



**HKU
Med**

LKS Faculty of Medicine
Clinical Trials Centre
香港大學臨床試驗中心



Platform for Electronic Adverse Reports Submission



User Manual for Corporate Account and Corporate Sub-account Account

Version 03

Effective on 01-Nov-2022

© Clinical Trials Centre

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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

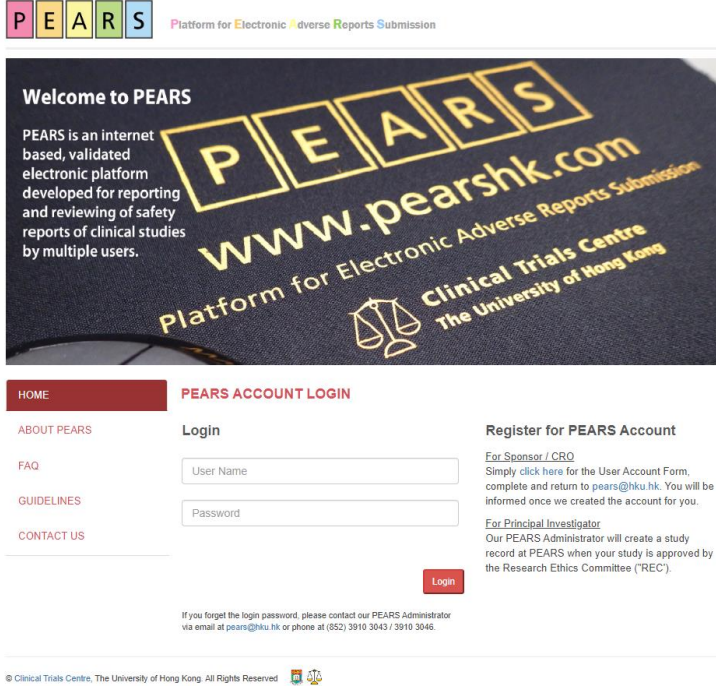
Corporate Sub-account is created and managed by Corporate Account.

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?

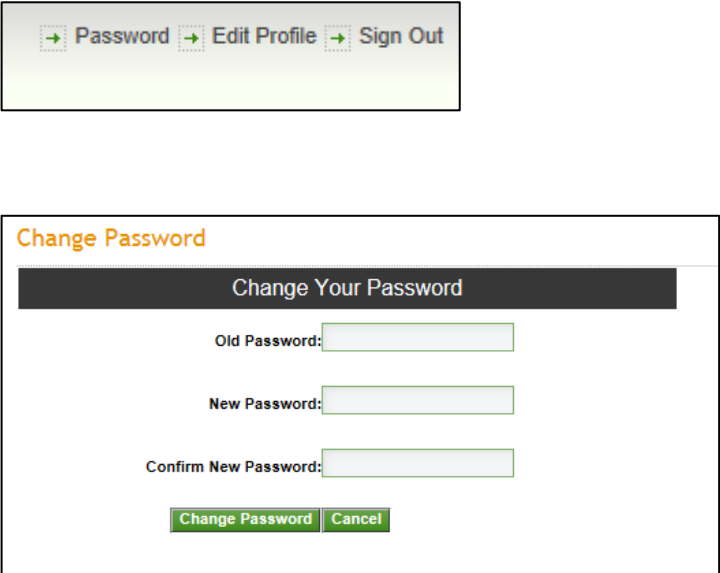
3.1 Login

Procedures	
<ol style="list-style-type: none">1. Browse PEARS link at http://pearshk.com to display the login page2. Type in user name and password3. Click <Log In>	
<p>Remarks:</p> <ol style="list-style-type: none">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 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.	

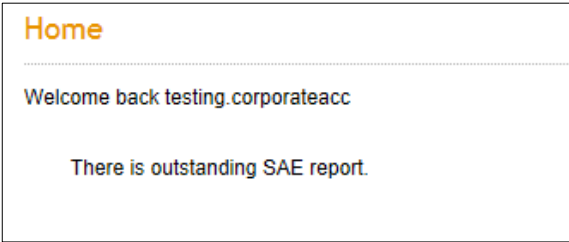
3.3 Change Password

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.	

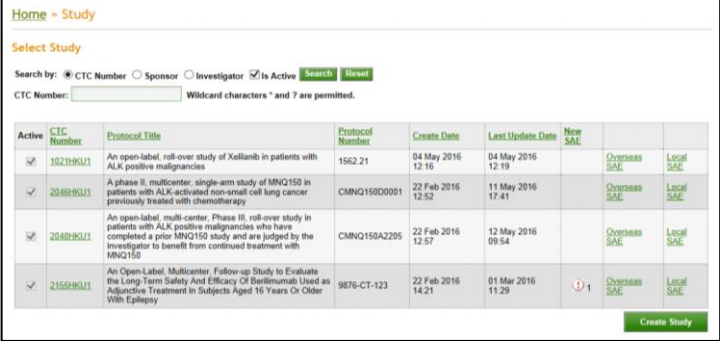
3.4 Edit Profile

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 data-bbox="703 344 1163 454"></div> <p>Corporate Account:</p> <div data-bbox="703 557 1362 927"><p>Edit User Profile</p><p>General Account Info</p><p>User Name: testing.corporateacc</p><p>E-mail: <input type="text" value="testing.corporateacc@gn"/></p><p>Corporate Staff Name: <input type="text" value="Calvin Tsang"/></p><p>Corporate: TESTING Limited</p><p><input type="button" value="Submit"/></p></div> <p>Corporate Sub-account:</p> <div data-bbox="703 1028 1425 1462"><p>Home » Create User</p><p>General Account Info</p><p>User Name: <input type="text"/></p><p>Staff Name: <input type="text"/></p><p>E-mail: <input type="text"/></p><p><input type="button" value="Create User"/></p></div> <div data-bbox="703 1503 1335 1570"><p> Account CRA-1 has been created successfully.</p></div>
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.

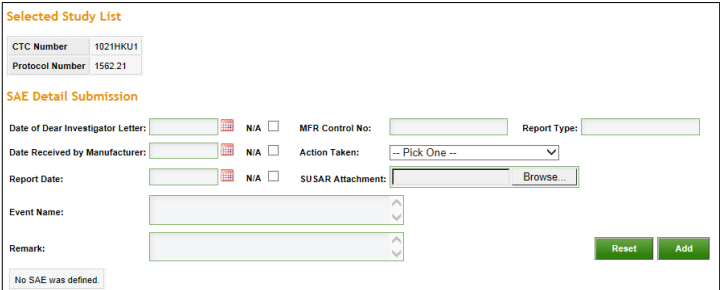
3.5 View Alert Message

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 	

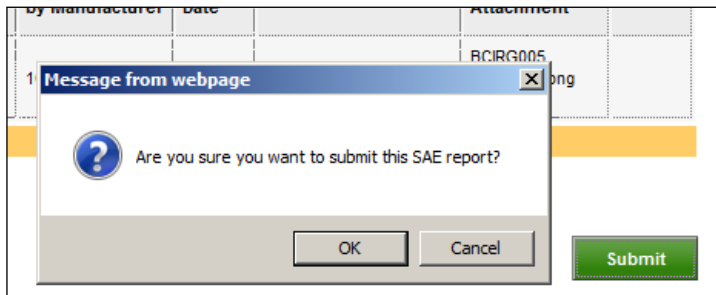
3.7 Dispatch Overseas SAEs

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.



 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:	Coriue (Corporate staff name)	Company:	Novartis
Total Number of Dispatched Items:	1	Date of Dispatch:	11 Oct 2010 16:54
Tracking ID:	161	Status:	Submitted to CTC. Not Yet Compile Cover Letter.

Principle Investigator List

Investigator Name	Hospital	Department	IRB Number
Dr. Robert Chan	The University of Hong Kong/Queen Mary Hospital	Demo	UW10-000

Dispatched Items

Date of Dear Investigator Letter	MFR Control No	Report Type	Event Name	Date Received by Manufacturer	Report Date	Action Taken	SUSAR Attachment	Remark
	MFR-111-demo	follow up 2	Adrenal insufficiency	10 Oct 2010	11 Oct 2010	Discontinued/Terminated Study	BCIRG005 study Kwong A.1.pdf	

<<< 1 >>>

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 	<div style="border: 1px solid black; padding: 5px;"> <p>Tracking Log of 1021HKU1</p> <p>Date of Dispatch From (dd MMM yyyy): <input type="text"/> To: <input type="text"/> Status: Any <input type="button" value="Search"/> <input type="button" value="Reset"/></p> <table border="1"> <thead> <tr> <th>Tracking ID</th> <th>Status</th> <th>Create Date</th> <th>Dispatch Date</th> <th>Admin Submit Date</th> <th>Last PI Endorse Date</th> <th>IRB Submission Date</th> </tr> </thead> <tbody> <tr> <td>17</td> <td>0</td> <td>24 Nov 2016 14:21</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>16</td> <td>1</td> <td>24 Nov 2016 14:14</td> <td>24 Nov 2016 14:17</td> <td></td> <td></td> <td></td> </tr> <tr> <td>15</td> <td>1</td> <td>24 Nov 2016 14:12</td> <td>24 Nov 2016 14:13</td> <td></td> <td></td> <td></td> </tr> <tr> <td>13</td> <td>2</td> <td>04 May 2016 12:24</td> <td>04 May 2016 12:26</td> <td>04 May 2016 12:31</td> <td></td> <td></td> </tr> </tbody> </table> <p>Status:</p> <ul style="list-style-type: none"> ➤ 0 - New SAE Report. Not Yet Submitted to CTC. ➤ 1 - Pending Admin. Submitted to CTC but Not Yet Compile Cover Letter. ➤ 2 - Pending PI. Pending for PI Endorsement. ➤ 3 - Endorsed by All PI. ➤ 4 - Submitted to IRB. ➤ 5 - Confirmed by IRB. ➤ 9 - Cancelled. </div>	Tracking ID	Status	Create Date	Dispatch Date	Admin Submit Date	Last PI Endorse Date	IRB Submission Date	17	0	24 Nov 2016 14:21					16	1	24 Nov 2016 14:14	24 Nov 2016 14:17				15	1	24 Nov 2016 14:12	24 Nov 2016 14:13				13	2	04 May 2016 12:24	04 May 2016 12:26	04 May 2016 12:31		
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4. Questions

4.1 Enquiry Contact

For enquiry about PEARS, please contact PEARS Administrators at:

Name:	Mr. Andy Au Yeung	Ms. Cynthia Choi	Mr. Everett Lor
Telephone:	3910 3043	3910 3046	3910 3052
Email:	pears@hku.hk		

Appendix 1: Overview of PEARS Operations

