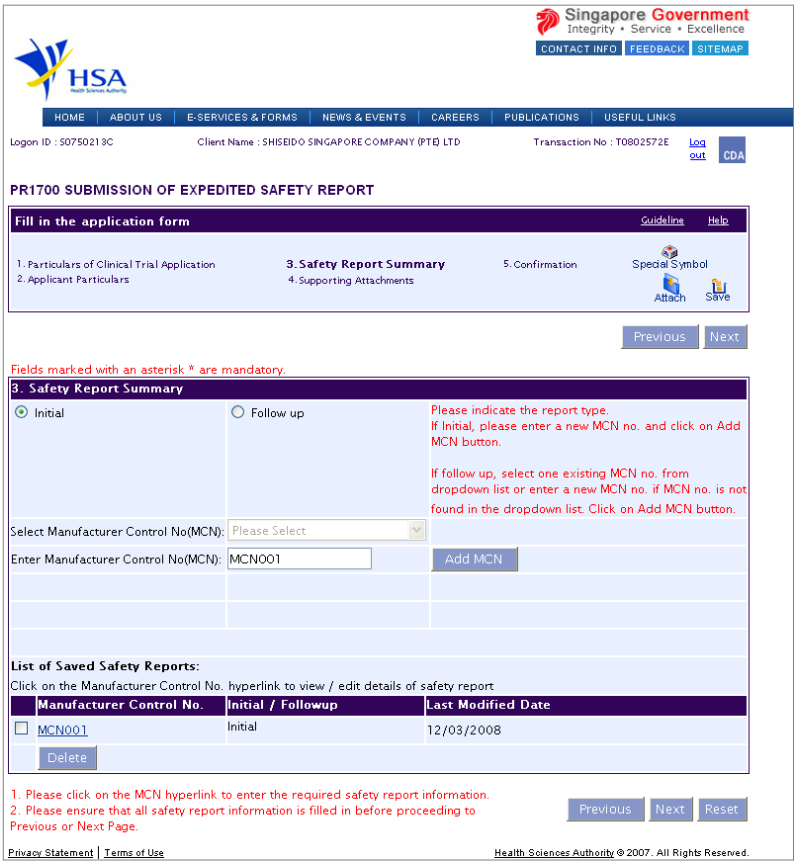


Follow up Safety Report

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Search for Manufacturer Control Number (MCN)



Safety Report Added

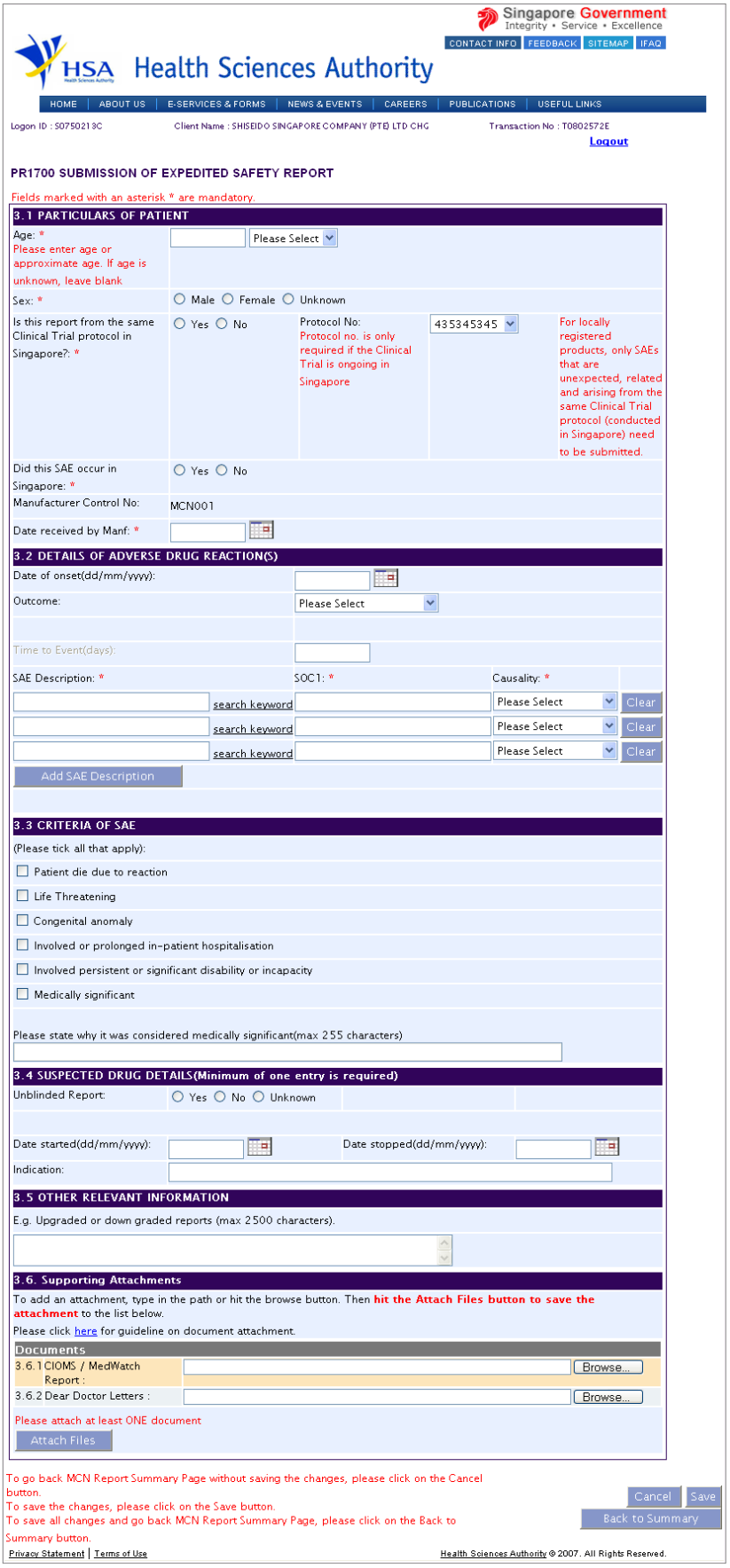
To add a Safety Report

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

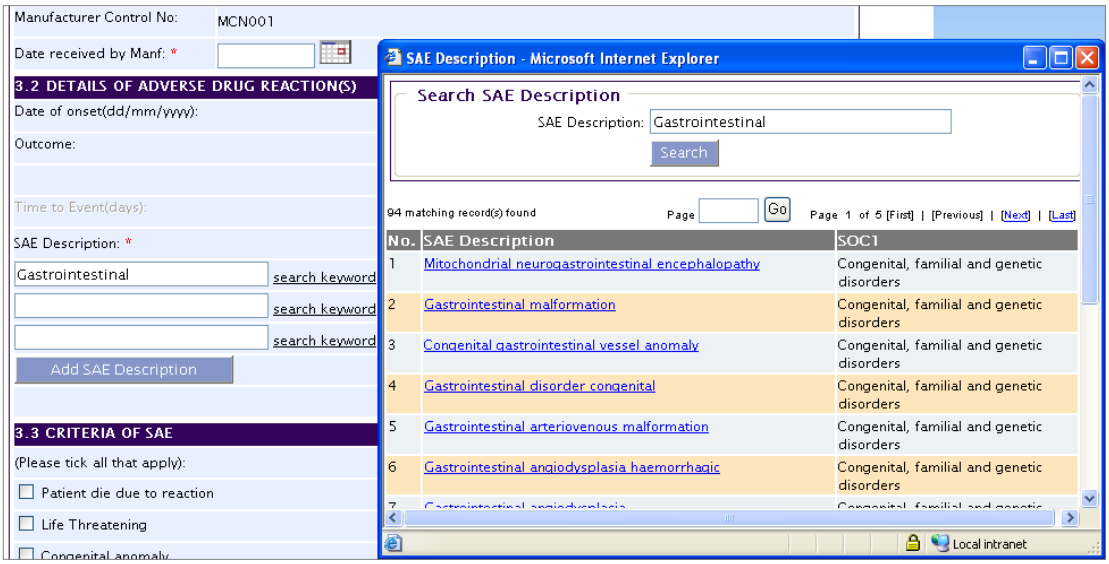
1) Select a report type, initial or follow up report.
2) For initial report, enter a Manufacturer Control Number (MCN) and click **Add MCN** button.
   For follow up report, select a Manufacturer Control Number (MCN) from dropdown list and click **Add MCN** button. To search for Manufacturer Control 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.

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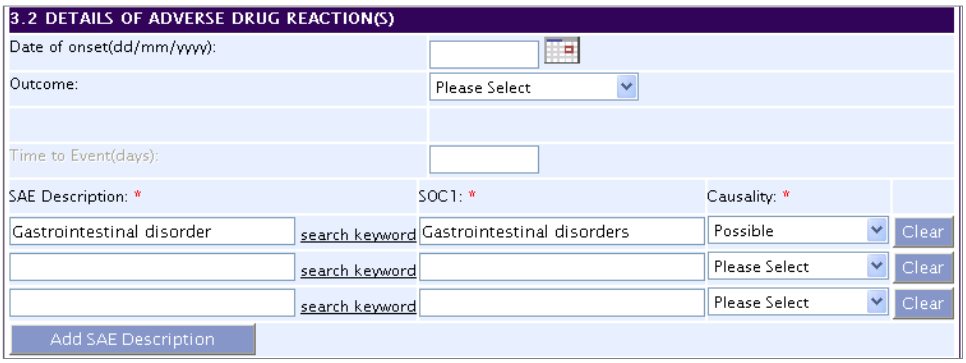
Safety Report Details



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Search for SAE Description and SOC1



SAE Description and SOC1 are populated

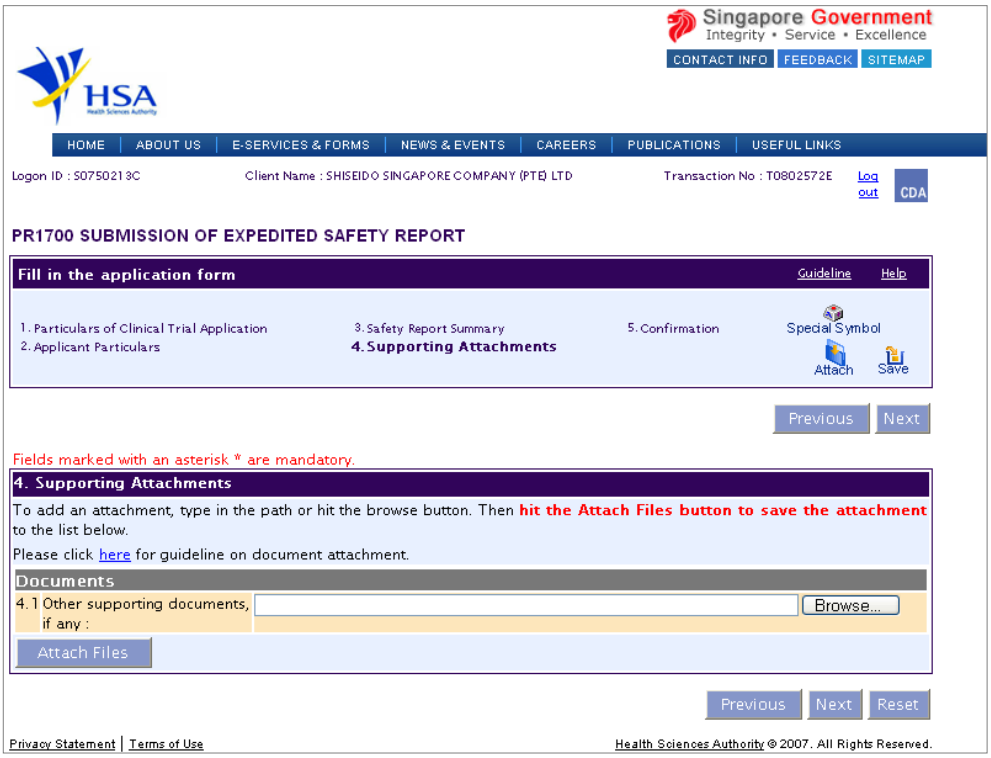
To enter Safety Report Details

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.

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2.3.5 Supporting Attachments



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)

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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 : 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

Fields marked with an asterisk * are mandatory.

1. Particulars of Clinical Trial Application

HSA Clinical Trial Application Number	0600450G
Title of Clinical Trial	sdfasdfasdfasd
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	MCN001	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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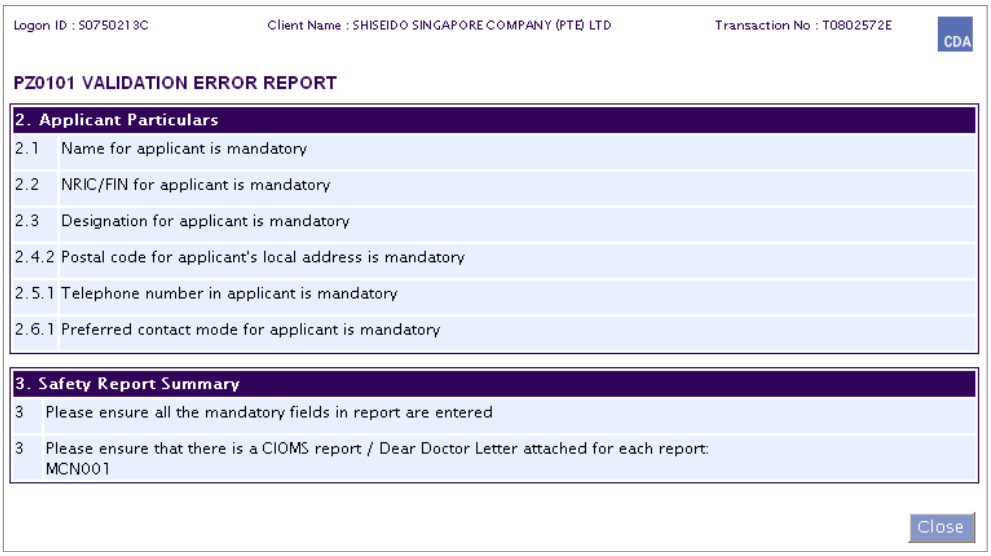


Confirmation Page for Submitter

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.

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

PZ0101 VALIDATION ERROR REPORT

2. Applicant Particulars	
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

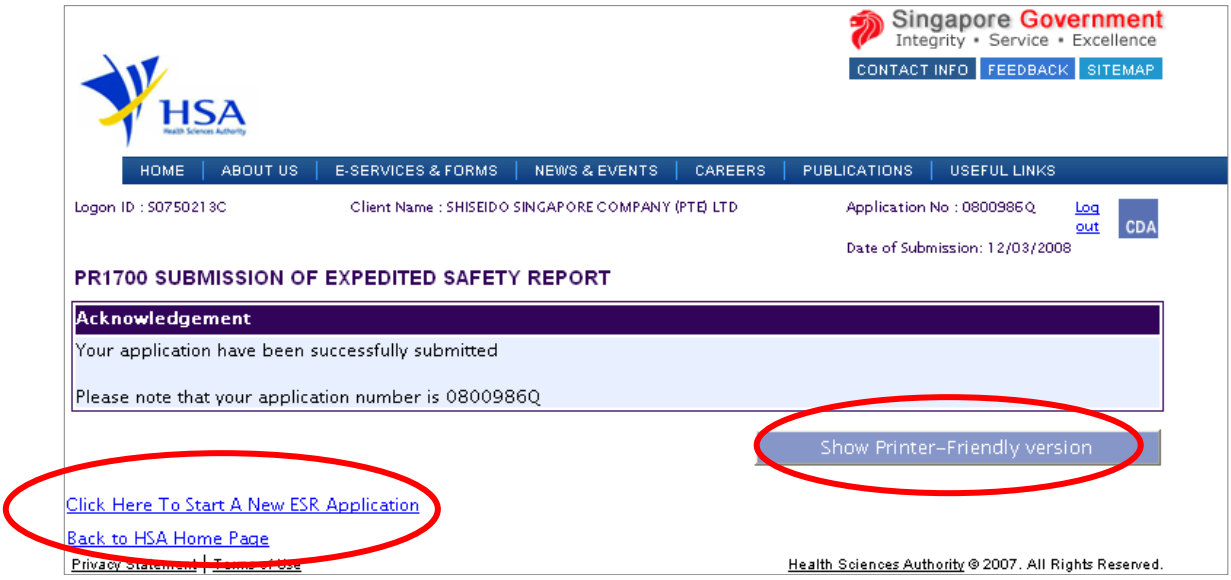
3. Safety Report Summary	
3	Please ensure all the mandatory fields in report are entered
3	Please ensure that there is a CIOMS report / Dear Doctor Letter attached for each report: MCN001

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.

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2.3.7 Acknowledgment



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.

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