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<td>No more forced password changes (maybe)</td>
<td>45</td>
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Chapter 1

Overview

Access allows users to login and access Sealed Envelope services such as Red Pill and randomisation. Users can update their account settings such as password and email address and turn email notifications on or off. Access also allows administrative staff at the trial coordinating centre to view, create and update user accounts, including resetting lost passwords.

Sealed Envelope will create the first administrator account when a system is initialised, usually for the trial manager. This account should then be used to create additional administrator and investigator accounts as needed.

This documentation applies to version 6.1, released Jun 2018.
Chapter 2

Log in

Log in to Access via the trials page on Sealed Envelope’s main website. Users are requested to authenticate themselves before access is granted to the system by providing their registered email address and password. If a user does not have an account on the system, or provides an incorrect password, they will not be allowed access.

New users can request an account by asking an existing administrator user to create one for them. When a trial is first set-up by Sealed Envelope, an administrator account will be created, usually for the trial manager. The trial manager can then create new administrator or investigator accounts as required. If the user already has an account, it can be linked to the new trial.

When a user has logged in their name and unique user ID number is always shown at the top of every page in the navigation bar. Once a user has finished using the system it is good practice to log out. This is particularly important if the user is not using his or her own computer. To log out click on the ‘Logout’ link in the navigation bar at the top of the page.

Note that to comply with good clinical practice (GCP) it is very important that users do not share accounts or allow others to access their accounts, even temporarily.
Figure 2.1: log in screen
Staging environment

Test systems are separate from the live environment, and users accounts are independent of each other. This means a user may have two separate accounts — one for test systems and one for live systems. When logging in to the test environment, a message is shown to remind users that real data should not be entered.

![Figure 2.2: log in screen](image-url)
Auto timeout

After a set period of inactivity (usually 20 minutes but may differ for some trials) the user is automatically logged out of the system.

Account suspension

Accounts can be suspended if too many failed log in attempts are made in a short space of time. An email will be sent to the account holder with details about the suspension. Suspensions last a maximum of one hour after which they are automatically lifted. Users can reset their password if they cannot remember it.
Chapter 3

Trials summary page

After logging in, users are presented with a list of trials to which they have access. The trials may be in different environments: test (staging) or live (production). The environment is shown by a coloured header or a *LIVE* badge in the top right corner of the trial panel. The environments are:

- **Live** is the system for use in the trial
- **Test** is for user acceptance testing by the sponsor, site training and demonstration purposes

In each trial panel a button is provided to access the trial with a particular role. The role determines a user’s privileges and the site data they have access to.

Users with an administrator role for a trial will see options to view users, notification accounts and the audit log. Users with other roles will not see these options.

Once a user has accessed a trial, the summary page can be returned to at any time by clicking on ‘Access’ in the navigation bar at the top of the page.

Multiple roles

Users can have more than one role in a trial, in which case several access buttons will be shown. Clicking a button will take the user to the trial application with the privileges and site determined by the role shown.
Notifications

Each role can have notifications turned on or off. Notifications are emails sent when events such as randomisation, unblinding or query creation occur. If notifications are off, click the ‘Enable notifications for this role’ link to turn them on. If notifications are on, click the ‘Disable notifications for this role’ link to turn them off.

Suspended roles

Roles can be suspended by administrators, which prevents further access with the role and disables notifications.
Figure 3.2: User with multiple roles
Figure 3.3: User with a suspended role
Chapter 4

Viewing user accounts and roles

Viewing accounts for a trial

Administrators can view user accounts and roles for a specific trial from the Users link in the trial panel.

Roles in italics are suspended. New accounts can be created using the Create a new user button. Clicking on a name in the list shows details about that account including name, email address, date of last log in and password change. The user’s password can be reset using the Reset password button on this page. This sends a unique password reset link to the user’s email address.

The name and email address can be updated by editing the user account.

Viewing all users

Administrators can view user accounts across all trials that they administer by clicking the Users link in the navigation bar at the top of the screen.
Demo 1 (blinded) (TEST)

This is a list of user accounts with access to Demo 1 (blinded) (TEST). Roles shown in italics are currently suspended. Select a role to change it, suspend access or change notification settings.

Create a new user

<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrea Amins (Me)</td>
<td><a href="mailto:a.amin@foundling.nhs.uk">a.amin@foundling.nhs.uk</a></td>
<td>Administrator</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Archivist at all sites</td>
</tr>
<tr>
<td>Clem Fandango</td>
<td><a href="mailto:fandango@hearingloss.org">fandango@hearingloss.org</a></td>
<td>Investigator at Dunedin</td>
</tr>
<tr>
<td>Iain Pearsons</td>
<td><a href="mailto:ipearson@clinicalcentre.org">ipearson@clinicalcentre.org</a></td>
<td>Investigator at Helsingør</td>
</tr>
<tr>
<td>Jenny Jens</td>
<td><a href="mailto:jennyj@foundling.nhs.uk">jennyj@foundling.nhs.uk</a></td>
<td>Unblinding at all sites</td>
</tr>
</tbody>
</table>

Figure 4.1: Viewing user accounts for a trial
User account for Jenny Jens

<table>
<thead>
<tr>
<th>Jenny Jens</th>
<th>Edit details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email: <a href="mailto:jennyj@foundling.nhs.uk">jennyj@foundling.nhs.uk</a></td>
<td></td>
</tr>
<tr>
<td>Last log in: 21 Mar 2018 12:44 (today)</td>
<td></td>
</tr>
<tr>
<td>Last password change: 21 Mar 2018 12:44 (today)</td>
<td></td>
</tr>
</tbody>
</table>

Add a new role for Jenny Jens

- Add role for Demo 1 (blinded) (TEST)
- Add role for JUMP (LIVE)
- Add role for SETI-2 (TEST)

Current roles for Jenny Jens

Roles allow a user to access trials with certain privileges and to have access to data at particular sites. A person can have multiple roles both within and across trials. Roles shown below in italics are suspended. Select a role to change it, suspend access or change notification settings.

- **Demo 1 (blinded) (TEST)**
  - Unblinding at all sites
- **JUMP (LIVE)**
  - Administrator

Figure 4.2: Viewing user account detail
# Users

User accounts assigned to trials that you administer.

You are an administrator for:

- Demo 1 (blinded) (TEST) - create a new user
- JUMP (LIVE) - create a new user
- SETI-2 (TEST) - create a new user

Select a user’s name to change their email address, reset their password, and to view and edit their roles on the trials you administer.

<table>
<thead>
<tr>
<th>Name</th>
<th>Email address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrea Amins (Me)</td>
<td><a href="mailto:a.amin@foundling.nhs.uk">a.amin@foundling.nhs.uk</a></td>
</tr>
<tr>
<td>Clem Fandango</td>
<td><a href="mailto:fandango@hearingloss.org">fandango@hearingloss.org</a></td>
</tr>
<tr>
<td>Iain Pearsons</td>
<td><a href="mailto:ipearson@clinicalcentre.org">ipearson@clinicalcentre.org</a></td>
</tr>
</tbody>
</table>

Figure 4.3: Viewing all user accounts
Roles and privileges

Each trial has several roles with different privileges. The roles and privileges will vary by trial. However the following roles are normally available:

**Superuser**  Has access to all trials and all features. Reserved for Sealed Envelope staff only.

**Administrator**  Has access to selected trials, but usually all features within those trials. Intended for use by trial managers and other staff at the trial co-ordinating centre.

**Investigator**  Has limited access to selected trials. Investigator accounts are linked to a particular trial site and only subject data or randomisations from that site may be viewed. Investigators have no access to administrative functions (such as reports, sites, user accounts and log sections).

**Notification**  Used for notifications only - this account cannot log in to the system. May, optionally if enabled, be used to send notifications to fax recipients.

Some trials may have the following account types:

**Statistician**  Read only access to subject data and ability to download for analysis.

**Monitor**  Read only access to subject data and ability to create or respond to queries.

**Archivist**  Download an archive containing all application data. This role can only be assigned by Sealed Envelope on request.

**Warning** archives may contain sensitive data such as randomisation lists and unblinded data. Think carefully about the risks before assigning this role to anyone involved in the day-to-day running of the study.

Randomisation systems may also have the following account types:

**Randomisation**  Limited account that can only randomise and view previous randomisations for a particular site.

**Unblinding**  Limited account that can only unblind treatment and view previous randomisations for a particular site.

The privileges available to each account type are fine tuned by the configuration for a particular trial - for instance investigators may or may not be allowed to unblind treatment. The actual privileges available are shown on the account creation screen.
Viewing roles for a user

Clicking on a user’s name shows all the user’s current roles. Trials which are administered by the logged in user are clickable and show more detail on roles. Alternatively, clicking on a user’s role in the trial specific user list shows all roles in the trial. New roles can be added from this page and existing roles edited.

Andrea Amins

Andrea Amins (a.amin@foundling.nhs.uk) has 2 roles within this trial:

- **Administrator**
  - Created 21 Mar 2018 15:43 (today)
  - Notifications are On

- **Archivist at all sites**
  - Created 11 Aug 2017 14:40 (222 days ago)
  - Notifications are Off

[Assign new role]

Figure 4.4: Viewing roles in a trial
Chapter 5

Creating accounts and roles

New accounts

An existing administrator can create new accounts for a particular trial from the users page for a trial or the global users list. When creating a new account, a role must also be chosen.

To create an account the user’s real name and email address must be supplied. For roles that can be limited by site a site selection control is displayed.

The account can be set to receive notifications or not. Notifications are emails sent out when events like randomisation or unblinding occurs. Administrators receive notifications for all such events in the trial. Accounts that are limited to a particular site only receive notifications related to that site. Notification only accounts can also be created.

Invitations

Once the account is created an automatically generated email is sent to the email address with an invitation to log in and set-up the account. Invitations expire after 2 weeks and must be re-sent after this time. If the invitation was sent in error or is no longer required it can be deleted as long as the invitee has not already set up their account.
Demo 1 (blinded) (TEST)

New user

Create administrator account
Create investigator account
Create monitor account
Create statistician account
Create unblinding account

Figure 5.1: Creating a new user account
Figure 5.2: Screen shown when creating an investigator account
Figure 5.3: User account for invited user
Existing accounts

Sometimes a user may already have an account on the system for a different trial. Attempting to create a new account for an existing email address will trigger an error. A link will be shown to allow the existing account to be associated with the new trial.

Adding a role

Administrators can add a role to an existing account by first locating the user from the users page for a trial or the global users list. Links to add a new role are shown on the account details page.
The user will receive an email informing them that their existing account has been associated with the new trial and they will obtain immediate access.

Figure 5.5: Assigning a role

**Telephone randomisation**

If a trial is making use of Sealed Envelope’s telephone randomisation service, access to this service is granted by specifying an investigator number when creating the account. The investigator number must be a unique 3 digit number in the range 100-999.

When the user calls the telephone randomisation service they must enter the study number and investigator number to gain access to the system. These are shown to administrators and users with telephone access on the trials summary page.
Figure 5.6: Showing investigator number for telephone randomisation
Chapter 6

Editing accounts

Existing accounts may be edited by an administrator by clicking on the Edit details link when viewing an account. It is possible to change the account email address and name only. The user’s name should only be changed to correct spelling mistakes.

Existing user accounts should not be re-allocated to new users. User accounts that are no longer in use should be suspended and new accounts created for new users.

Editing roles

A role can be edited to change the site, status (active or suspended) and to enable or disable notifications. To edit a role find the user and view their roles, then click the Edit role link.

Deleting accounts

There is no facility for deleting accounts except notification accounts. This is to preserve the audit trail and history of who performed which actions. To remove the ability for an account to access a trial the account should be edited and the status set to suspended.
Edit account for Jenny Jenns

Changing these details affects the user's name and email address across all trials.

Do not use this form to allocate this account to a new person.

Only change the name or email address to correct mistakes or update the information for the person the account belongs to.

Name:

Jenny Jenns

Email address

jennyj@foundling.nhs.uk

Update  Cancel

Figure 6.1: Editing a user account
Update role for Iain Pearson

Investigator at Helsingør

Iain Pearson (ipearson@clinicalcentre.org)

Investigator role

Site

Helsingør

You can create and manage sites by accessing the Demo 1 (blinded) trial as an administrator.

Status

- ☐ Active
- ☑ Suspended

Send email notifications?

Update  Cancel

Figure 6.2: Editing a role
Chapter 7

Changing your own account details or password

The My account link is shown in the navigation bar at the top of the page. This link directs the user to a page where they can edit their name, email address, timezone, back-up email, mobile phone number or password. Administrators can update name and email address by editing accounts and can reset passwords for any user.

Self-service password resets are enabled by entering a back-up email address or mobile phone number to receive a security code.

New passwords must be at least 8 characters long and sufficiently complex to be labelled at least Acceptable strength by the password strength indicator. Some complex passwords are suggested above the new password box.

Timezone

The timezone setting applies to dates and times shown in the Access interface only. It does not affect dates and times in randomisation or Red Pill applications. These have their own timezone settings based on the site a subject was recruited at.
Update your details

Name:
Iain Pearsons

Email address
lpearson@foundling.nhs.uk

Timezone
(GMT+00:00) UTC

Add a back-up email address or mobile phone number to allow you to reset your password if you forget it.

Back-up email address
me@alternative.com

This email will only be used for account security purposes.

Country

Mobile phone number

This number will only be used for account security purposes.

Confirm your current password to make changes to your account

Change your password

You must change your password every 6 months. You last changed your password Wed, 30 Dec 2020 10:00:00 +0000 (over 2 years ago)

Confirm your current password
current password

Some password suggestions:
it fake aw
own False shad
foxy penny Baxter

Suggest more passwords

Your new password
new password

Your new password must be at least 8 characters long.

Confirm your new password
new password again

Change

You cannot submit this form with a weak password.

Recent log ins

Thu, 14 Jun 2018 14:26:12 +0000 (9 minutes ago)
Wed, 21 Mar 2018 19:01:14 +0000 (3 months ago)
Tue, 20 Mar 2018 17:39:07 +0000 (3 months ago)
Tue, 20 Mar 2018 10:35:49 +0000 (3 months ago)
Tue, 13 Mar 2018 18:43:27 +0000 (3 months ago)

Chrome 67.0.3396.79 on Mac 10.13.5
Chrome 65.0.3325.162 on Mac 10.13.3
Chrome 65.0.3325.162 on Mac 10.13.3
Internet Explorer 11.0 on Windows 10
Internet Explorer 11.0 on Windows 10

London, England, United Kingdom, IP: 128.40.2
London, England, United Kingdom, IP: 128.40.2
London, England, United Kingdom, IP: 128.40.2
Bromley, United Kingdom, IP: 82.16.30.167
Bromley, United Kingdom, IP: 82.16.30.167

Figure 7.1: Changing password
Recent log ins

Details of the five most recent log ins are displayed on the My account page. The date and time of each log in together with browser information and IP address are tabulated. The geographical location of each IP address is shown if available.

Password expiry

Passwords may expire after a number of months, after which time a user is forced to change their password. Users with expired passwords have no access to the system except for the change password screen. This setting is trial specific and if a user has roles in several trials, the most frequent password change interval will apply.
Chapter 8

Forgotten passwords

If a user forgets their password they may be able to reset their own password. The user must have stored a back-up email or mobile phone number to do this, in order to receive a security code.

Self service reset

Users should click on the *Forgot your password?* link on the log in page and enter their email address. If the email address is for a valid account, an email will be sent with instructions. This will contain a unique password reset link that expires after 10 minutes. A security code will also be sent to the user’s back-up email or mobile number which is needed on the password reset page.

Administrator reset

If the user has not stored a back-up email or mobile phone number, they should contact the trial manager or other holder of an administrator account. Administrators can reset a user’s password on the user account details screen. This sends out an email to the account holder with a special link to reset their password. The link is valid for 2 hours. A security code is not required by the user to change their password.
Figure 8.1: Reset own password
Administrators are advised to verify the identity of users requesting a password reset in this way.

Requests for password resets made by investigators to Sealed Envelope will be referred to the trial manager since Sealed Envelope has no way of authenticating the validity of such requests.

User account for Jenny Jenns

<table>
<thead>
<tr>
<th>Jenny Jenns</th>
<th>Edit details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email: <a href="mailto:jennyj@foundling.nhs.uk">jennyj@foundling.nhs.uk</a></td>
<td></td>
</tr>
<tr>
<td>Last log in: 02 Jun 2017 10:25 (290 days ago)</td>
<td></td>
</tr>
<tr>
<td>Last password change: 01 Dec 2017 10:00 (108 days ago)</td>
<td></td>
</tr>
</tbody>
</table>

Figure 8.2: Viewing user account detail

Password change email

Once a user successfully changes their password, an email is sent to them informing them of the change. Unexpected password changes should be investigated without delay in case an account has been compromised. Contact Sealed Envelope for assistance if required.
Chapter 9

Security

This page explains the various security features of the Access log in system and how you can help keep your account secure.

Recommendations

1. Choose a strong password that you do not use elsewhere.

Passwords must be at least 8 characters long and sufficiently complex to be labelled at least Acceptable strength by the password strength indicator. Some complex passwords are suggested above the new password box.

Tip: two or three word phrases are generally stronger than single word passwords especially if one or more of the words is not in the dictionary. Create non-dictionary words by adding digits or punctuation.

2. Use a password manager

A password manager helps you create and store secure passwords for all your online accounts. Many integrate with your web browser to make filling in password fields easy. Even if you are
using a work PC on which you can’t install password manager software, you can still use a mobile app on your phone to help you create and remember passwords. Popular password managers include 1Password, LastPass and Dashlane.

3. **Add a backup-email or mobile phone number**

By adding a backup-email or mobile phone number to your Sealed Envelope account you will be able to use the self-service password reset feature if you ever forget your password. If you don’t, you will need to contact an administrator to reset your password instead.

4. **Look out for account related emails**

We will send you an email notification if any of the following occur:

- The reset password feature is used for your account email address. This will contain instructions on how to reset your password.
- Your password is changed. Only you can change your password so if you receive this email unexpectedly you should report it to a trial administrator or Sealed Envelope for investigation.
- Your account details such as name or email address are changed. You can do this on the My account page or an administrator can make these changes for you. The notification will be sent to both your old and new email addresses (if applicable). If you are not sure why the changes have been made you should contact a trial administrator.
- Your account has been suspended because too many log in attempts have been made. If you receive this email unexpectedly it may be a sign that someone is trying to break into your
Figure 9.2: Reset password email
account by guessing your password. If you think this may be the case please contact a trial administrator or Sealed Envelope for investigation.

5. Check your recent log ins

You should check your recent log ins on the My account page regularly and report any suspicious activity from unknown locations or web browsers.

About enforced password resets

In the past it has been generally considered good practice to regularly change passwords and this has fed through to regulations (such as 21 CFR Part 11) and corporate policies. However, it is increasingly recognised that this practice might be counter productive and several influential bodies including NIST and the UK Government now advise against periodic enforced password changes.

Sealed Envelope support enforced password reset intervals at the trial level but by default this setting will be off. We recommend it is not used unless your trial has to comply with 21 CFR Part 11 or your own corporate policies. Trial administrators should contact Sealed Envelope if they require a password reset interval to be set.
Chapter 10

Notification accounts

Notification accounts cannot be used to log in to the system but allow receipt of notifications for a trial. They can be created and edited in a similar way to standard user accounts. Notification accounts may also be deleted by clicking on the name in the list and using the delete button.

Figure 10.1: List of notification accounts
### Notification account details

<table>
<thead>
<tr>
<th>John B. McLemore (<a href="mailto:john@woodstock.nhs">john@woodstock.nhs</a>)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited to site</td>
</tr>
<tr>
<td>Access granted to this trial <strong>27 Nov 2014 16:24 (1210 days ago)</strong></td>
</tr>
<tr>
<td>Edit notification account details</td>
</tr>
</tbody>
</table>

Figure 10.2: Viewing a notification account
Chapter 11

Audit log

Changes to user account data are shown in the audit trail. Click on ‘Audit log’ in the navigation bar to view this file. Entries can be searched, and sorted by clicking the header row.

Figure 11.1: Audit log
Chapter 12

Archives

Users with the archivist role are able to download an archive containing all application data.

Archivist user accounts cannot be created by administrators and must be requested by contacting Sealed Envelope. The archivist role may be useful, for instance, by a statistician to download data required for interim analyses for Data Monitoring Committee meetings. It may also be used at the end of trial during close-out.

Archives may include sensitive data such as randomisation lists and unblinded data. For this reason the archivist role should not normally be assigned to any staff involved in the day to day running of the study.

Archive contents

Users with the archivist role will see a button to download the archive. The archive is a zip file containing:

- README.txt with a description of the archive contents and MD5 checksums for each file in the archive
- Complete MySQL dump file for the study database
- Comma separated value (CSV) files for all forms in the CRF and other datasets such as randomisation and code lists
- Stata files for all forms in the CRF and other datasets such as randomisation and code lists
CAP-IT

Efficacy, safety and impact on antimicrobial resistance of duration and dose of amoxicillin treatment for young children with Community-Acquired Pneumonia (CAP): A randomised controlled trial

Download an application archive

Warning: archives contain sensitive data such as randomisation lists and unblinded data.

Figure 12.1: Download archive
• A data dictionary showing the structure of every form in the database. Additional information on each column shows the question as it appeared in the CRF or randomisation form.
• Copy of the final audit log. This text file contains a timestamped record of every action that created, updated or edited data. Each action is linked to the relevant user account.
• Log of user account actions. This text file contains a timestamped record of every action that created or updated a user account, role or notification account linked to the system and the user account that performed each action.
Chapter 13

What’s new

June 2018 - version 6.1.0

A timezone setting has been added to user accounts so you can see times in the Access interface (such as times of your recent log ins) in your own timezone.

Some people were getting the test and live environments mixed up. A warning is now shown on the log in page for test systems to hopefully reduce confusion.

Some tweaks were made to the security code text messages for compatibility with North American mobile networks.

March 2018 - version 6.0.0

This update is all about security, making it easier for you to keep your account secure and recover from that common modern affliction – forgotten passwords.

You can now recover your own password using the Forgot your password? link on the log in page, provided you have added a back-up email or mobile phone number to your account to receive security codes. If you haven’t done this you can still ask an administrator to reset it for you.

We’ve added a help page on ways you can keep your account secure. Check it out for some hopefully helpful advice.
No more forced password changes (maybe)

Security guidance has finally caught up with common sense and heavy-weight bodies such as NIST in the US and the UK Government now advise against periodic enforced password changes. Why? Because making passwords expire means people tend to forget their new passwords, pick simple variations on their previous password, and are more likely to write them down on a sticky note.

Unfortunately some standards such as 21 CFR Part 11 contain requirements to enforce regular password changes, and so we have made this a trial level setting. We’ll be asking customers whether they need to enforce regular password changes when we set up new trials. Customers can also ask us to turn off enforced changes for existing trials.

Watch over your account

We’ve added a recent log ins section to the My account page which shows where and when you logged in from. If you think something suspicious is going on, this is the first place to check. We also show you the last time you logged in when you log in.
Figure 13.2: Globe
We now send you emails when things change concerning your account including:

- Changed account information
- Changed password
- Account suspension because of too many failed log in attempts

If you see any of these emails when you weren’t expecting them, you should channel your inner Sherlock and investigate.

**Other changes and bug fixes**

- Older versions of Access are being retired and user accounts will be migrated to the latest version. We’ll be in touch with customers affected by this change with more details.
- We’ve refreshed the way Access looks, and reduced the space each trial takes up on the trials summary page
- Search added to the trials summary page when there are more than 3 trials. Pagination added with 12 trials per page.
- User’s can now change their own name (an administrator had to do it before)
- Deleted roles and notification accounts are now shown in the audit log
- The dictionary used to check for weak passwords has been interfrastically updated
- Invitation links are now sent to new users rather than passwords. Invitations expire after 2 weeks but can be renewed by administrators or cancelled.
- Subject entered forms invitation links now always take the user to a welcome screen with a button to start the survey (previously this screen was only shown if a memorable word was set). This prevents issues with email previews or virus checkers visiting links and inadvertently logging in as a subject.
- A subject who has logged out after entering forms is shown a finished message and no longer shown the usual user log in page if they try to visit a protected page
- Log in throttling should help prevent bad guys from trying automated password guessing to break into accounts
- We fixed an issue for users with longer timeout intervals for their trials. Access now also respects these longer timeout intervals so you can enjoy being logged in for longer.