

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

User Manual

Version 3.1 (Aug 2018)



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

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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.

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

Corp Pass Ett	A A Contact Us Feedback Sitemap FAQ
Is your business CorpPass-ready? From 1 Sep 2018, business entities can ONLY use CorpPass to log in to governm agencies such as CPF, IRAS and MOM, to prevent disruption to your business flo	
Log in with Co	rpPass
UEN/ENTITY ID	Ø
CORPPASS ID	Ø
Password	Ø
Remember Entity ID	Ø
Forgot <u>Entity / CorpPass ID</u> or <u>Passwo</u>	rd
Cancel	ogin ►

2.1.1 Login

- 1) Fill in your CorpPass ID and password and click the **Submit** button.
- 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.

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HSA	
The SAN	
HOME ABOUT US E-SERVICES & FO	RMS NEWS&EVENTS CAREERS PUBLICATIONS USEFULLINKS
CR0007 AUTHORISATION AND AUTHENT	ICATION MODULE > AUTHORISED INDIVIDUALS / DIRECTORS
You are the registered user for the following cor	mpanies. Please choose from the list the one you wish to represent.
Company	
O NCS (PRISM)	
	Submit Reset
Privacy Statement Terms of Use	Health Sciences Authority © 2007. All Rights Reserved.

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

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	CONTACT INFO
	CONTACTINFO FEEDBACK STIEMAP
X HSA	
Health Sciences Authority	
HOME ABOUT US E-SERVICES & FORMS NEWS & EVENTS CA	REERS PUBLICATIONS USEFUL LINKS
CR0010 AUTHORIZATION AND AUTHENTICATION MODULE > TERM	AS AND CONDITIONS
CROOTE ACTION AND ACTIENTICATION MODULE - TEN	IS AND CONDITIONS
Terms and Conditions of Use	
Updated as of 19/01/2005	
By accessing this website and these electronic services	
accept unconditionally and without any amendments the f	ollowing terms:-
 You are responsible for all usage/access authentic 	ated by your SingPass and/or
HSA PIN (where applicable).	
The information/materials/contents contained in th	
by copyright, trademark and other forms of proprietary and interest in the same are owned by, licensed to or c	
and include in the bane are build by, fitchbed to be b	Sherefied by how
3. You shall therefore not reproduce, transmit or dis	tribute in any way, the
information/materials/contents of the HSA website witho	ut HSA's prior written
consent.	
 You may not set robots, crawlers, software agents 	or any other events and/or
devices to retrieve data from the HSA website or databa	
Accept Cancel	
Privacy Statement Terms of Use	Health Sciences Authority © 2007, All Rights Reserved.

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

HOME ABOUT US E-SERVICES & FORMS NEWS & EVENTS CAREERS PUBLICATIONS USEFUL LINKS gon ID : 50750213C Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD Transaction No : T0802572E Log out ODA R1700 SUBMISSION OF EXPEDITED SAFETY REPORT elds marked with an asterisk * are mandatory. troduction T application Submitted online via Prism If this expedited safety report occurred in an on-going clinical trial conducted in Singapore, please select the actual CTC application no. 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.	WHSA			Singapore Gov Integrity • Service • CONTACT INFD FEEDBACK	
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not conducted in Singapore. You may select an application no. involving the use of the same	ate the CTC Application No.	: * 0600450G - 43534	345 🔻 Retrieve	occurred in an on-goin trial conducted in Singa please select the actual application no. If this expedited safety	g clinical pore, I CTC report
				not conducted in Singa; may select an applicati	oore. You on no.
					same

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

HISA			// Integrit	y • Service • Excellence FEEDBACK SITEMAP
HOME ABOUT US	E-SERVICES & FORMS NE	WS&EVENTS CAREERS	PUBLICATIONS 1	JSEFUL LINKS
Logon ID : S0750213C	Client Name : SHISEIDO SINGA	PORE COMPANY (PTE) LTD	Transaction No	: T0802572E Log out CDA
PR1700 SUBMISSION OF	EXPEDITED SAFETY RE	PORT		
Fill in the application for	m			<u>Guideline Help</u>
1. Particulars of Clinical T 2. Applicant Particulars	rial Application	3. Safety Report Summary 4. Supporting Attachments	5. Confirmation	Special Symbol Attach Save
				Next
Fields marked with an asteris	sk * are mandatory.			
1. Particulars of Clinical	Frial Application			
HSA Clinical Trial Application Number	0600450G			
Fitle of Clinical Trial	sdfasdfasdfasd			
Protocol Number	435345345			
Protocol Date	28/06/2006			
List of Principal Investiga				
Principal Investigator adasdfasd	Clinical Trial Institution Changi General Hospital	Date Of Approva 31/01/2007	I CTC Expiry E	Pate CTC Status Ongoing
uasurasu	Changi General Hospital	51/01/2007	19/03/2008	Ongoing
CT Study Drugs				
SN Drug Drug Name Type	ATC Code		Class of Drug	
⊙ 1 STD weaqwerasd	fa Antineoplastic	: and immunomodulatii	Class III – Approv	ed drug undergoinc
	······	,	-	,
Trial Summary				
(a) Therapeutic Area:	Dentistry			
(b) DSMB:	Yes O No			
(e) ls:		🔿 Double-Blind 🔿 Op	en-Label	
	o outers			Next

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

				Dir	gapore Gov	Excellence
				-	FINFO FEEDBAC	
HSA						
HOME ABOUT US	E-SERVICES & FORMS	NEWS & EVENTS	CAREERS	PUBLICATIONS	USEFUL LINKS	
.ogon ID : S0750213C	Client Name : SHISEIDO :	SINGAPORECOMPAN	Y (PTE) LTD	Transaction	n No : T0802572E	Log out CDA
						OUL CDA
PR1700 SUBMISSION OF		REPORT				
Fill in the application for	m				<u>Guidelin</u>	<u>e Help</u>
1. Particulars of Clinical Trial Ap	plication	3. Safety Report Sum	nary	5. Confirmation	Special S	ymbol
2. Applicant Particulars		4. Supporting Attach	ments		Attac	h Save
					Previou	is Next
Fields marked with an asteris	;k * are mandatory.					
2. Applicant Particulars						
2.1 Name : *			Retrieve			
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 Mod *	(Please ensure that the r this preferred contact m course of this applicatio	relevant contact deta node is the mode whic on, you will receive o	h you will receiv ur input requests	e the final notificatio ; (i.e. queries), if any,	n of this application	n. During the
	your email address abo	ve, regardless of you	r selected prefer	reu contact mode.)		
				P	revious Nex	t Reset
Privacy Statement Terms of Use				Health Sciences Aut	thority © 2007. All R	ights Reserved.

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

HSA				FEEDBACK SITEMAP
HOME ABOUT US E-SI	ERVICES & FORMS 📔 NEWS & EVE	NTS CAREERS	PUBLICATIONS USE	FUL LINKS
Logon ID : 50750213C C	ient Name : SHISEIDO SINGAPORE CON	IPANY (PTE) LTD	Transaction No : TO	0802572E Log out CDA
PR1700 SUBMISSION OF EXP Fill in the application form 1. Particulars of Clinical Trial Applicat 2. Applicant Particulars		•	5. Confirmation	Cuideline Help Special Symbol Attach Save
Tields marked with an asterisk * a 3. Safety Report Summary ④ Initial	C Follow up		licate the report type. lease enter a new MCN	Previous Next
		lf follow u dropdowr	p, select one existing Mi 1 list or enter a new MCI in the dropdown list. Cl	N no. if MCN no. is
Select Manufacturer Control No(MC	:N): Please Select	*		
Inter Manufacturer Control No(MC	N): MCN1111	Add M	CN	
 Please click on the MCN hyperlin Please ensure that all safety rep Previous or Next Page. 			Previou	s Next Reset

Initial Safety Report

HSA				• Service • Excellence • FEEDBACK SITEMAP
HOME ABOUT U	IS E-SERVICES & FORMS NEWS & E	VENTS CAREERS P	UBLICATIONS US	SEFUL LINKS
ogon ID : 50750213C	Client Name : SHISEIDO SINGAPORE C	OMPANY (PTE) LTD	Transaction No :	T0802572E Log out CDA
PR1700 SUBMISSION	OF EXPEDITED SAFETY REPORT	r		<u>Guideline Help</u>
1. Particulars of Clinical Tria 2. Applicant Particulars	l Application 3. Safety Repo 4. Supporting Attr		. Confirmation	Special Symbol
				Previous Next
3. Safety Report Sumr			te the report type. se enter a new MC	Previous Next
	nary	lf Initial, pleas MCN button. If follow up, s dropdown list	se enter a new MC elect one existing	N no. and click on Add MCN no. from CN no. if MCN no. is
3. Safety Report Sumr	nary ⊙ Follow up	lf Initial, pleas MCN button. If follow up, s dropdown list not found in t	se enter a new MC elect one existing t or enter a new M	N no. and click on Add MCN no. from CN no. if MCN no. is
3. Safety Report Sumr O Initial Select Manufacturer Contr	rol No(MCN): Please Select	If Initial, pleas MCN button. If follow up, s dropdown list not found in t button.	se enter a new MC elect one existing t or enter a new M	N no. and click on Add MCN no. from CN no. if MCN no. is
3. Safety Report Sumr Initial Select Manufacturer Contr Enter Manufacturer Contr	rol No(MCN): Please Select	If Initial, pleas MCN button. If follow up, s dropdown list not found in t button.	se enter a new MC elect one existing t or enter a new M he dropdown list.	N no. and click on Add MCN no. from CN no. if MCN no. is
Select Manufacturer Cont Enter Manufacturer Contr Search Manufacturer Cont 1. Please click on the MCI	rol No(MCN): Please Select ol No(MCN):	If Initial, pleas MCN button. If follow up, s dropdown list not found in t button. Add MCN To search for for MCN link. ty report information.	se enter a new MC elect one existing t or enter a new M he dropdown list.	N no. and click on Add MCN no. from CN no. if MCN no. is Click on Add MCN ase click on the Search

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HSA	CONTACT INFO FEEDBACK SITEMAP
HOME ABOUT US	E-SERVICES & FORMS NEWS & EVENTS CAREERS PUBLICATIONS USEFUL LINKS
.ogon ID : S0750213C	Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD Transaction No : T0802572E Log out CDA
PR1700 SUBMISSION OF	EXPEDITED SAFETY REPORT
Search For MCN	
Search Criteria * Please enter minimum ONE	field to search
MCN:	Begins With 💌
Patient Age:	To Please Select 💙
Submission Date:	
Did the SAE occur in Singapo	re: O Yes O No
Reset Search Cance	1

Search for Manufacturer Control Number (MCN)

1 RED Science Activity					
HOME ABOUT US E-SER	VICES & FORMS NEWS & E	VENTS CAREERS	PUBLICATIONS	USEFUL LINKS	
on ID : 50750213C Clier	nt Name : SHISEIDO SINGAPORE C	OMPANY (PTE) LTD	Transaction N	lo : T0802572E	Log out CDA
1700 SUBMISSION OF EXPE	DITED SAFETY REPORT				
ll in the application form				<u>Guideline</u>	<u>Help</u>
Particulars of Clinical Trial Application Applicant Particulars	3. Safety Repo 4. Supporting Atta		5. Confirmation	Special Sy Attach	mbol Save
				Previous	Next
elds marked with an asterisk * are	mandatory.				
Sarety Report Summary					
	O Follow up		dicate the report typ please enter a new M con.		ck on Add
	○ Follow up	If Initial, (MCN but If follow (dropdow	olease enter a new M ion. ip, select one existin n list or enter a new	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not
) Initial		If Initial, (MCN but If follow (dropdow	olease enter a new M con. up, select one existing	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not
: Safety Report Summary D Initial elect Manufacturer Control No(MCN) ater Manufacturer Control No(MCN)	: Please Select	If Initial, J MCN but If follow o dropdow found in	olease enter a new M con. Ip, select one existin n list or enter a new the dropdown list. Cl	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not
) Initial	: Please Select	lf Initial, j MCN but If follow (dropdow found in	olease enter a new M con. Ip, select one existin n list or enter a new the dropdown list. Cl	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not
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) Initial lect Manufacturer Control No(MCN) ter Manufacturer Control No(MCN) st of Saved Safety Reports:): Please Select	If Initial, MCN but dropdow found in	olease enter a new M ron. Ip, select one existin Inist or enter a new the dropdown list. Cl ICN	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not
) Initial lect Manufacturer Control No(MCN) ter Manufacturer Control No(MCN) st of Saved Safety Reports:): Please Select MCN001). hyperlink to view / edit di Initial / Followup	ff Initial, J MCN but froglow found in Add M	olease enter a new M ron. Ip, select one existin Inist or enter a new the dropdown list. Cl ICN	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not
) Initial lect Manufacturer Control No(MCN ter Manufacturer Control No(MCN) st of Saved Safety Reports: ick on the Manufacturer Control No): Please Select MCN001	ff Initial, J MCN but froglow found in Add M	olease enter a new M ion. ip, select one existin ilst or enter a new the dropdown list. Cl ICN ICN	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not
Initial lect Manufacturer Control No(MCN) ter Manufacturer Control No(MCN) st of Saved Safety Reports: ick on the Manufacturer Control No Manufacturer Control No.): Please Select MCN001). hyperlink to view / edit di Initial / Followup	If Initial, MCN but dropdow found in Add M etails of safety repo Last More	olease enter a new M ion. ip, select one existin ilst or enter a new the dropdown list. Cl ICN ICN	ICN no. and cli g MCN no. fron MCN no. if MCI	n V no. is not

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 <u>initial report</u>, enter a Manufacturer Control Number (MCN) and click Add MCN button. For <u>follow up report</u>, 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

Wusa Ha	alth Sci	ences Author	CONTACT INFO FEE	DEACK SITEMAP IFAQ
,				
HOME ABOUT US		RMS NEWS & EVENTS CAF		SEFUL LINKS No : T0802572E
3gon 10 : 50750213C	Client Name : SHIS	EIDO SINGAPORE COMPANY (PLE) EI	D'CHG Transaction I	Logout
R1700 SUBMISSION OF	EXPEDITED SAI	FETY REPORT		
ields marked with an asterisk		6		
3.1 PARTICULARS OF PAT Age: *	ENT			
Please enter age or approximate age. If age is		Please Select 🎽		
unknown, leave blank Sex: *	🔘 Male 🔘 Fe	male 🔘 Unknown		
ls this report from the same Clinical Trial protocol in Singapore?: *	○ Yes ○ No	Protocol No: Protocol no. is only required if the Clinic Trial is ongoing in Singapore	435345345 ▼ al	For locally registered products, only SAEs that are unexpected, related and arising from the same Clinical Trial protocol (conducted in Singapore) need
Did this SAE occur in	🔿 Yes 🔘 No			to be submitted.
Singapore: *				
Manufacturer Control No:	MCN001			
Date received by Manf: *				
3.2 DETAILS OF ADVERSE Date of onset(dd/mm/yyyy):	DRUG REACTIO	(2) NC		
Outcome:		Please Select	~	
Time to Event(days):				
		SOC1: *	Causality:	*
SAE Description: *	caarch	keyword	Causaiity: Please Se	
		keyword	Please Se	
		keyword	Please Se	
Add SAE Description			,	
	-			
3.3 CRITERIA OF SAE				
(Please tick all that apply):				
Patient die due to reaction	n			
Life Threatening				
Congenital anomaly				
Involved or prolonged in-				
Involved persistent or sign	nificant disability	or incapacity		
Medically significant				
Please state why it was consic	lered medically si	ignificant(max 255 characters)		
3.4 SUSPECTED DRUG DE	TAII S(Minimum	of one entry is required)		
Unblinded Report:	O Yes O No			
Date started(dd/mm/yyyy):		Date stopp	ed(dd/mm/yyyy):	
Indication:				
3.5 OTHER RELEVANT INF				
E.g. Upgraded or down grade	d reports (max 2	500 characters).		
			 × 	
3.6. Supporting Attachme				
To add an attachment, type ir attachment to the list below.		he browse button. Then <mark>hit t</mark> l	ne Attach Files button to	save the
Please click <u>here</u> for guideline		achment.		
Documents				Braure
3.6.1 CIOMS / MedWatch Report :				Browse
3.6.2 Dear Doctor Letters :				Browse
Please attach at least ONE do	cument			
Attach Files				
o go back MCN Report Summ	ary Page without	saving the changes, please cli	ck on the Cancel	
utton. o save the changes, please cli	ck on the Save bu	utton.		Cancel
o save all changes and go bao		immary Page, please click on	the Back to	Back to Sumr
ummary button. ?rivacy Statement <u>Terms of Use</u>			Health Sciences Authorit	ر © 2007. All Rights Reserved.

Manufacturer Control No: MCN001					
Date received by Manf: *	🗿 si	AE Description - Microsoft Internet Explorer			
3.2 DETAILS OF ADVERSE DRUG REACTION(S) Date of onset(dd/mm/ywy): Outcome: SAE Description: Gastrointestinal Search					
Time to Event(days):	94 m a	atching record(s) found Page G0 P	age 1	of 5 [First] [Previous] [<u>Next</u>] [La	≡ ast]
SAE Description: *	No.	SAE Description		DC1	
Gastrointestinal search keyword	1	Mitochondrial neurogastrointestinal encephalopathy		ongenital, familial and genetic sorders	
search keyword	2	Gastrointestinal malformation		ongenital, familial and genetic sorders	
Add SAE Description	3	Congenital gastrointestinal vessel anomaly		ongenital, familial and genetic sorders	
Add SAE Description	4	Gastrointestinal disorder congenital		ongenital, familial and genetic sorders	
3.3 CRITERIA OF SAE	5	Gastrointestinal arteriovenous malformation		ongenital, familial and genetic sorders	
(Please tick all that apply):	6	Gastrointestinal angiodysplasia haemorrhagic		ongenital, familial and genetic	
Patient die due to reaction	7	Contraintectinal angiedvenlagia		sorders	~
Life Threatening	<		_		>
Congenital anomaly	ê			🗎 😼 Local intranet	

Search for SAE Description and SOC1

3.2 DETAILS OF ADVERSE DRUG F	REACTION(S)		
Date of onset(dd/mm/yyyy):			
Outcome:		Please Select 💌	
Time to Event(days):			
SAE Description: *		SOC1: *	Causality: *
Gastrointestinal disorder	search keyword	Gastrointestinal disorders	Possible 🕑 Clear
	search keyword		Please Select 🕑 Clear
	search keyword		Please Select 🛛 🖌 Clear
Add SAE Description			

SAE Description and SOC1 are populated

To enter Safety Report Details

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

- 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

HSA				CONTACT IN	apore Gover ity • Service • Ex IFO FEEDBACK	
HOME ABOUT US	E-SERVICES & FORMS	NEWS & EVENTS	CAREERS	PUBLICATIONS	USEFUL LINKS	
Logon 10 : 507 Sozi se	Chent Name : SHISEDO	SINGAPORECOMPANY	(10) (10)	Transaction N	0:10802572E <u>00</u> <u>00</u>	
PR1700 SUBMISSION O	F EXPEDITED SAFET	REPORT				
Fill in the application fo	orm				<u>Guideline</u>	<u>Help</u>
1. Particulars of Clinical Trial Aj 2. Applicant Particulars		fety Report Summary Ipporting Attachm	ients	5. Confirmation	Special Symb Attach	ol Save
					Previous	Next
Fields marked with an aster						
4. Supporting Attachme						
To add an attachment, type to the list below.	in the path or hit the br	owse button. Then I	hit the Atta	th Files button t	o save the atta	chment
Please click <u>here</u> for guideli	ne on document attachm	ent.				
Documents						
 Other supporting docun if any : 	nents,				Browse	
Attach Files						
				Pre	vious Next	Reset
Privacy Statement Terms of Use				Health Sciences Autho	rity © 2007. All Rights	s Reserved.

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 : 50750213C	Client Name : SHISEIDO SI	NGAPORE COMPANY (PTE) LI	TD Transaction No	: T0802572E Log out CDA
PR1700 SUBMISSION OF E	XPEDITED SAFETY	REPORT		
Fill in the application form				<u>Guideline Help</u>
1 - Particulars of Clinical Trial Applic 2 - Applicant Particulars		ety Report Summary porting Attachments	5. Confirmation	Special Symbol
				Previous
Fields marked with an asterisk I. Particulars of Clinical Tr				
-SA Clinical Trial Application	0600450G			
lumber itle of Clinical Trial	sdfasdfasdfasd			
Protocol Number	435345345			
Protocol Date	28/06/2006			
Frotocol Date	28/08/2008			
List of Principal Investigato				
	Clinical Trial Institut			
adasdfasd 0	Changi General Hospita	d 31/01/2007	19/03/2008	Ongoing
study Drug Information				
Drug Type:	STD			
Drug Name:	weaqwerasdfa			
ATC Code:	Antineoplastic a	and immunomodulating	agents (Endocrine therapy)
Class of Drug:		oved drug undergoing and/or dosages,etc	clinical trial for new indicati	ons, method of
Frial Summary				
Therapeutic Area:	Dentistry			
DSMB:	Yes			
s:	Single-Blind			
2.1 Name : * 2.2 NRIC/FIN : * 2.3 Designation : *				
2.4 Address				
2.4.1 Address Type : * 2.4.2 Postal Code : *	Local			
2.4.2 Postal Code : " 2.4.3 Block / House No :		2.4.4 Level - L		
		2.4.4 Level - L	Jnit : # -	
2.4.5 Street Name :				
2.4.6 Building Name :				
2.4.7 Country :	Singapore			
2.5 Contact Details		2525		
2.5.1 Tel : *		2.5.2 Fax :		
2.5.3 Handphone : 2.5.5 Email :		2.5.4 Pager :		
2.6 Preferences 2.6.1 Preferred Contact Mode				
, of the referred Contact Mode	(Please ensure that the rel this preferred contact mor course of this application,	de is the mode which you wil	is entered for your preferred co Il receive the final notification of equests (i.e. queries), if any, via I preferred contact mode.)	this application. During the
3. Safety Report Summary			_	
List of Saved Safety Report	s:			
Click on the Manufacturer Cont				
SN Manufacturer Control I 1 <u>MCN001</u>	NO.	Initial / Followup Initial	Last Modifi 12/03/2008	
4. Supporting Attachments				
Sn Attachment Name	Attachment Type	Size (Kb)	Rem ark s	
			Previous Valida	ate 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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			Integrity • Se CONTACT INFO	Government rvice • Excellence EDBACK SITEMAP
HSA				EUDACK STIEWA
HOME ABOUT US	E-SERVICES & FORMS NEWS	& EVENTS CAREERS	PUBLICATIONS USEFUL	LINKS
on ID : 50750213C	Client Name : SHISEIDO SINGAPO	RECOMPANY (PTE) LTD	Transaction No : T0802	572E Log out CDA
1700 SUBMISSION OF	EXPEDITED SAFETY REPO	ORT		
ll in the application fo	rm		2	iuidelin <u>e Help</u>
Particulars of Clinical Trial Ap Applicant Particulars		port Summary 5. Co g Attachments	nfirmation Sp	ecial Symbol
				Previous
elds marked with an aster Particulars of Clinical				
A Clinical Trial Application Imber	0600450G			
le of Clinical Trial	sdfasdfasdfasd			
otocol Number	435345345			
otocol Date	28/06/2006			
st of Principal Investiga	ator(s) & Clinical Trial Instit	tution(s)		
incipal Investigator	Clinical Trial Institution	Date Of Approval	CTC Expiry Date	CTC Status
lasdfasd	Changi General Hospital	31/01/2007	19/03/2008	Ongoing
udy Drug Information				
ug Type:	STD			
rug Name:	weaqwerasdfa			
FC Code:	Antineoplastic and in	nmunomodulating agents (Endocrine therapy)	
ass of Drug:	Class III - Approved administration and/o	drug undergoing clinical tr or dosages,etc	ial for new indications, m	ethod of
rial Summary				
herapeutic Area:	Dentistry			
SMB:	Yes			
	Single-Blind			
. 1 Name : *				
.1 Name : * .2 NRIC/FIN : *				
.1 Name : * .2 NRIC/FIN : * .3 Designation : *				
.1 Name : * .2 NRIC/FIN : * .3 Designation : * .4 Address				
. Applicant Particulars .1 Name : * .2 NRIC/FIN : * .3 Designation : * .4 Address .4.1 Address Type : *	Local			
.1 Name : * .2 NRIC/FIN : * .3 Designation : * .4 Address .4.1 Address Type : * .4.2 Postal Code : *	Local			
11 Name : * 2 NRIC/FIN : * 3 Designation : * 4 Address 4.1 Address Type : * 4.2 Postal Code : * 4.3 Block / House No :	Local	2,4,4 Level - Unit :	# -	
11 Name : * 2 NRIC/FIN : * 3 Designation : * 4 Address 4.1 Address Type : * 4.2 Postal Code : * 4.3 Block / House No : 4.5 Street Name :	Local	2,4,4 Level - Unit :	# -	
11 Name : * 2 NRIC/FIN : * 3 Designation : * 4 Address 4.1 Address Type : * 4.2 Postal Code : * 4.3 Block / House No : 4.5 Street Name : 4.6 Building Name :		2.4.4 Level - Unit :	# -	
11 Name : * 2 NRIC/FIN : * 3 Designation : * 4 Address 4.1 Address Type : * 4.2 Postal Code : * 4.3 Block / House No : 4.5 Street Name : 4.6 Building Name : 4.7 Country :	Local	2.4.4 Level – Unit :	# -	
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11 Name : * 2 NRIC/FIN : * 3 Designation : * 4 Address 4.1 Address Type : * 4.2 Postal Code : * 4.3 Block / House No : 4.3 Block / House No : 4.5 Street Name : 4.6 Building Name : 4.7 Country : 5 Contact Details 5.1 Tel : * 5.3 Handphone : 5.5 Email : 6 Preferences	Singapore Singapore	2.5.2 Fax : 2.5.4 Pager :	for your preferred contact mo final notification of this tage (genetis), if any, via email if y	lication. During the
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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 : 50750213C	Client Name : SHISEIDO SINGAPORE COMPANY (PTE) LTD	Transaction No : T0802572E	CDA
PZ01	01 VALIDATION EF	ROR REPORT		
2. Aj	oplicant Particular	s		
2.1	Name for applicant	is mandatory		
2.2	NRIC/FIN for applica	nt is mandatory		
2.3	Designation for appl	icant is mandatory		
2.4.2	Postal code for appl	icant's local address is mandatory		
2.5.1	Telephone number i	n applicant is mandatory		
2.6.1	Preferred contact m	ode for applicant is mandatory		
3. Sa	fety Report Summ	ary		
3 P	lease ensure all the r	nandatory fields in report are entered		
	lease ensure that the ICN001	re is a CIOMS report / Dear Doctor Letter attached for each	report:	

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

HSA				•	gapore Go grity • Service INFO FEEDBAC	
HOME ABOUT US	E-SERVICES & FORMS	NEWS & EVENTS	CAREERS	PUBLICATIONS	USEFUL LINKS	
Logon ID : \$0750213C	Client Name : SHISEIDO :	SINGAPORECOMPANY	(PTE) LTD	Application 1	No:0800986Q	Log out CDA
				Date of Subm	nission: 12/03/20	
PR1700 SUBMISSION O	F EXPEDITED SAFETY	REPORT				
Acknowledgement						
Your application have been	successfully submitted					
Please note that your applic	ation number is 080098	6Q				
				Show Printer	–Friendly ver	sion
Click Here To Start A New ES	R Application					
Back to HSA Home Page						
Privacy Statement Terms of Her				Health Sciences Auth	<u>ority</u> © 2007. All F	Rights Reserved.

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

<u>Links</u>

- 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.