



Merge eClinical: Process Improvement and Education

### eClinicalOS: Study Designer Training

New User Help

Authored by: Emily Malok

Effective Date: 06 November 2015



### **System Access**

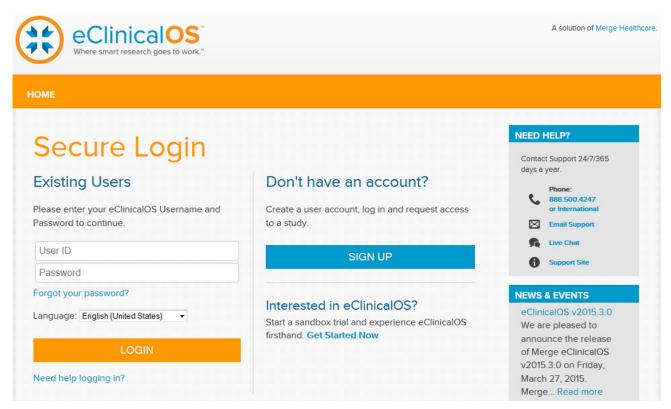
Study Designer

#### How do I get access to eClinicalOS?

All users, whether accessing design or study EDC, will use the same URL/Website address and log in the same. The users will be directed to the correct area of the setting based on their account settings.

### https://secure.eclinicalos.com/

If you use an old bookmark or link and access the <u>www.eclinicalos.com</u> website, you will be automatically redirected to the more secure site.



You will see both the New User access and Existing User access on the same screen. If you need assistance, Help links are also provided. You can check the latest Merge eClinical and eClinicalOS news as well.





### **System Access**

**Study Designer** 



IMPORTANT: Unsupported (or "Legacy") browsers will be identified by the system and you may see a warning message on the login screen. Not all Legacy browsers will be able to access eClinicalOS. Known restrictions are:

- Internet Explorer v6 Access is blocked as of the January 2015 release
- Internet Explorer v7 Access is blocked as of the January 2015 release
- **Internet Explorer v8 Access will be blocked as of January 2016**

#### ACCESSING FROM THE PRODUCT PAGE

If you reach the product page, it contains information about the product, Merge Healthcare, and how we can help you with your trials. New and Existing users will click the LOGIN button at the top right to reach the account section. Further instructions for accounts are in the next section.







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### Creating an eClinicalOS Account

#### How do I get an eClinicalOS account?

All users will create an eClinicalOS General User account. Once an account is created, Merge or a manager on your study team can upgrade your General User account to a Study Designer account, thus providing access to the development area for your studies. You will only need one Study Designer account to access both the Designer and the EDC for a study and you can access multiple studies with the same account.



#### NOTES:

- ♦ The management of EDC access to a study is covered in the Conduct Tools manual in the User Management section.
- ♦ Once you have an account, you will use the same address to access the system. You will enter your User ID and password in the Login area instead of using the New User link.
- Information to the right highlights recent releases and updates to the system as well as providing contact information to get support on login or other system issues.
- ♦ If you need assistance with eClinicalOS, please contact:

#### Merge Healthcare Help Desk

Website: <a href="http://www.merge.com/Support/Clinical-Trials.aspx">http://www.merge.com/Support/Clinical-Trials.aspx</a>
By Phone: 1.888.500.4247 (non-US numbers available on website)

By Email: <u>support@merge.com</u>

#### TO CREATE A GENERAL USER ACCOUNT

Step	Action
1.	Navigate to <a href="https://secure.eclinicalos.com/login.jsp">https://secure.eclinicalos.com/login.jsp</a> in a browser.
	NOTES:
	• <i>eClinicalOS</i> is designed to run on the majority of operating systems and browsers; however, Internet Explorer (IE) version 9.0+, Firefox version 3.6+, and Chrome are the supported browsers.
	♦ All users can access eClinicalOS using the same web address.
	• Users accessing via the Mobile Application Trial Connect may see a different view. Trial Connect should not be used until after the user has an eClinicalOS account.
Optional	If you reach the main product page, click the <b>LOGIN</b> button at the top right of the screen. See previous page for screenshot.

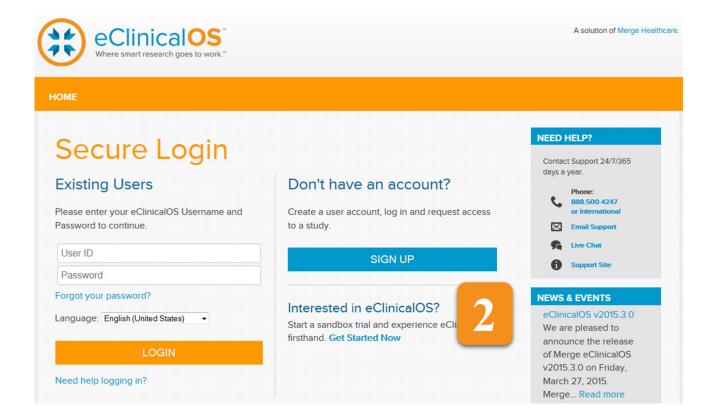




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### Creating an eClinicalOS Account

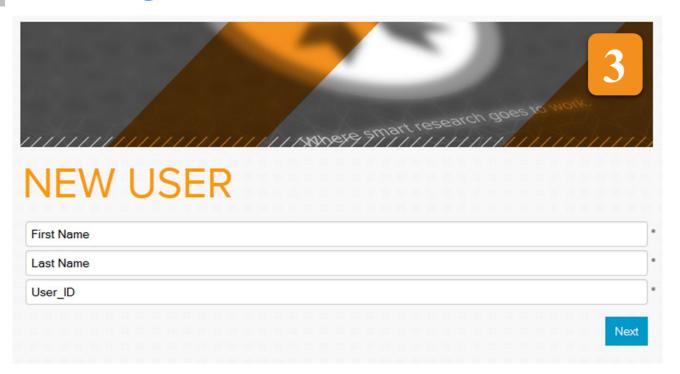
Step	Action
2.	Click the <b>SIGN UP</b> button at the bottom of the screen.
3.	Complete the each page of the information form. Use the <b>NEXT</b> button to proceed. All questions with an asterisk (*) are required.
4.	Click REGISTER.







### **Creating an eClinicalOS Account**



Attribute	Options	Details
First Name	Free Text	Your first or given name. The field will allow up to 48 characters.
Last Name	Free Text	Your last or family name. The field will allow up to 48 characters.
User ID	Free Text	This is the ID you will use to login/access eClinicalOS and also to electronically sign within the system. The User ID must be at least 5 characters and can be up to 15 characters.



#### *NOTES:*

- ♦ You can choose any ID you want; however, it must be unique within the system. You will see an error message at the top of the screen if your choice is already being used and you will need to select another ID.
- ♦ Do not use the Study Name or Passcode from your study access request details as your User ID.
- ♦ A User ID cannot contain spaces or special characters such as  $\sim!@\#\$\%^*()+|\}{":?><,./;'[]}=$





# Creating an eClinicalOS Account

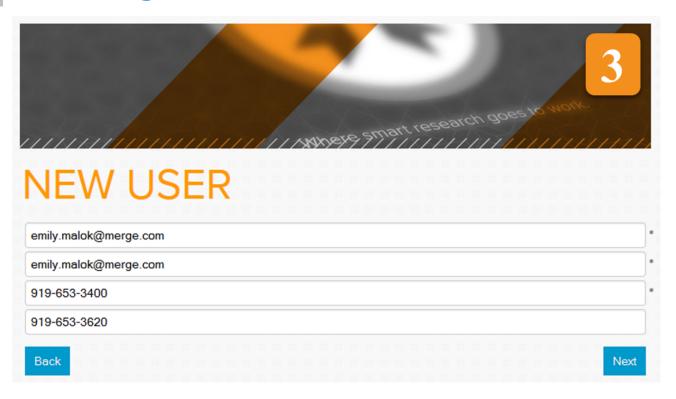
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		New
Back		Next

Attribute	Options	Details
Company/ Organization	Free Text	The organization you will represent when using eClinicalOS. This is usually the company you work for.
Organization Type	Dropdown list of Organization Types	Select your company's organization type.
Job Role(s)	Free Text with Selection List	Begin typing your role to see a list from which you can choose. You can add as many roles as apply.
Country	Dropdown list of countries	The country associated with the address of your company/organization
Primary Time Zone	A dropdown list of time zone choices	You should select the time zone where you will be using eClinicalOS. The system will display actions in your time zone. Any system windows (i.e. patient reported outcomes) will be enforced according to this information. You can update your time zone at any time in user settings.





# Creating an eClinicalOS Account



Attribute	Options	Details
Email	Free Text (Required)	Your email address. This will be used to contact you with account information such as password resets.
Confirm Email	Free Text (Required)	You should enter the same address a second time. This is just to confirm accuracy.
Phone	Free Text (Required)	You should enter a contact phone number. This will not be used except to return calls or follow up on issues you have reported.
Fax	Free Text	You can enter a contact fax number. This will not be used except to follow up on issues you have reported.





2.

## Creating an eClinicalOS Account



Attribute	Options	Details
Question 1, 2, or 3	A dropdown of the questions listed below	Choose three questions.
Answer 1, 2, or 3	Free Text	This is your personal response for the question chosen.



#### *NOTES:*

*These are the question options:* 

- ♦ What is your city of birth?
- ♦ What is your favorite color?
- ♦ What is the maiden name of your mother?
- ♦ What is the middle name of your father?
- ♦ What is the name of your favorite pet?
- ♦ What is the name of your high school?
- ♦ What is the town of birth for your mother?





**Creating an eClinicalOS Account** 

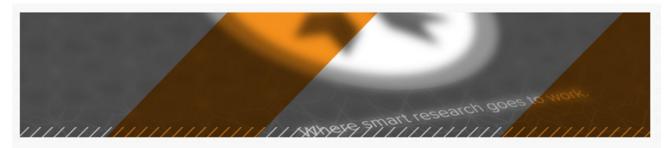
	3
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<b>NEW USER</b>	
Secret Question 2:	
What is your favorite color?	• • • • • • • • • • • • • • • • • • • •
Secret Question 2 Answer:	
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Back	Next
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Secret Question 3:	
What is the maiden name of your mother?	* = = = = = = = = = = = = = = = = = = =
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### Creating an eClinicalOS Account



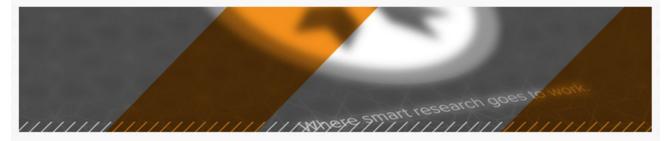
### **NEW USER**

This action will create a new login account. You will receive an email confirmation to the email p with a temporary password to use on first login. Once you successfully login, you must further r access to studies via study representatives already using eClinical OS.



Back

Register



### **NEW USER**

Thank you. Your account has been created. Please confirm this account via the email sent, further instructions to login are contained in the email.

Return to login





### Creating an eClinicalOS Account

### MERGE



This is an automated email generated from eClinical OS.

The following user has been added. Full Name: First Name Last Name

User ID: User ID

Company / Organization: Merge eClinical

Role: General User

Email: emily.malok@merge.com

Phone: 919-653-3400 Fax: 919-653-3620

Primary Timezone: US EST/EDT (GMT-5)

To login into the application, use the temporary password below.

Temporary Password: Afksrod7

Password change will be required on first login.

Login to your account

#### Have Questions?

Please contact the eClinical Solutions Support Team 24/7!

### What's New?

#### LATEST PRODUCT RELEASE NOTES

Download the eClinical OS v5.5.6 Release Notes (PDF)

#### **DEMO**

If you would like a short demonstration of the new features, please contact your account manager or our Inside Sales Manager Bruce Avery at bruce.avery@merge.com.

#### SUPPORT

If you have questions or concerns about the impact of the latest product update on your studies, please contact technical support or our eClinical Help Desk.

Merge eClinical OS Technical Support eclinicalossupport@merge.com

Merge eClinical Division Help

1.888.500.4247 (US) eclinicalhelp@merge.com



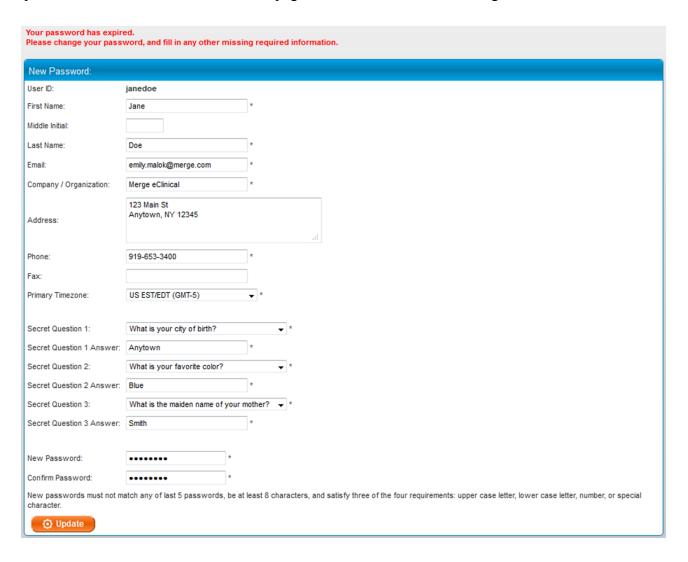




### **First Login**

#### What happens the first time I log in with my new account?

After your account is created, you will receive an email from the system with your temporary password. You will return to the main page and use the LOGIN button again.



#### OPTIONAL CONTACT INFORMATION

During your first login, some additional information can be added, such as address and phone contact information. The contact information is optional, but may be used to help identify you when seeking help or to allow the Help Desk to contact you for follow up. You will also be asked to provide a set of three secret questions and answers.





### First Login

**Study Designer** 

Attribute	Options	Details
Middle Initial	Free Text	You can include a middle initial if desired. This field allows up to 3 characters.
Address	Free Text	This is your mailing or contact address. This may be used to help verify your identity when contacting Merge.
Phone	Free Text	This is your contact phone number. This is used if Merge is providing assistance and needs to contact you directly.
Fax	Free Text (Optional)	This is a contact fax number. This may be used if Merge is providing assistance and needs to provide documentation.

#### SETTING YOUR PERSONAL PASSWORD

You will have to provide a password of your own choosing the first time you login. Passwords must be at least 8 characters in length, no more than 15 characters, and contain 3 of the 4 following criteria:

- Upper case letter
- Lower case letter
- ♦ Number
- ♦ Special Character

#### PASSWORD NOTES:



- Passwords are case sensitive.
- ♦ Passwords expire every 90 days but can be reset as needed on your personal settings.
- ♦ Your User account is locked after:
  - ♦ *Five (5) invalid login attempts*
  - ♦ Five (5) invalid attempts at a secret question/answer wizard
  - ♦ Five (5) invalid attempts at electronic signature
- ♦ Your new password cannot match the last five (5) passwords you used.
- ♦ If your password is reset and a new temporary password is issued, you will also be required to update it on the first login.





### **First Login**

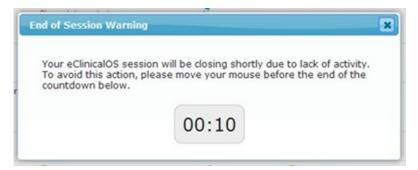
**Study Designer** 

#### OTHER THINGS TO KNOW

The system has an automatic time-out function. This is a required feature for systems that support 21 CFR part 11. If your session is inactive for more than 30 minutes (this is activity in eClinicalOS, not the browser or elsewhere on your computer), the system will log you out. This timeout also applies to modules and tools associated/interfaced with eClinical OS, such as the DICOM uploader.

With the release of eClinicalOS v5.7.0.0, additional management features have been added to alert you to time-outs:

- ◆ The system has been updated to check for keystrokes and mouse movement as well as button clicks, so that data entry without a page save will be captured as activity.
- An alert window will appear when you are within 3 minutes of the time-out. This allows you to click and delay the action.



♦ Previously, when a time-out occurred, the last page viewed remained on screen. This caused confusion and unnecessary frustration for users who continued entry only to be unable to save. The system will now return to the login page on time-out.







Two help options are available on the login screen.

#### ACCOUNT ISSUES (A)

Help for a forgotten user name or password is available on the main login screen by clicking the "Forgot your password" link. The system will also prompt you when you enter your ID/Password incorrectly and will display how many attempts you have left. A total of 5 attempts are allowed before your account is locked.

#### **INSTRUCTIONS (B)**

If you use the "Need Help Logging In" link, you will access a shortened user manual that includes information for adding a new user and retrieving user account information (this document).

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1 || FORGOT USER ID

Step	Action
1	Click Forgot your password.

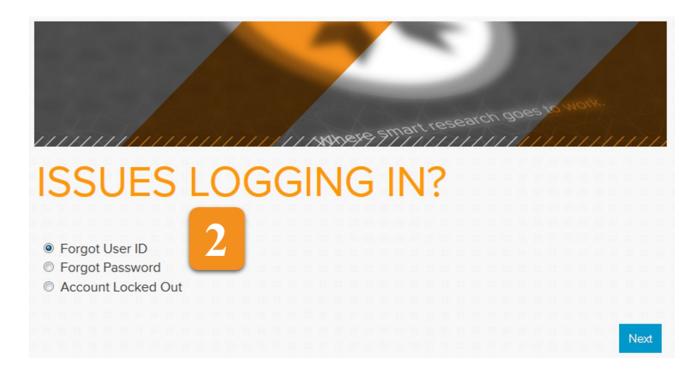






**Study Designer** 

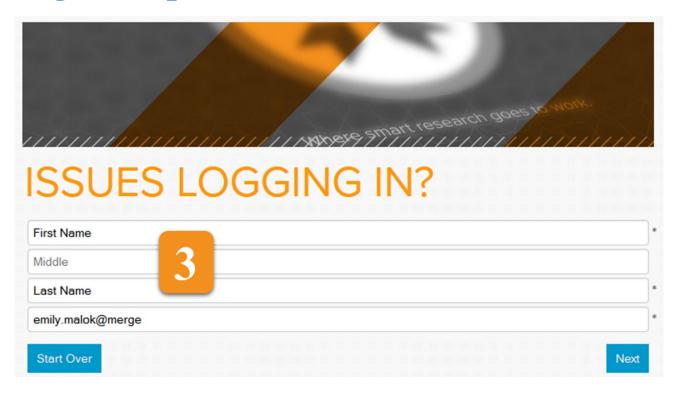
Step	Action
2.	Select Forgot User ID and click Next.
3.	Enter your first name, middle initial, last name, and email address and click Next. They must be the same as you used for your account or you will get an error.
Alternate	If you have multiple accounts, you will be asked to select which user account to use. Capitalization, spaces, and punctuation will matter in this case.
4.	Enter the answers to the three secret questions you selected for your account and click Next. They must be the same as you used for your account or you will get an error.
Output	You will receive an email from the system with your user ID. It will not contain a your password or a temporary one.











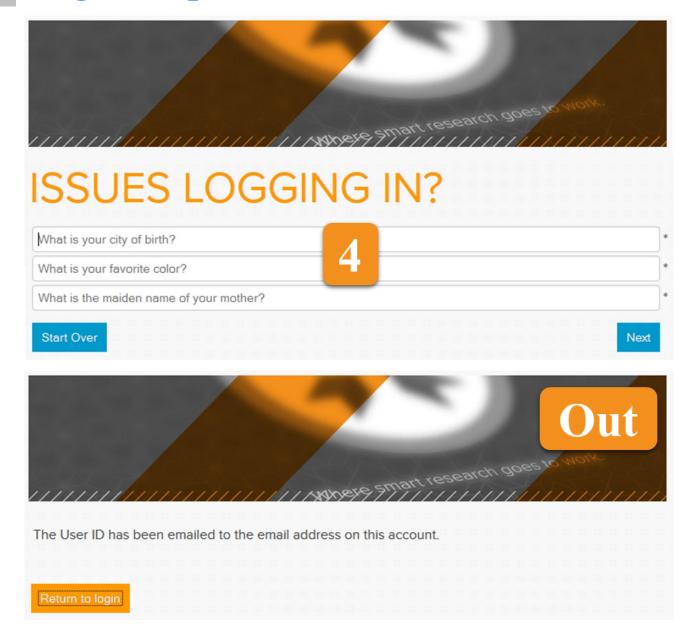








## **Login Help**









### MERGE



This is an automated email generated from eClinical OS.

The following user has requested a forgotten User ID.

Full Name: First Name Last Name

User ID: User ID

Company / Organization: Merge eClinical

Role: General User Phone: 919-653-3400 Fax: 919-653-3620

Email: emily.malok@merge.com

Login to your account

#### **Have Questions?**

Please contact the eClinical Solutions Support Team 24/7!

### What's New?

#### LATEST PRODUCT RELEASE NOTES

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#### **DEMO**

If you would like a short demonstration of the new features, please contact your account manager or our Inside Sales Manager Bruce Avery at bruce.avery@merge.com.

#### SUPPORT

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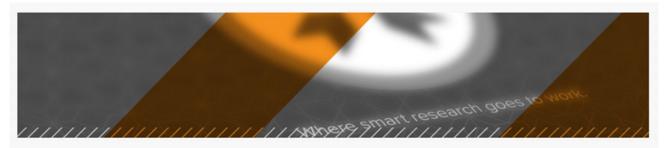




**Study Designer** 

### 2 || FORGOT PASSWORD

Step	Action
1.	Click Forgot your password.
2.	Select Forgot Password and click Next.
3.	Enter your User ID.
4.	Enter the answers to the three secret questions you selected for your account and click Next. They must be the same as you used for your account or you will get an error.
Output	You will receive an email from the system with a temporary password. You will be required to change it the first time you log in after completing this wizard.



# ISSUES LOGGING IN?

- Forgot User ID
- Forgot Password
- Account Locked Out











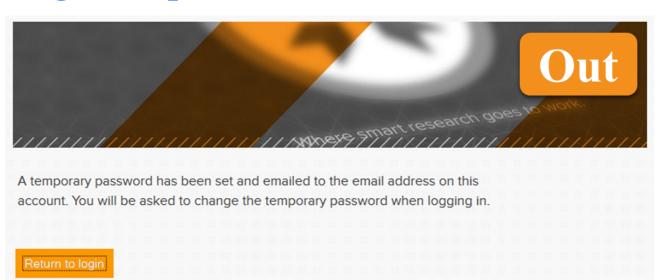
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### MERGE



This is an automated email generated from eClinical OS.

The following user has had a temporary password set. Full Name: First Name Last Name

To login into the application, use the temporary password below.

Temporary Password: Iksperf4

Password change will be required on first login.

Login to your account

#### **Have Questions?**

Please contact the eClinical Solutions Support Team 24/7!

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Merge eClinical | 4000 Aerial Center Pkwy | Suite 101 | Morrisville, North Carolina | 27560 | Contact Us



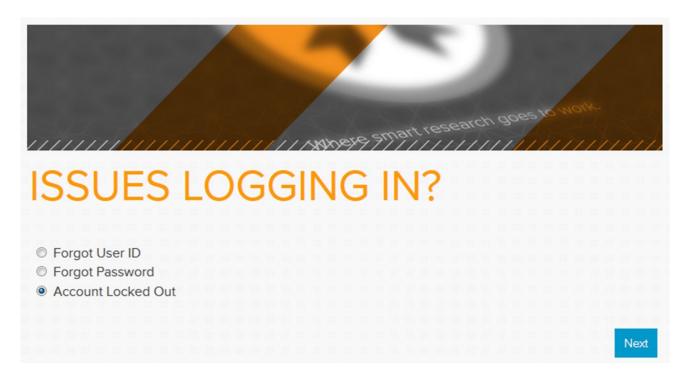


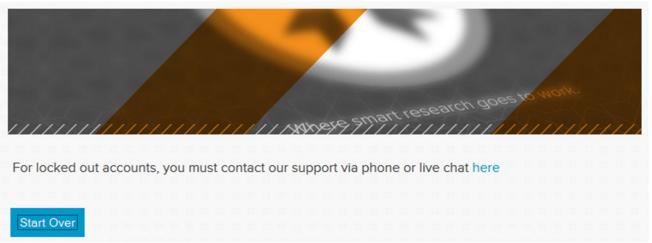


Study Designer

#### 3 || ACCOUNT LOCKED

If you have made 5 incorrect attempts to log in, the system cannot help you with a simple reset. You will be required to contact Merge support. A link is provided on screen or you can use the information below.











### Clinical Trials Product Support

Available 24/7, 365 days a year











Every client of Merge Clinical Trials has the support of a dedicated and highly trained in-house team, which operates 24 x 7 x 365, and is available to deal with issues via telephone, email and fax. Our support technicians pride themselves in offering high quality support and all issues raised to the support team are tracked until closure.



1.888.500.4247

Click here for additional



eclinicalhelp@merge.com

For Veracity Support support\_veracity@merge.com



Live Chat

Click here for Live Chat

Please have the following information available: Protocol number, Site number, Subject number

#### Merge Healthcare Help Desk

Website: http://www.merge.com/Support/Clinical-Trials.aspx By Phone: 1.888.500.4247 (non-US numbers available on website)

By Email: support@merge.com

#### 4 || ERRORS

If you cannot complete the wizard because you forgot the information on your account, you will also need to contact Merge support.

