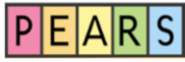


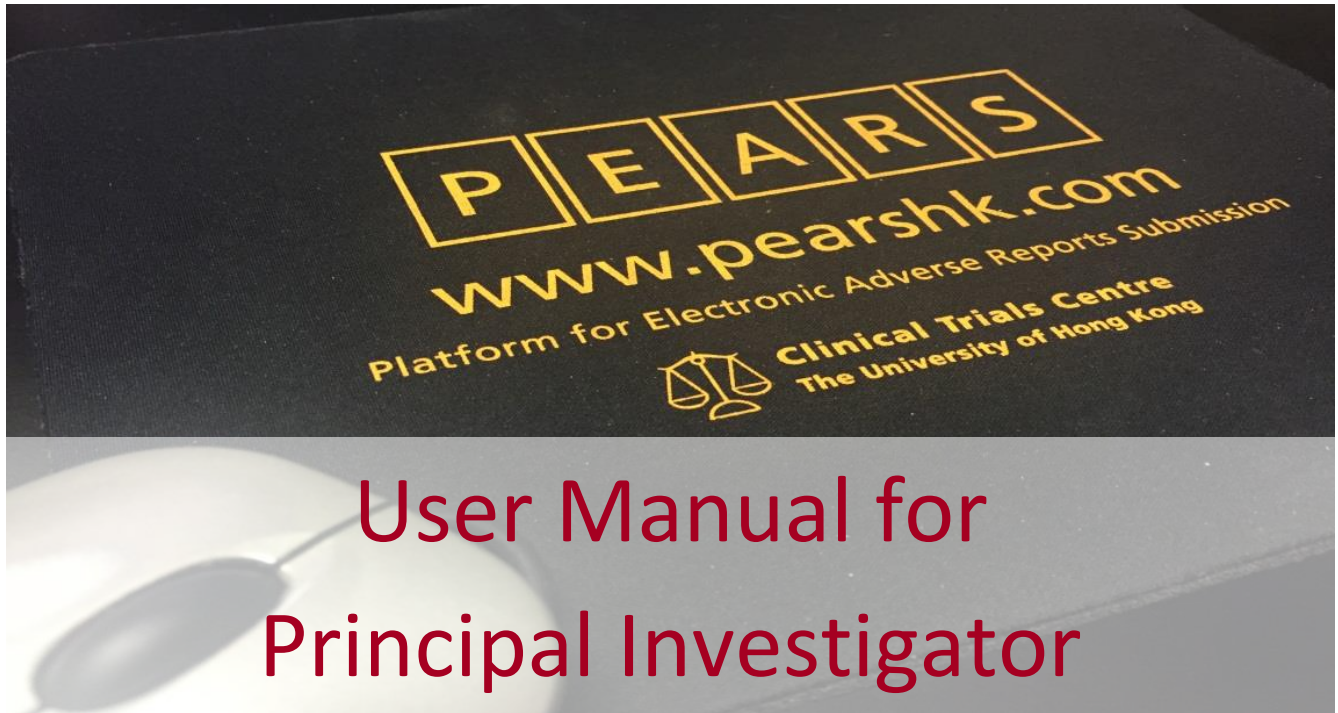


**HKU
Med**

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 Principal Investigator

Version 05

Effective on 11-Nov-2024

© 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 Part 11 (Part 11, Title 21 of the U.S. Code of Federal Regulation; Electronic Records; Electronic Signature) 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 Create Account

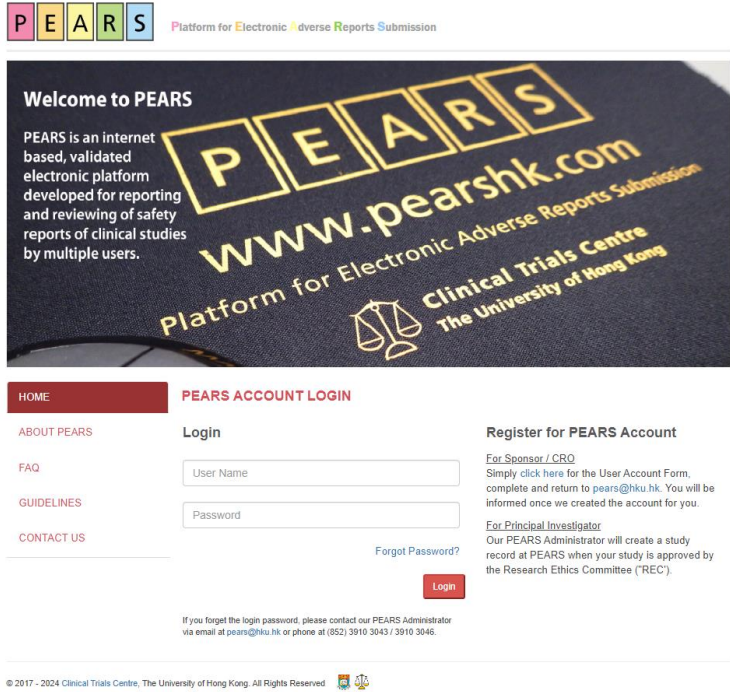
PEARS administrator will create a study record at PEARS when the study is approved by the Ethics Committee. He/ She will contact the PI (principal investigator) for the following procedures:

- (a) arrange a training for using PEARS;
- (b) assist the PI to complete the PEARS User Account Form (CTC-FOM-SMOS-PEA-0070); and
- (c) assist the PI to complete the PEARS User Electronic Signature Certification Form (CTC-FOM-SMOS-PEA-0020).

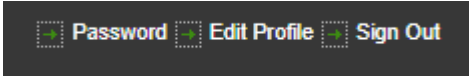
After verification and approval, an automatic email from PEARS Administrator (Re: “Your PEARS User Account”) will be sent to the user indicating the user name and password.

3. What are PEARS Functions?

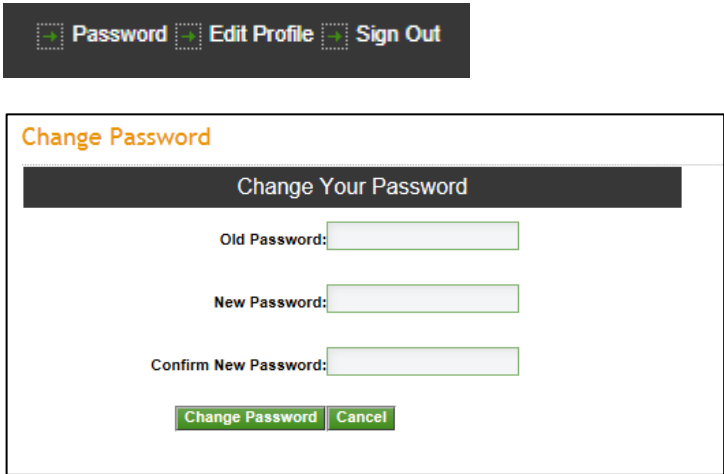
3.1 Login

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.	

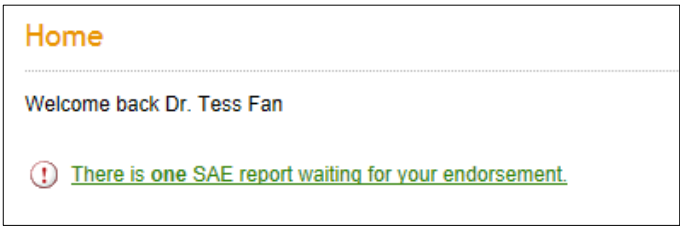
3.3 Change Password

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.	

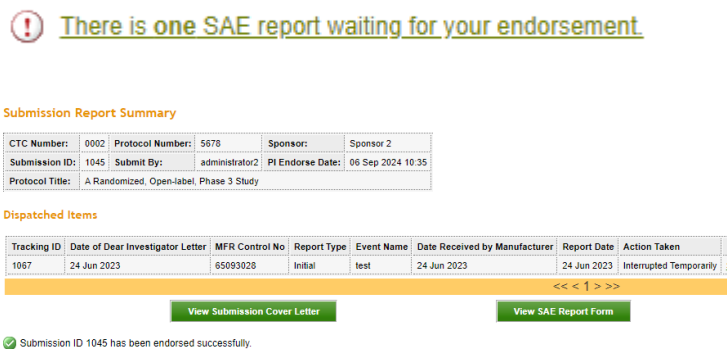
3.4 Edit Profile

Procedures	
1. Click <Edit Profile> on the top right hand corner of the webpage 2. Update profile when necessary 3. Click <Submit> to confirm updated information	→ Password → Edit Profile → Sign Out Edit User Profile General Account Info User Name: Dr. Tess Chan E-mail: testing.investigator.acc2@g Investigator Account Info First Name: Tess Last Name: Chan Investigator Title: Dr. Hospital Name: Queen Mary Hospital Department: Medicine Secretary / SC Name: John Wong Phone Number: 2255 2632 Fax Number: 2853 2632 Attach CV: Choose File No file chosen Submit
Remarks: 1. PI is not allowed to change User Name, E-mail, Hospital Name and Department name. PEARS Administrator will update the required fields whenever appropriate. 2. Modification on profile information will be recorded in system audit trail.	

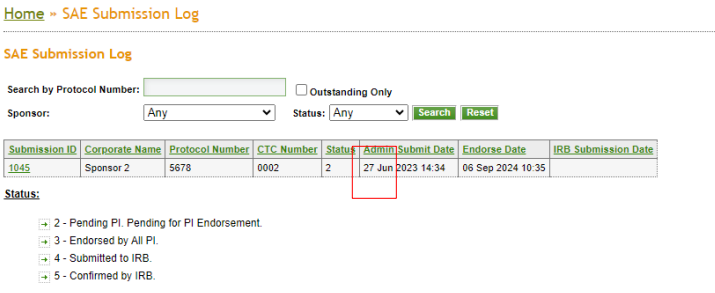
3.5 View Alert Message

Procedures	
1. Click <Home> at the toolbar 2. Alert message will be shown (if any)	 The screenshot shows a 'Home' header, a 'Welcome back Dr. Tess Fan' message, and a red alert icon with the text 'There is one SAE report waiting for your endorsement'.
Remarks: 1. Alert message is a reminder to PI for the pending document review/endorsement.	

3.6 SAE Submission Log

Procedures	
1. Click <alert message> at Home page 2. Click <Submission ID> to view Submission Summary Report 3. Click <SUSAR Attachment> to view individual Safety Reports dispatched by sponsor/ CRO 4. Click <View Submission Cover Letter> and <View SAE Report Form> to review submission documents 5. Click <E-signature> to endorse the IRB submission documents. An alert message will be pop-up for re-confirmation. 6. Click <OK> to re-confirm document endorsement 7. Click <Back> to view other pending submission logs	 The screenshot shows a 'Submission Report Summary' section with a table of submission details. Below the table is a 'Dispatched Items' table with columns for Tracking ID, Date of Dear Investigator Letter, MFR Control No, Report Type, Event Name, Date Received by Manufacturer, Report Date, and Action Taken. At the bottom, there are two green buttons: 'View Submission Cover Letter' and 'View SAE Report Form'. A status message at the bottom indicates 'Submission ID 1045 has been endorsed successfully'.
Remarks: 1. For e-signature, the PI will need to enter User Name and Password for re-confirmation. 2. E-signature will be recorded in system audit trail.	

3.7 Tracking

Procedures	
1. Click <SAE Submission Log> of a study at Home page 2. Input Protocol Number or unclick <Outstanding Only> to search for all submission history 3. Click <Search> to display the submission status	

4. Questions

4.1 Enquiry Contact

For enquiry about PEARS, please contact PEARS Administrators at:

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

Appendix 1: Overview of PEARS Operations

