



User Manual for

Corporate Account and Corporate Sub-account Account

Version 01

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© Clinical Trials Centre

8/F, Clinical Pathology Building

Queen Mary Hospital

102 Pokfulam Road, Hong Kong

Phone: 2255 3956 Email: pears@hku.hk

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1. What is PEARS?

1.1 Background

PEARS is an internet based, 24-hour security controlled, 21 CFR 11 (U.S. Code of Federal Regulations Title 21 Part 11) compliant electronic platform developed for multiple users submission of SAE (serious adverse event). PEARS is a validated system, which allows sponsors and/or CROs (contract research organizations) to submit SAE reports to investigators and CTC (Clinical Trials Centre of HKU) electronically for the purpose of HKU/HA HKW IRB (Institutional Review Board of The University of Hong Kong/Hospital Authority Hong Kong West Cluster, in short “IRB”) submission.

Through PEARS, investigators can review and endorse SAE submission documents electronically upon receipt of automatic email notification. The preparation and submission process under PEARS are properly tracked. PEARS users can monitor the progress of SAE submission of their assigned study on a real-time basis. In brief, PEARS enables:

- (a) sponsors and/or CRO dispatch SAE reports to investigators electronically for review;
- (b) sponsors and/or CRO dispatch SAE reports to CTC electronically for review and compilation;
- (c) investigators review and endorse SAE reports submission electronically; and
- (d) sponsors, CROs, investigators and CTC to monitor the SAE reports preparation and submission progress electronically.

2. How to Apply a PEARS Account?

2.1 Account Type

There are two (2) types of account types of corporate users (i) Corporate Account and (ii) Corporate Sub-account. PEARS Administrator is only responsible to create a Corporate Account for a management level staff of a Corporate. This user type is responsible to create and manage Corporate Sub-account users.

2.2 Create Corporate Account

PEARS administrator will create a study record at PEARS when the study is approved by the Ethics Committee. He/ She will contact corresponding sponsor/CRO's representatives for the following procedures:

- (a) create Corporate Account for sponsor/CRO; and
- (b) guide Corporate Account user to create Corporate Sub-account user.

After verification and approval, an automatic email from PEARS Administrator (Re: "Your PEARS User Account") will be sent to the user indicating the user name and password.

User should inform PEARS Administrator for the provision of appropriate rights to perform tasks for the study (i.e. None/View/Submit).

2.3 Create Corporate Sub-account

Corporate Sub-account is created and managed by Corporate Account.

An automatic email from PEARS Administrator (Re: "Your PEARS User Account") will be sent to the user indicating the user name and password.

User should inform PEARS Administrator for the provision of appropriate rights to perform tasks for the study (i.e. None/View/Submit).

3. What are PEARS Functions?

3.1 Login

Procedures


1. Browse PEARS link at <http://pearshk.com> to display the login page
2. Type in user name and password
3. Click <Log In>



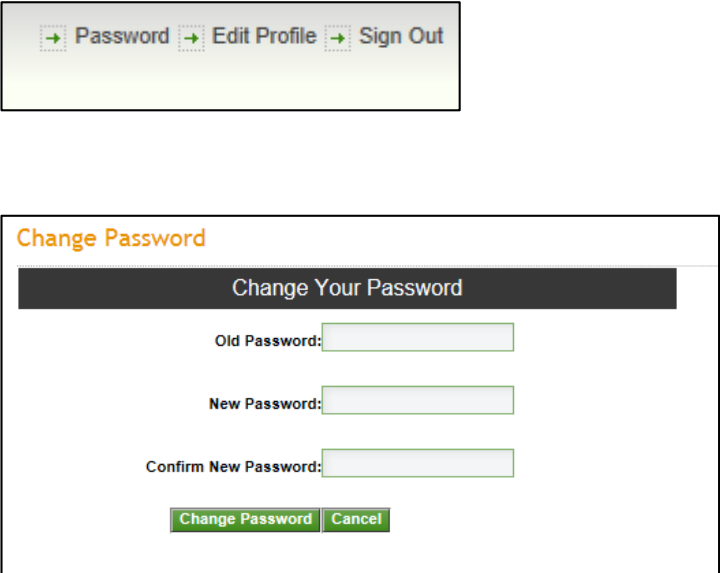
Remarks:

1. A user account should be locked and no user access should be allowed if the user cannot enter the correct password after six (6) attempts.
2. Warning message will be prompted if user unable to provide valid authentication information (maximum login attempts: 6). If user forgot his/her password, he/she could either:
 - (a) click <Forgot Password?> to request for a new password. PEARS will send a new password to the user via email automatically; or
 - (b) call Administrator for help. New password will be sent to the user via email automatically.

3.2 Logout

Procedures	
1. Click <Sign Out> on the top right hand corner of the webpage	
Remarks: 1. User should always sign out PEARS after use.	

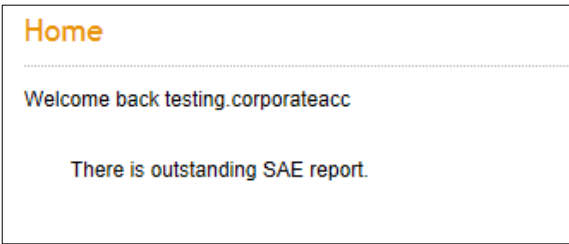
3.3 Change Password

Procedures	
1. Click <Password> on the top right hand corner of the webpage 2. Type in old password 3. Type in new password and confirm new password 4. Click <Change Password>	
Remarks: 1. User receives initial password via email. 2. User should change password at initial login, and user can change password at any time. A confirmation email will be received after changing the password. 3. Minimum password length: eight (8) characters 4. System requests user to change password every 180 days. 5. System does not allow user to re-use the previous one old password. 6. Maximum login attempts: six (6) 7. Password transactions will be recorded in system audit trail.	

3.4 Edit Profile

Procedures															
<ol style="list-style-type: none">1. Click <Edit Profile> on the top right hand corner of the webpage2. Update profile when necessary3. Click <Submit> to confirm updated information	<div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"><p style="text-align: center;">→ Password → Edit Profile → Sign Out</p></div> <p>Corporate Account:</p> <div style="border: 1px solid black; padding: 10px; margin-bottom: 10px;"><p style="text-align: center;">Edit User Profile</p><div style="background-color: #333; color: white; text-align: center; padding: 2px;">General Account Info</div><table style="width: 100%;"><tr><td style="width: 30%;">User Name:</td><td>testing.corporateacc</td></tr><tr><td>E-mail:</td><td><input type="text" value="testing.corporateacc@gn"/></td></tr><tr><td>Corporate Staff Name:</td><td><input type="text" value="Calvin Tsang"/></td></tr><tr><td>Corporate:</td><td>TESTING Limited</td></tr></table><p style="text-align: right;"><input type="button" value="Submit"/></p></div> <p>Corporate Sub-account:</p> <div style="border: 1px solid black; padding: 10px; margin-bottom: 10px;"><p style="text-align: center;">Home » Create User</p><div style="background-color: #333; color: white; text-align: center; padding: 2px;">General Account Info</div><table style="width: 100%;"><tr><td style="width: 30%;">User Name:</td><td><input type="text"/></td></tr><tr><td>Staff Name:</td><td><input type="text"/></td></tr><tr><td>E-mail:</td><td><input type="text"/></td></tr></table><p style="text-align: right;"><input type="button" value="Create User"/></p></div> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"><p style="text-align: center;"> Account CRA-1 has been created successfully.</p></div>	User Name:	testing.corporateacc	E-mail:	<input type="text" value="testing.corporateacc@gn"/>	Corporate Staff Name:	<input type="text" value="Calvin Tsang"/>	Corporate:	TESTING Limited	User Name:	<input type="text"/>	Staff Name:	<input type="text"/>	E-mail:	<input type="text"/>
User Name:	testing.corporateacc														
E-mail:	<input type="text" value="testing.corporateacc@gn"/>														
Corporate Staff Name:	<input type="text" value="Calvin Tsang"/>														
Corporate:	TESTING Limited														
User Name:	<input type="text"/>														
Staff Name:	<input type="text"/>														
E-mail:	<input type="text"/>														
Remarks:	<ol style="list-style-type: none">1. User is not allowed to change the User Name and Corporate Name. PEARS Administrator will update the required fields whenever appropriate.2. Modification on profile information will be recorded in system audit trail.														

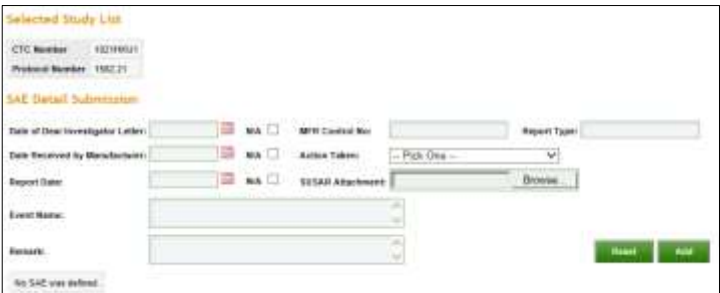
3.5 View Alert Message

Procedures	
<ol style="list-style-type: none"> Click <Home> at the toolbar Alert message will be shown (if any) 	
<p>Remarks:</p> <ol style="list-style-type: none"> Alert message is a reminder to users for the documents under preparation. 	

3.6 Select Study

Procedures	
<ol style="list-style-type: none"> Click <Study> at Study page to display study list(s) Select the study(ies) for SAE dispatch. Multiple studies selection are allowed Click <Search> to display the submission status 	

3.7 Dispatch Overseas SAEs

Procedures	
<ol style="list-style-type: none"> A selected study list is indicated on the dispatch SAE page Enter individual SAE information (Sponsor Letter Date, MFR Control No., Report Type, Date Received by Manufacturer, Report Date, Action Taken, Event Name and Remarks) Attach safety report 	

Procedures

4. Click <Add> to update the SAE list and click <Reset> to clear the fields
5. Confirmation message will be displayed
6. To finish batch submission, click <Submit> to dispatch all added SAEs. A pop-up message will be showed and seek for user's re-confirmation or click <Cancel> to keep editing the page
7. Click <OK> for re-confirmation of SAE submission or click <Cancel> to keep editing the information
8. Confirmation message will be displayed after successful submission
9. Click <Back> to view tracking log and dispatch summary
10. Click <Tracking Log> of the study at Study page
11. Click <Tracking ID> to view the SAE report summary and dispatched items
12. Click <Export Excel> to export the dispatch summary in excel format

✓ MFR-111-demo has been added successfully.

by manufacturer Date Attachment

BCIRG005

1 Message from webpage

Are you sure you want to submit this SAE report?

OK Cancel Submit

✓ SAE has been submitted successfully.

SAE Report Summary

CTC Number:	101	Protocol Number:	demo1
Protocol Title:	A control study for abc		
Name of Person Responsible for Dispatch:	Carrie (Corporate staff name)	Company:	Novartis
Total Number of Dispatched Items:	1	Date of Dispatch:	11 Oct 2010 16:54
Tracking ID:	101	Status:	Submitted to CTC. Not Yet Sample Cover Letter

Principal Investigator List

Investigator Name:	Hospital:	Department:	IRB Number:
Dr. Robert Chan	The University of Hong Kong/Queen Mary Hospital	Demo	UM15-080

Dispatched Items

Date of Dear Investigator Letter	MFR Control No.	Report Type	Event Name	Date Received by Manufacturer	Report Date	Action Taken	ISSAR Attachment	Remark
	MFR-111-demo	Follow up 2	Adrenal insufficiency	10 Oct 2010	11 Oct 2010	Discontinued/Terminated Study	ISSAR0005 Study Summary A.1.pdf	

Cancel Export Excel Back

Remarks:

1. The following SAE information is mandatory: MFR Control No., Report Type, Action Taken (Drop-down list) and Event Name.
2. Safety report could be in PDF or Word format.
3. Cancellation of entire SAE batch is allowed with audit trail record.
4. The SAE Report Summary shows the submission information and status.

3.8 Tracking

Procedures	
<ol style="list-style-type: none"> 1. Click <Tracking Log> of a study at Study page to view the current status of the dispatch 2. Click <Tracking ID> to view the dispatch summary/ status 	

4. Questions

4.1 Enquiry Contact

For enquiry about PEARS, please contact PEARS Administrators at:

Name:	Ms. Karman Choi	Ms. Brenda Lui
Telephone:	2255 3956	2255 3959
Email:	pears@hku.hk	pears@hku.hk

Appendix 1: Overview of PEARS Operations

