

# Multi-Sponsor Environment

# SAS® Clinical Trial Data Transparency User Guide

Version 6.0 01 December 2017

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### 1 Overview

Three environments or websites encompass the SAS® Clinical Trial Data Transparency system:

#### Research Environment

How to access: Log on to the SAS Solutions OnDemand Secure Portal
 (<a href="https://shqaccess.ondemand.sas.com/dana-na/auth/url\_3/welcome.cgi">https://shqaccess.ondemand.sas.com/dana-na/auth/url\_3/welcome.cgi</a>). From the landing page, click the Clinical Trial Data Transparency Research Environment link. A remote terminal server session launches, requiring an additional logon (with same account). You then access the Research Environment.

### • Tasks you can perform:

- o Perform research work using SAS Clinical Trial Data Transparency or R.
- Collect files for export from the Research Environment.
- Review user guides and how-to videos.

### • SAS Clinical Trial Data Transparency (CTDT) Portal:

 How to access: Log on to the SAS Solutions OnDemand Secure Portal https://mseportal.ondemand.sas.com/ctdt/

#### Tasks you can perform:

- o Import files into the Research Environment.
- o Receive exports from the Research Environment.
- o Administrators can review reporting.

#### SAS Secure Access Management:

• **How to access**: Enter <a href="https://www.ondemand.sas.com/sam/">https://www.ondemand.sas.com/sam/</a> from your browser for access through the internet.

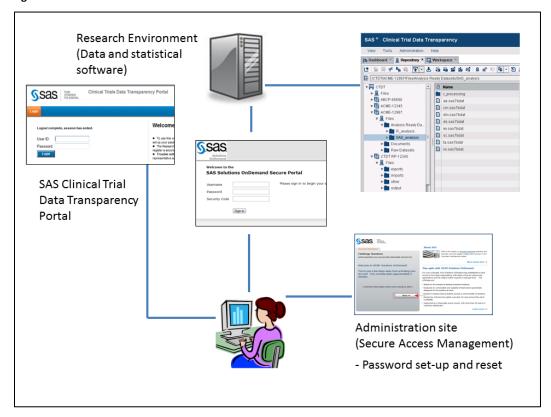
#### Tasks you can perform:

- Set-up your password for the first time.
- Reset your password.
- Administrators can add and update users.

**Note:** Once you setup your password and challenge questions, you are required to accept the Terms of Use Agreement in the SAS Clinical Trial Data Transparency Portal. Accepting these terms unlocks your account in the SAS Clinical Trial Data Transparency Repository system, which is available at the Research Environment desktop.

Figure 1 provides an overview of the environments.

**Figure 1: Environment Overview** 



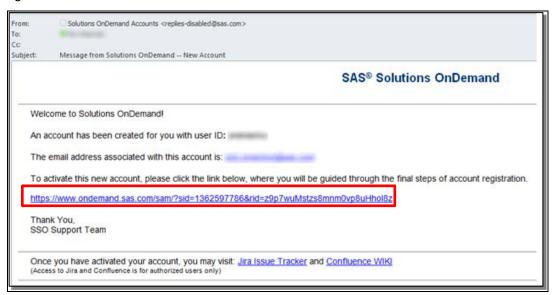
**Note:** Your account information (user name (or user ID) and password) enable you to access all the components of the SAS Clinical Trial Data Transparency system. An additional security code is required to access the Research Environment through the secure portal.

# 2 Setting up Your Account

## 2.1 Completing the Initial Email and Password Setup

1. Receive an e-mail from SAS Solutions OnDemand with your user name (or user ID) for the SAS Clinical Trial Data Transparency system. To activate the account and set-up a password, click the link in the e-mail (Figure 2).

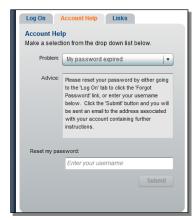
Figure 2: Welcome E-Mail



**Note:** The link in the e-mail expires after 72 hours. If you do not activate your account within 72 hours, visit the Account Help tab (Figure 3) at the <a href="https://www.ondemand.sas.com/sam/">https://www.ondemand.sas.com/sam/</a> website. Use the **My password expired** or **I don't know my username** options. Otherwise, contact SAS Technical Support as follows:

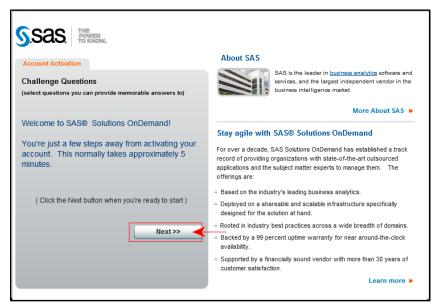
- o Email: CTDTsupport@sas.com
- URL: http://support.sas.com/ctx/supportform/index.jsp
- North America: Call 919-677-8008

Figure 3: Account Help



2. Click the link to setup a password. The Secure Access Management system guides you through the process of setting up a password (Figure 4).

**Figure 4: SAS Secure Access Management** 



**Note:** The Secure Access Management system provides password rules when you set a password. Your account's password expires after 90 days. Beginning eight days prior to your password's expiration, you receive a daily e-mail reminder to re-set your password.

# 2.2 Installing and Setting Up the Security Token (One-Time Only)

Access to the Research Environment requires a secure connection. To make this secure connection, you must enter your SAS Clinical Trial Data Transparency system user name (or user ID) and password and use a security token to provide a security code. This section outlines the steps necessary to install and set up the security token provided by Verisign. You only need to perform these steps once.

1. Download the VIP Access application by visiting the website link <a href="https://vip.symantec.com/">https://vip.symantec.com/</a>

2. Click **Download for Windows** or **Download for Mac**, when appropriate, and follow the instructions provided (Figure 5).

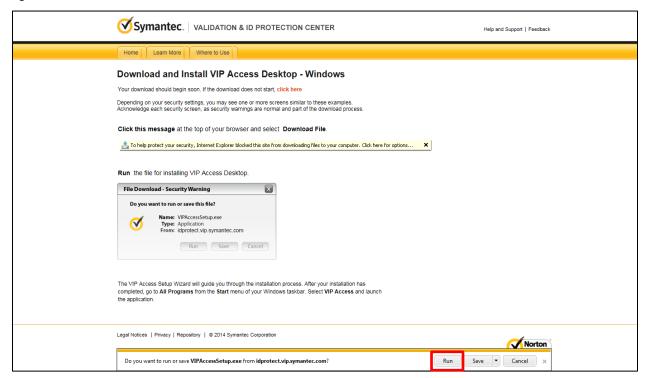
Figure 5: Download VIP Access



**Note:** The following are instructions for Windows users. Mac users follow similar steps, but use Mac DMG application setup files.

3. To initiate the VIP Access application, select Run when prompted (Figure 6).

Figure 6: Download and Install VIP Access



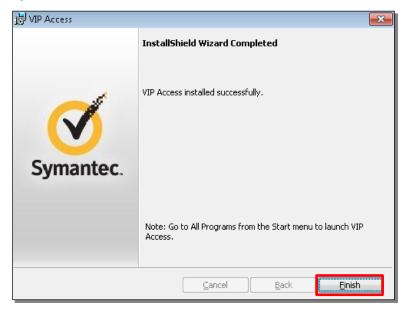
4. The VIP Access Setup Wizard appears (<u>Figure 7</u>). Select **Next** for all screens, accept the terms in the license agreement, as well as all defaults, and select **Install** in the final step of the wizard screens.

Figure 7: VIP Access Setup



5. Upon successful completion, the **InstallShield Wizard Completed** screen appears (<u>Figure 8</u>). Select **Finish** to launch the **VIP Access** application.

Figure 8: VIP Access - Finish Installation



# 2.3 Open VIP Access / How the Token Works

Launch the **VIP Access** application (<u>Figure 9</u>). You must create a *Credential ID* to identify your computer. Using the *Security Code* identifies you as a registered user.

- Credential ID: This ID is machine or device-specific. You need to register this ID. (See <u>2.4 Registering Your Credential ID.</u>)
- **Security Code**: Use this code to log on to the computer that hosts the Research Environment through a secure portal or connection.
  - The code changes every 30 seconds, with a countdown clock next to the Security Code that shows the time remaining before the code is changed.
  - shows the time remaining before the code is changed.

    Selecting the **copy** button next to the code copies the Security Code to the clipboard. This enables you to easily paste it into the required field when logging on to the Research Environment.

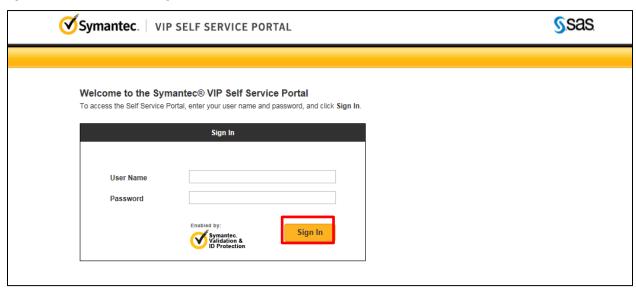
Figure 9: VIP Access - Main Screen



# 2.4 Registering Your Credential ID

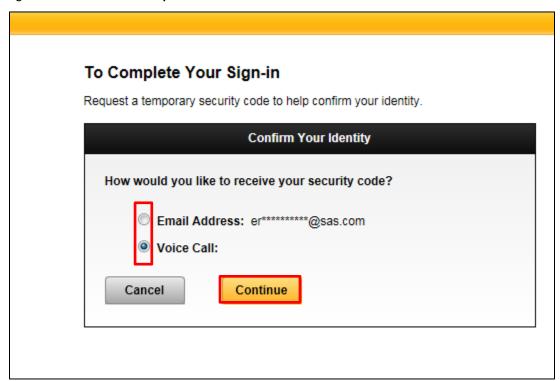
- 1. Go to <a href="https://vip.sas.com/vipssp/">https://vip.sas.com/vipssp/</a>.
- 2. The Welcome to the Symantec® VIP Self Service Portal appears (<u>Figure 10</u>). Enter your SAS Clinical Trial Data Transparency system **User Name** (or **User ID**) and **Password** from section <u>2.1 Completing the Initial Email and Password Setup</u> and click **Sign In**.

Figure 10: Self Service Portal - Sign In



3. The **Confirm Your Identity** screen appears, prompting you for a location to send a temporary security code (Figure 11). Choose an option and click **Continue**.

Figure 11: Confirm Your Identity



4. Select **Email Address** (recommended). An e-mail containing a temporary VIP security code (<u>Figure 12</u>) is sent to the e-mail address you provided previously in the VIP setup process.

**Note:** If you have any questions or need further assistance, contact the SAS Technical Support as follows:

o Email: CTDTsupport@sas.com

o URL: http://support.sas.com/ctx/supportform/index.jspa

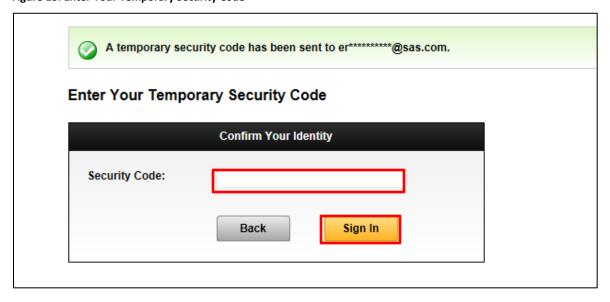
o North America: Call 919-677-8008

Figure 12: Temporary VIP Security Code



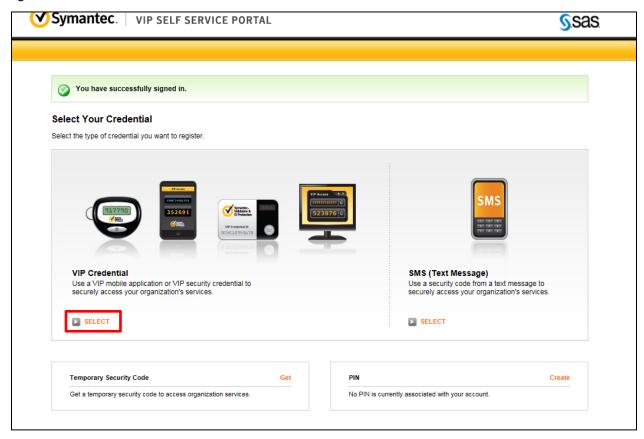
5. The **Enter your Temporary Security Code** screen appears (<u>Figure 13</u>). Enter your temporary VIP **Security Code** and select **Sign In**.

Figure 13: Enter Your Temporary Security Code



6. The **Welcome to VIP Self Service** screen appears (<u>Figure 14</u>) where you can register your **Credential ID** for use. Click **Select** in the **VIP Credential** section.

Figure 14: VIP Welcome Screen



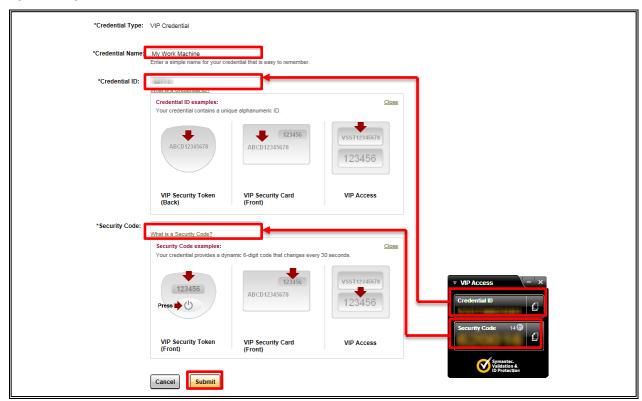
- 7. Register your credentials (Figure 15):
  - Enter a Credential Name (for example, My Work Machine).
  - Copy the current Credential ID number from the VIP Access window and paste it into the Credential ID field.

**Note:** If you install the VIP Access application on a smart phone, and the smart phone is upgraded, your smart phone may change this credential ID. You need to log on to https://vip.sas.com/vipssp/ and change the Credential ID to the new one.

- Copy the current Security Code number from the VIP Access window and paste it into the Security Code field.
- Click Submit.

**Note:** Ensure that enough time remains in the Security Code countdown before you paste the code. If a new Security Code is generated before you attempt to proceed to the next step, you must enter the new Security Code (Figure 15).

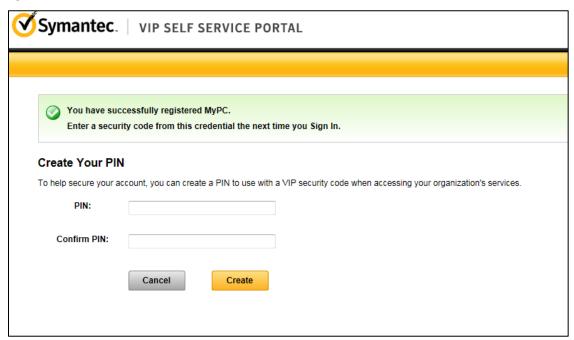
Figure 15: Register Your Credential



8. The **Create Your PIN** screen appears (<u>Figure 16</u>). Enter and re-enter a PIN that is 6 to 12 numbers and click **Create**.

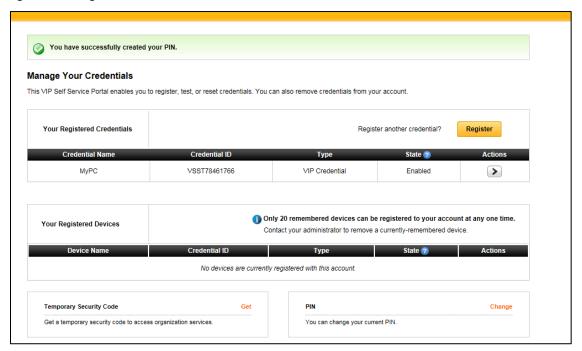
**Note:** This PIN is not your security code number. Use it to change any details associated with your registered security code.

Figure 16: Create Your PIN



9. When the PIN setup is successfully completed, the Credential Name you entered for your machine appears, along with your Credential ID (Figure 17).

Figure 17: Manage Your Credentials

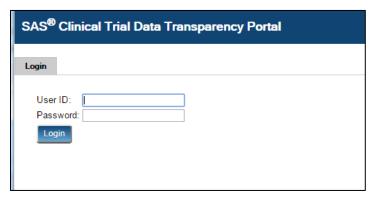


## 2.5 Accepting Terms in the Portal

Before you can access files and study data in the Research Environment, you must first accept the Terms of Use Agreement at the SAS Clinical Trial Data Transparency Portal.

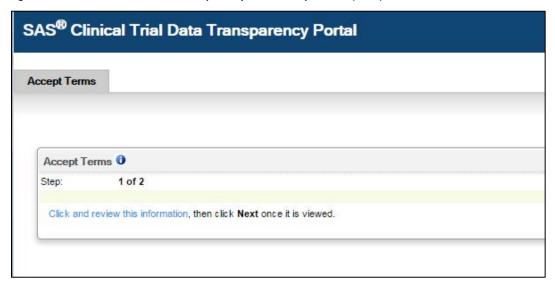
- 1. Access the SAS Clinical Trial Data Transparency Portal at https://mseportal.ondemand.sas.com/ctdt/
- 2. On the logon screen, enter your SAS Clinical Trial Data Transparency system **User ID** (or user name) and **Password** (Figure 18).

Figure 18: SAS® Clinical Trial Data Transparency Portal Logon



After logon is complete, Accept Terms is the only option that displays (<u>Figure 19</u>). Select the **Click**and review this information link.

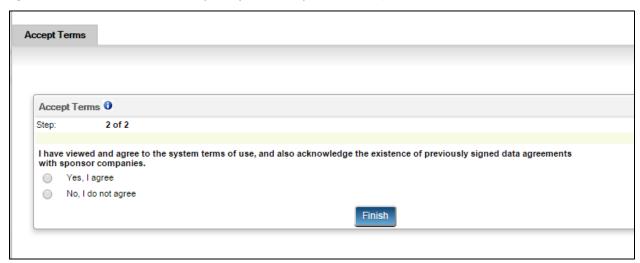
Figure 19: SAS® Clinical Trial Data Transparency Portal Accept Terms (Start)



- 4. A PDF of terms appears. Review the text of the PDF.
- 5. Once the review is complete, select the **Next** button.

6. A statement appears enabling you to accept the terms (<u>Figure 20</u>). Select the **Yes, I agree** radio button and then click the **Finish** button.

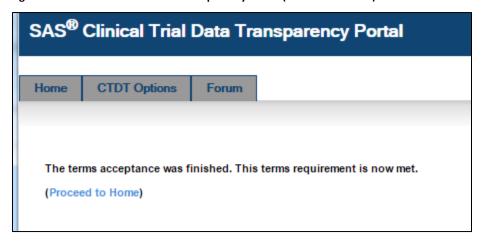
Figure 20: SAS® Clinical Trial Data Transparency Portal Accept Terms (Finish)



7. Once the statement is accepted, a confirmation appears (<u>Figure 21</u>). Click the **Proceed to Home** link to open the Home tab.

**Note:** A copy of the terms accepted is available on your research access request for reference.

Figure 21: SAS® Clinical Trial Data Transparency Portal (Proceed to Home)



# 3 Accessing the Research Environment

**Note:** If you have not accepted the terms at the SAS Clinical Trial Data Transparency Portal, you must follow those steps first. See section <u>2.5 Accepting Terms in the Portal</u>.

Accessing the Research Environment involves two steps:

- Connect to the SAS Solutions OnDemand Secure Portal using your user name (or user ID), password, and security code.
- Log on to a remote terminal server session. (This is the computer that hosts the Research Environment.)

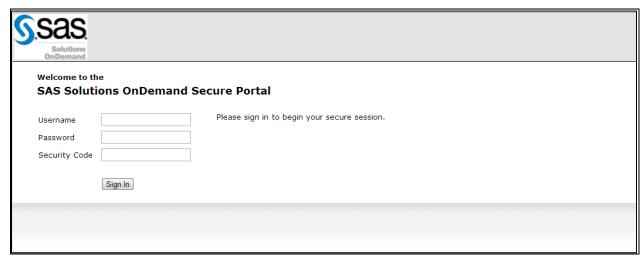
**Note:** The Research Environment is not accessible from tablet computers (for example, an iPad) or other devices.

#### 3.1 Windows Users

### 3.1.1 Connecting to the Secure Access Portal

1. Visit the website: https://shqaccess.ondemand.sas.com and access the welcome screen (Figure 22).

Figure 22: Secure Access Portal - Logon Screen



- 2. For **Username**, enter your SAS Clinical Trial Data Transparency system user name (or user ID).
- 3. For **Password**, enter your SAS Clinical Trial Data Transparency system password.
- 4. For Security Code:
  - a. Open your **VIP Access** application.
  - b. Copy the **Security Code** by using the copy icon



c. Paste the Security Code into the field.

**Note:** The VIP Access application provides a 30-second countdown to copy the **Security Code**. Make sure you have at least 15 seconds left in the countdown before copying the VIP **Security Code** (Figure 23).

Figure 23: Copy Security Code



- 5. Click Sign In.
- 6. The Welcome to the SAS Solutions OnDemand Secure Portal page appears. Click the Clinical Trial Data Transparency Research Environment link listed under Terminal Sessions (Figure 24).

**Note:** If your account has rights to the Test/UAT system, you might see multiple choices on the landing page.

Figure 24: Secure Access Portal – Welcome Screen



#### 3.1.1.1 Installing or Updating Java for Windows

If Java is not installed on your computer or your Java version is old, a dialog appears (Figure 25).

1. Click Update.

Figure 25: Java Update Needed



2. A web site launches in a separate tab or window of your internet browser (Figure 26). Click **Free Java Download**.

Figure 26: Download Java



3. The screen changes (Figure 27). Click Agree and Start Free Download.

Figure 27: Start Java Download



4. The Java installer appears (Figure 28). Click Install.

Figure 28: Installing Java - Screen 1



5. Uncheck the boxes (Figure 29). Click Next.

Figure 29: Installing Java - Screen 2



6. If certain programs are running, a dialog appears asking you to close them before continuing (Figure 30). Save your work and click Close Programs and Continue. If a confirmation dialog appears, click OK.

Figure 30: Installing Java - Close Programs and Continue



7. The installer begins installing Java (Figure 31).

Figure 31: Installing Java - Screen 3



8. When the installer is finished, click Close (Figure 32).

Figure 32: Installing Java - Screen 4



#### 3.1.1.2 Launching Terminal Server Session

A terminal server session launches.

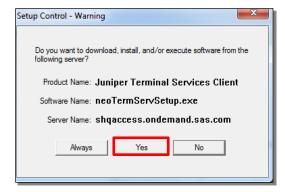
- 1. If the Java(TM) needs your permission to run message appears, click Always run on this site (Figure 33).
- 2. The Welcome to the SAS Solutions OnDemand Secure Portal page appears again. Click the Clinical Trial Data Transparency Research Environment link listed under Terminal Sessions (Figure 24).

Figure 33: Launching Terminal Session



**Note:** You might be required to accept the installation of **Juniper Terminal Services Client**, as part of accessing the Research Environment (<u>Figure 34</u>). Click **Yes**.

Figure 34: Install Juniper Terminal Services Client



### 3.1.2 Logging on to the Research Environment (Terminal Session)

The log on screen for the computer that hosts the Research Environment (terminal server) appears (Figure 35 or Figure 36 depending on Windows 7 version or Windows 10 version).

1. Select the icon with your User ID.

Figure 35: Logging on to the Computer that Hosts the Research Environment from Windows 7 machine

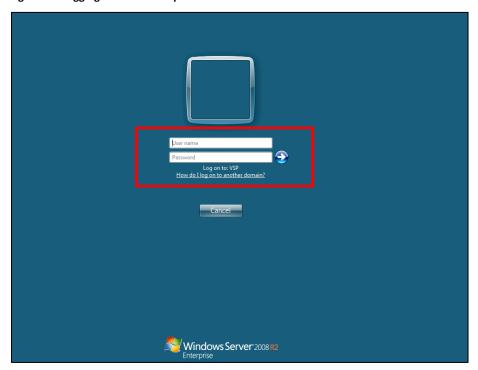
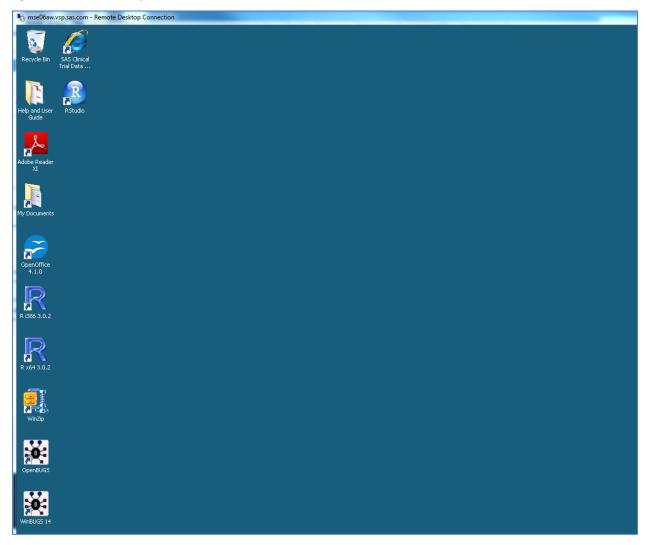


Figure 36: Logging on to the Computer that Hosts the Research Environment from Windows 10 machine



2. Enter your SAS Clinical Trial Data Transparency userid (NOTE: please make sure to first prepend 'vsp\', then endter your userid e.g vsp\mse0xyz) and password, and click the arrow icon. The Research Environment appears (Figure 37).

Figure 37: Remote Desktop Session



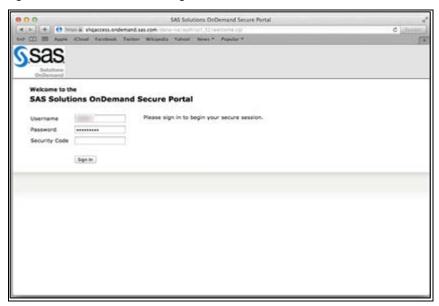
#### 3.2 Mac Users

#### 3.2.1 Connecting to the Secure Access Portal

**Note:** The screens in this section show the use of Safari on a Mac. The screens for other browsers can vary.

1. Visit the website: <a href="https://shqaccess.ondemand.sas.com">https://shqaccess.ondemand.sas.com</a>. The sign-in screen appears (Figure 38).

Figure 38: Secure Access Portal - Sign-in Screen



- 2. For **Username**, enter your SAS Clinical Trial Data Transparency system **Username** (or User ID).
- 3. For Password, enter your SAS Clinical Trial Data Transparency system Password.
- 4. For Security Code:
  - Open your VIP Access application.
  - Copy the Security Code by using the copy icon
  - Paste the Security Code into the field.
  - Click Sign In.

**Note:** The VIP Access application provides a 30-second countdown to copy the **Security Code**. Make sure you have at least 15 seconds left in the countdown before copying the VIP **Security Code**.

5. The Welcome to the SAS Solutions OnDemand Secure Portal page appears. Select the Clinical Trial Data Transparency Research Environment link listed under Terminal Sessions (Figure 39).

Figure 39: Secure Access Portal - Welcome Screen



6.

If	Then
A <b>Remote Office</b> dialog appears ( <u>Figure</u> <u>41</u> ).	Proceed to step 7.
A Remote Office dialog is not displayed and you see a message about pop-ups being blocked (Figure 40).	<ul> <li>Use Safari Preferences to allow pop-ups.</li> <li>Once complete, return to the Welcome Screen (Figure 39) and click the Clinical Trial Data Transparency Research Environment link again.</li> </ul>

Figure 40: Mac - Popup Blockers

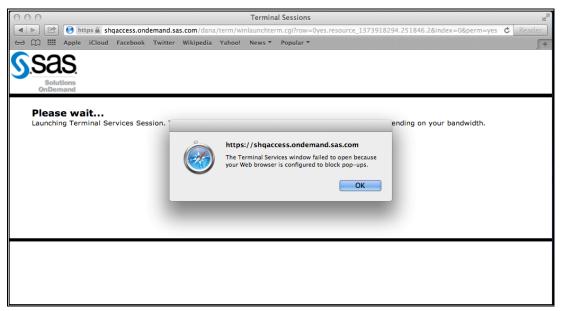


Figure 41: Mac – Remote Office Dialog



7.

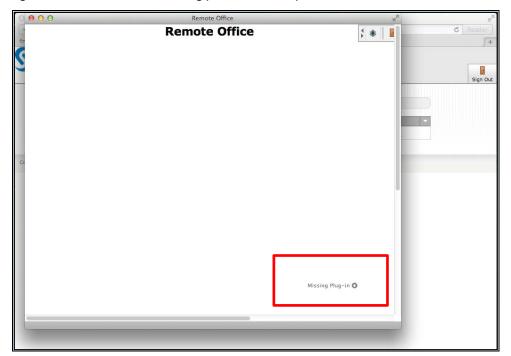
If	Then
You see <b>Missing Plug-in</b> or <b>Inactive Plug-in</b> in the lower-right corner of the screen (Figure 41)	Install Java. (See section <u>3.2.1.1 Java Installation</u> <u>on Mac</u> .)
You see <b>Active Plug-in</b> .	Log on to the Research Environment (See section 3.2.2 Logging into the Research Environment (Terminal Session)).

#### 3.2.1.1 Java Installation on Mac

This section is only applicable if the Remote Office dialog indicates a Java plug-in is not available (<u>Figure 42</u>).

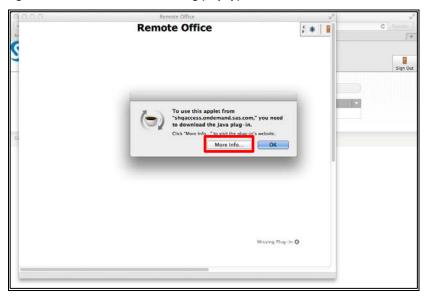
1. From the dialog, click the link in the lower right corner of the dialog (Missing Plug-in or Inactive Plugin).

Figure 42: Mac – Remote Office Dialog (Java not installed)



2. A dialog appears, as shown in Figure 43. Click More info.

Figure 43: Mac - Remote Office Dialog (Popup)



3. A website launches in a separate tab or window of Safari (Figure 44). Click Agree and Start Free Download.

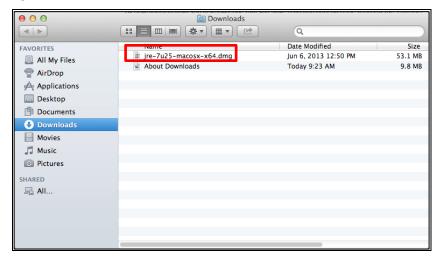
**Note:** Depending on your Mac Operating System (OS), you might see a different page, and the version of Java might be a later version.

Figure 44: Mac - Install Java Website



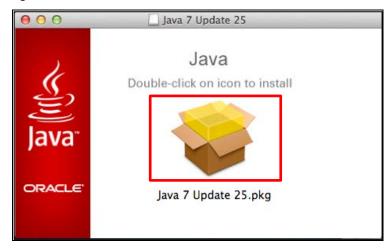
4. A Mac DMG install file is downloaded to your machine. Find and open the DMG file. <u>Figure 45</u> shows an example, **jre-7u25-macosx-x64.dmg.** 

Figure 45: Mac - JRE DMG File



5. When you open the DMG file, a dialog similar to the one below appears (<u>Figure 46</u>). Double-click the icon to start the installation.

Figure 46: Mac - JRE DMG File



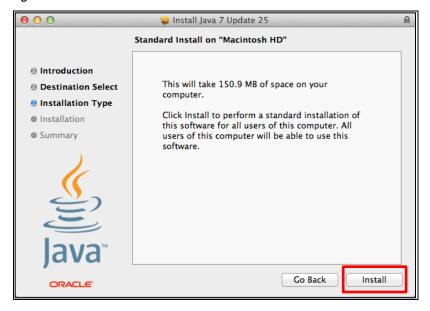
6. The installation screens might differ depending on your OS and the Java version being installed. Click **Continue** (Figure 47).

Figure 47: Mac - Java Install - Screen 1



7. Click Install (Figure 48).

Figure 48: Mac - Java Install - Screen 2



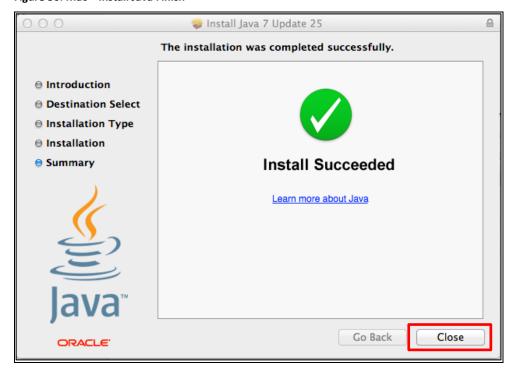
8. You are prompted to enter for your machine's administrator account (<u>Figure 49</u>). Enter this information and click **Install Software**.

Figure 49: Mac - Install Admin Screen



9. Figure 50 shows the final screen of the installation process. Click **Close**.

Figure 50: Mac - Install Java Finish



#### 3.2.1.2 Launching Terminal Server Session

- 1. Close all dialogs and browser tabs or windows.
- 2. Repeat the steps for signing in as described in section <u>3.1.2 Logging on to the Research Environment</u> (<u>Terminal Session</u>), which includes:
  - Log on to https://shqaccess.ondemand.sas.com with User ID, Password, and Security Code.
  - After logging in, select the **Clinical Trial Data Transparency Research Environment** link on the welcome screen.
  - The Remote Office dialog appears. Continue to section <u>3.2.2 Logging into the Research</u> Environment (Terminal Session).

### 3.2.2 Logging into the Research Environment (Terminal Session)

1. When the Remote Office dialog appears, an additional message is also displayed (Figure 51). Click **Allow**.

**Note:** If you do not have Java installed on your Mac, you need to download it to proceed further (see 3.2.1.1 Java Installation on Mac).

Figure 51: Mac - Accept Applet Dialog



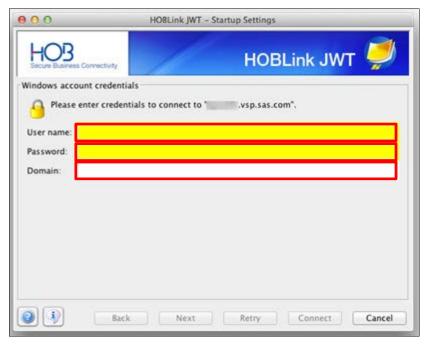
2. An additional security warning appears. Check the box I accept...application and click Run (Figure 52).

Figure 52: Mac - Allow HOBLink Dialog



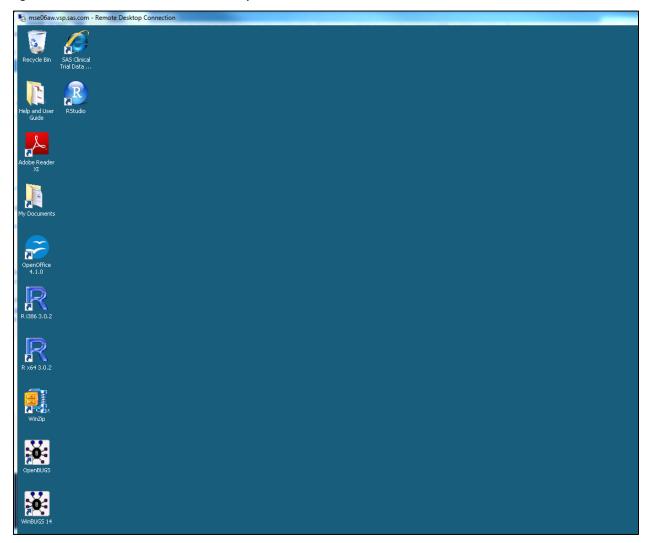
- 3. A HOBLink JWT dialog appears (Figure 53).
  - For Username, enter your SAS Clinical Trial Data Transparency system Username (or User ID).
  - For Password, enter your SAS Clinical Trial Data Transparency system Password.
  - For Domain, enter VSP.

Figure 53: Mac - HOBLink JWT Logon



4. The Research Environment appears (Figure 54).

Figure 54: Mac - Research Environment Desktop

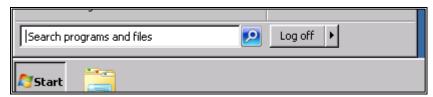


# 3.3 Logging off

To log off the Research Environment, navigate to **Start Menu** -> **Log off** (Figure 55).

**Note:** If you close the session window without logging off, you can return to the session in the same state as you left it. However, sessions do expire after a specified time period; therefore, you should always save your work and log off.

Figure 55: Logging off the Research Environment



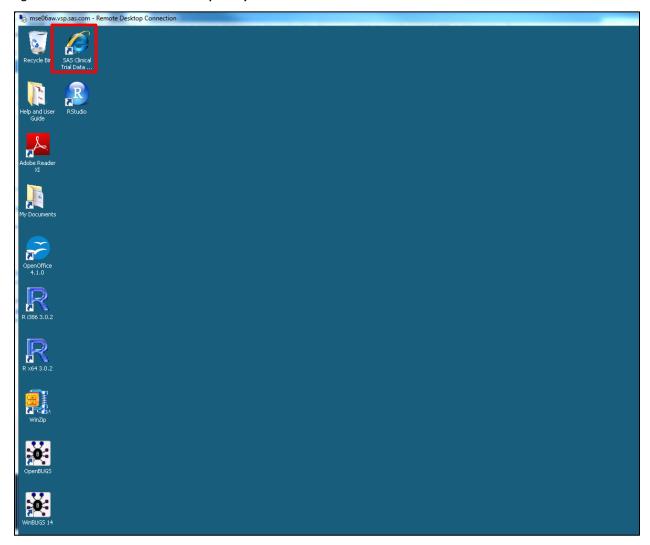
# 4 SAS® Clinical Trial Data Transparency Repository

The SAS Clinical Trial Data Transparency Repository provides access to the data for your project, whether you plan to perform your analyses with SAS software or with R.

## 4.1 Logging on

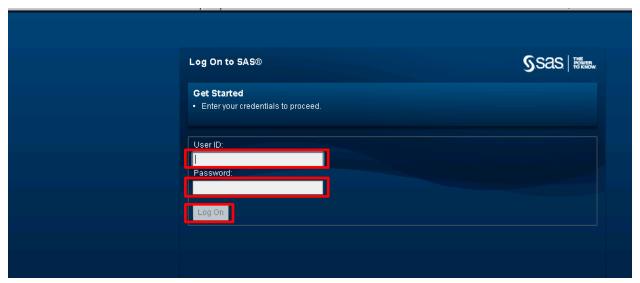
1. In the Research Environment, double-click the SAS Clinical Trial Data Transparency Repository icon (Figure 56).

Figure 56: SAS® Clinical Trial Data Transparency Icon



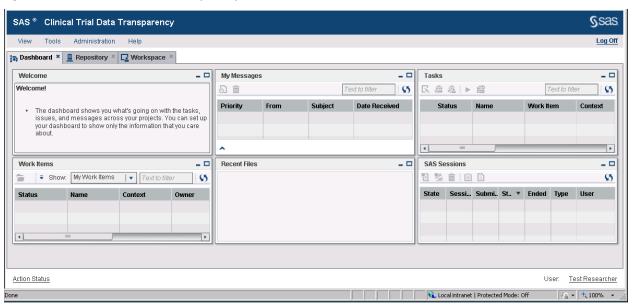
Internet Explorer opens and the SAS Clinical Trial Data Transparency Logon screen appears (Figure 57). Enter your SAS Clinical Trial Data Transparency system Username (or User ID) and Password. Click Log On.

Figure 57: SAS® Clinical Trial Data Transparency Logon Screen



3. The SAS Clinical Trial Data Transparency main screen appears (Figure 58).

Figure 58: SAS® Clinical Trial Data Transparency Main Screen



## 4.2 Organizing Tabs

SAS Clinical Trial Data Transparency uses a tab-based interface. The tabs include:

- **Dashboard**: This summarizes parts of the system. (Navigate to **View** -> **Preferences** to order this as the last tab as described below.)
- **Repository**: This is the location of the study data for your research and the location of your research project area where you save your work and make files available for export.
- Workspace: This is where you run SAS code on the study data.

When you log on for the first time, the **Dashboard** view is automatically displayed (Figure 59).

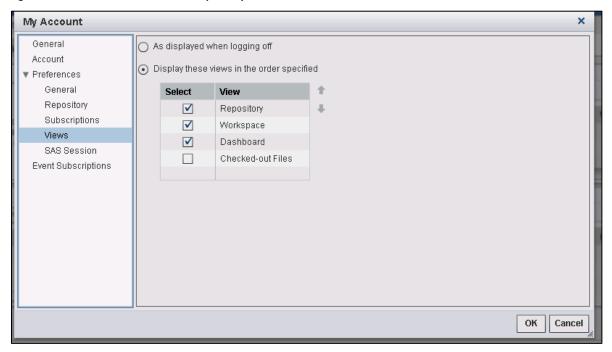
Figure 59: SAS® Clinical Trial Data Transparency Tabs



Because the **Dashboard** tab is not heavily used for the solution, you can move it to the third position. To change the order of the **View** of tabs, you can drag and drop them into a new order, or:

- 1. Navigate to View -> Preferences -> Views.
- 2. Move the **Dashboard** tab to third position (<u>Figure 60</u>).

Figure 60: SAS® Clinical Trial Data Transparency - Preferences -> Views



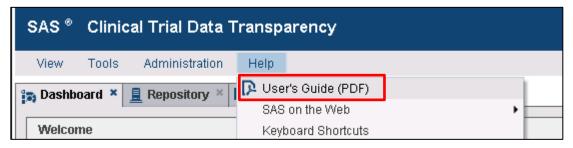
3. Click **OK**. The first two tabs are now **Repository** (your data access) and **Workspace**. The next time you log on, the **Repository** tab appears automatically.

## 4.3 Accessing the SAS® Clinical Trial Data Transparency Repository User Guide

The **Help** menu (<u>Figure 61</u>) provides a link to the comprehensive *SAS Clinical Trial Data Transparency User Guide*. This is also available from the SAS Clinical Trial Data Transparency Portal Help page, and from the desktop of the Research Environment.

**Note:** Not all functionality described in this guide applies to SAS Clinical Trial Data Transparency.

Figure 61: SAS® Clinical Trial Data Transparency - Help Tab



**Note:** The SAS on the Web link does not work from the Research Environment because the research server provides very limited internet access.

The following sections provide examples of approaches to using SAS Clinical Trial Data Transparency Repository for browsing data and programming in SAS. <u>Table 1</u> references relevant sections within this document and the corresponding sections within the full *SAS Clinical Trial Data Transparency Repository User Guide*.

Table 1: Guide Sections Related to the full SAS® Clinical Trial Data Transparency Repository User Guide

Section in this Guide	SAS Clinical Trial Data Transparency Repository User Guide Section(s)
4.4 Data Access	Chapter 2: Getting Started
4.5 Browsing Data	Chapter 2: The Data Explorer
4.6 Copying Files from the Repository to the Workspace	Chapter 2: Repository and Your Workspace
4.7 Running SAS	Chapter 19: SAS Sessions
	Chapter 20: Developing SAS Programs
4.8 Producing Graphical Results	Chapter 20: Developing SAS Programs

#### 4.4 Data Access

In the **Repository** view (<u>Figure 62</u>), the **CTDT** folder contains your research project area and studies you can access:

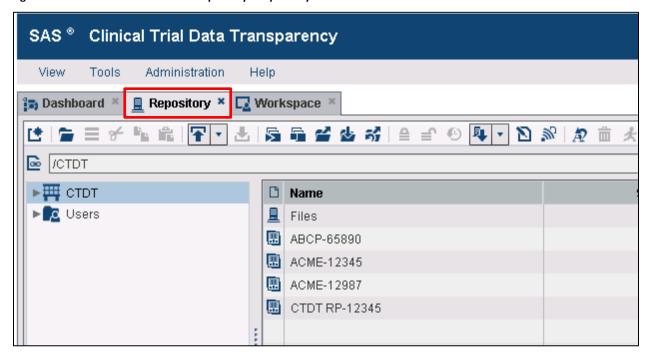
#### • Research Project

- If you are assigned Lead Researcher or Researcher permissions on the project, you can add, modify, and delete files.
- If you plan to run SAS, copy files from this area to the Workspace tab to run SAS programs and view results. (See section 4.6 Copying Files from the Repository to the Workspace.)
- To export files from the Research Environment, you must add them to the **exports** folder of your research project.

#### Studies

- These are the clinical studies available for use, according to your Data Sharing Agreement.
- You have read-only permissions. You cannot add, modify, or delete files or folders from a study.
- If you plan to run SAS, copy files from here to the Workspace tab for inclusion into SAS programs
  you write within your research area. (See section 4.6 Copying Files from the Repository to the
  Workspace.)
- If you plan to run R, download R-ready CSV files from the study to a folder (in **My Documents**) in the Research Environment (outside SAS Clinical Trial Data Transparency).

Figure 62: SAS® Clinical Trial Data Transparency - Repository Tab

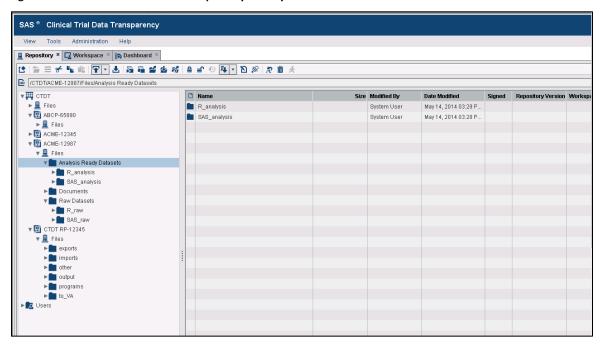


**Note:** To expand the folders, click the **Expand** icon.

Under a study, a number of folders (Figure 63) are available with information on that study, for example:

- SAS\_analysis and SAS\_raw folders contain study data in SAS format.
- R\_analysis and R\_raw folders contain study data in R-ready format (comma delimited). There is also
  an additional file for each CSV file that includes metadata describing the columns from the source
  SAS data set.
- Other folders contain supporting information to help you understand and navigate the data sets.
   Figure 63 shows an example of a folder structure.

Figure 63: SAS® Clinical Trial Data Transparency - Study Folders

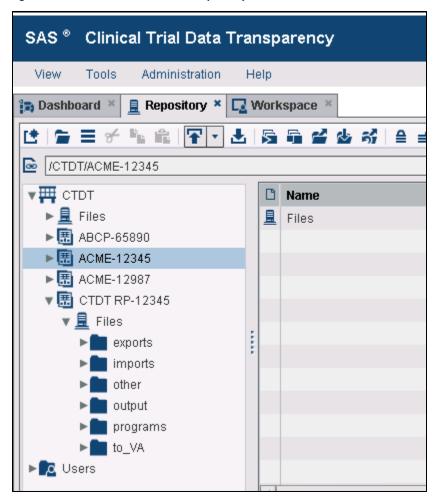


<u>Figure 64</u> shows three sample studies (**ACME-12345**, **ABCP-65890**, and **ACME-12987**), as well as an expanded view of an example research project area (**CTDT RP-12345**). Users assigned the **Researcher** or **Lead Researcher** role have full permissions to create, modify, and delete folders and files within the research project area.

**Note:** The folder structure pictured below might be different from your research project area.

**Note:** Do not change the folder names *imports* or *exports*. If you change these names, you can no longer import files into or export files from the SAS Clinical Trial Data Transparency Repository.

Figure 64: SAS® Clinical Trial Data Transparency – Research Area Folders



SAS programs are typically stored in the **programs** (or similarly named) folder.

- The **imports** folder is important. To bring files and supporting programs into the Research Environment, you must import them to this location. See section <u>6 Importing and Exporting</u> for details on importing.
- The **exports** folder is also important. To download files from the Research Environment, you must collect them here. See section <u>6 Importing and Exporting</u> for details on exporting.

## 4.5 Browsing Data

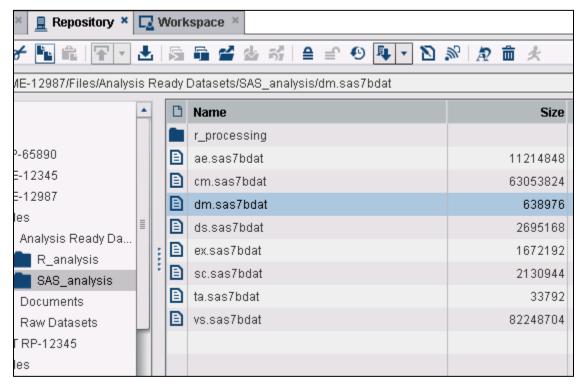
As part of your research, you might want to browse and filter data even if you intend to use R for your statistical programming. The SAS Clinical Trial Data Transparency Explorer can be used for this purpose.

**Note:** For full details, refer to *Chapter 2: Getting Started -> Data Explorer* within the SAS Clinical Trial Data Transparency Repository User Guide.

An abbreviated example is described below:

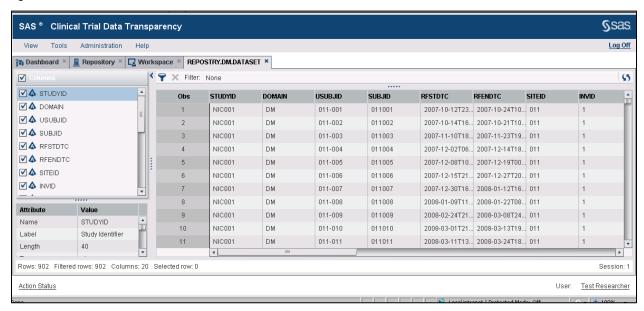
1. From within a folder, double-click the desired SAS data set (Figure 65).

Figure 65: Opening a SAS Data Set



- 2. A view of the data set appears (Figure 66). Review the data set:
  - The columns of the data set appear on the left-hand side.
  - Below the columns pane, attributes display for the currently selected column.
  - The rest of the view displays the data contained within the data set.

Figure 66: Data Set



3. To sort, click a column heading. Figure 67 shows the filter **SUBJID** sorted in ascending order.

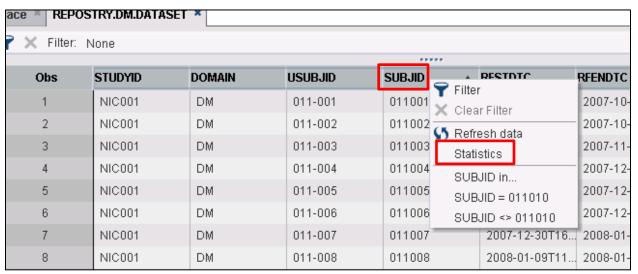
Figure 67: Sorting Columns



4. For more filtering options, right-click the column (Figure 68).

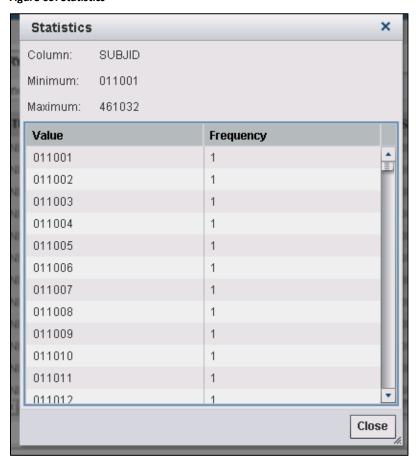
**Note:** Different options may be displayed for different columns.

Figure 68: Filtering Options



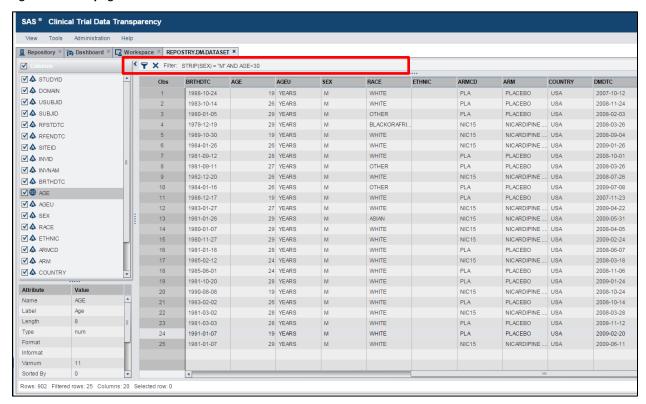
a. Select **Statistics** for a quick view of statistics that describe the currently selected column within the currently filtered view (Figure 69).

Figure 69: Statistics



- b. Select Filter to customize the filter. Figure 70 shows a filter for AGE <35 AND Sex=M.
  - The filter syntax appears above the data.
  - o The total number of rows and number of filtered rows appears below the data.
  - To modify the current filter, select the Filter icon.

Figure 70: Modifying Current Filter



# 4.6 Copying Files from the Repository to the Workspace

The SAS Clinical Trial Data Transparency application consists of two primary locations for files (tabs) (Figure 71):

- **Repository**: This is where master copies of files and programs are stored.
- Workspace: This is where you store working copies of files, programs, and results.

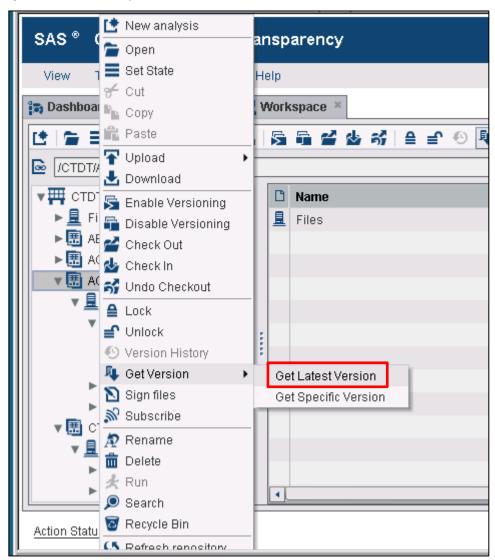
**Note:** Files and SAS data sets must be present in the Workspace to enable programs to read them.

Figure 71: Repository and Workspace Tabs



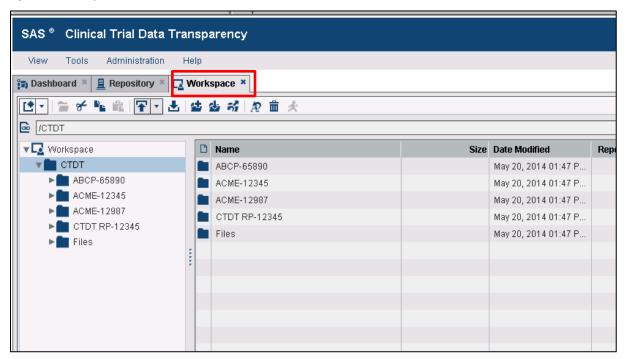
1. To copy files from the repository to your workspace, locate the folder(s) in the repository tree, right-click on it (them), and select **Get Latest Version** (Figure 72).

Figure 72: Get Latest or Specific Version



2. The folders and files are copied to your personal workspace. Navigate to the **Workspace** tab (<u>Figure 73</u>).

Figure 73: Workspace Tab



- 3. Within Workspace, you can:
  - a. Create new files.
  - b. Save SAS programs.
  - c. Review results.
  - d. Check in (add) files to your research project area in the Repository when you complete your work.
  - e. Copy files to the **exports** folder for your research project, for removal from the application. For details on exports, see section <u>6.2 Exports</u>.

# 4.7 Running SAS

This section provides information to enable you to run SAS within the SAS Clinical Trial Data Transparency Repository. SAS programs are run within a SAS Session.

Use one of the following methods to open a SAS Session:

- From the Menu Bar, click Tools -> SAS Session to open a SAS session with an empty Editor window.
   -Or
- Right-click and select **Open**, or double-click on an existing SAS program in the **Workspace** tab.

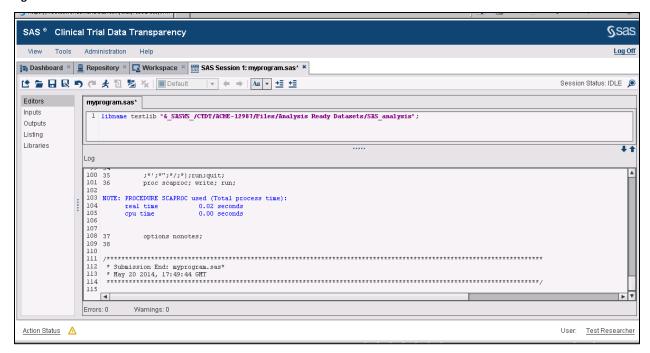
**Note:** SAS is not executed from the **Repository** tab.

Write a new SAS program in an empty Editor window, or modify an existing SAS program that you opened. Click the **Submit** icon on the tool bar to7 run the program in the active Editor window and review the log within the Log window. A section of code can be run by highlighting it first and clicking the **Submit** icon.

Important Workspace Concept: If you have not already done so, copy the files needed in your program from the Repository to the Workspace. (See section 4.6 Copying Files from the Repository to the Workspace.) These files must be referenced in your program by prepending all paths with the special SAS macro variable &\_SASWS\_ (Figure 74). This provides SAS with the physical location of your personal Workspace.

**Tip:** To ensure the correct path, click the **Workspace** tab and navigate to the file needed in your program. Highlight the full path displayed just under the tool bar, and then copy and paste it into your program. Insert the special macro variable &\_SASWS\_ in front of the path.

Figure 74: SAS Session Tab



SAS sessions support multiple Editor windows. This enables you to have more than one program open at a time. Use one of the following techniques to open additional Editor windows in your SAS Session:

- Click the Open icon on the tool bar to open an existing SAS program from the Workspace.
- Click the **New** icon on the tool bar to open an empty Editor window.
- Create an empty new program in the Workspace and then open it in a SAS Session.
  - From the Workspace tab, navigate to the folder in which you want to create a new program.
  - Click the New icon.
  - Select SAS Program from the folder where you want the program to be saved (Figure 75).
  - Open the new empty program in a SAS session.

Figure 75: New -> SAS Program



The additional items in the left-hand pane of the SAS Session window provide the following functionality:

- Inputs
- Outputs
- Listing: Displays output produced by your program.
- Libraries: Lists all libraries defined in your SAS Session. You can navigate them to open and view SAS data sets available to your program.

Once you have your program running to your satisfaction, save it by following these steps:

- 1. Click the Save or Save As icon on the tool bar
- 2. Navigate to the location in your Workspace where you want to save your program.
- 3. Supply a name for your program.
- 4. Click Save.

Note: If you eventually plan to check your program into your research area in the Repository, save the program to a corresponding directory in your Workspace. For example, perform a <code>GetVersion</code> on the **programs** directory of your research area. This places the necessary folder structure in your Workspace. Then, save your program to the **programs** directory in your Workspace. It is now in the correct location for use with the **Check In** feature. (See the SAS Clinical Trial Data Transparency Repository User Guide for more details.) The log and listing windows can be saved in the same manner.

**Note:** Refer to the *Chapter 20* of the *SAS Clinical Trial Data Transparency Repository User Guide* for more details.

## 4.8 Producing Graphical Results

Using SAS Output Delivery System (ODS), you can produce graphical results.

**Note:** Refer to *Chapter 20* of the *SAS Clinical Trial Data Transparency Repository User Guide* for SAS programming details.

Using the same sample program, <u>Figure 76</u> shows an example of sending your results to both the **Listing** tab of the **SAS Session** and to a PDF file.

Figure 76: Sending Results to Other Locations

```
ods PDF file="&_SASWS_/CTDT/CTDT RP-12345/Files/output"

proc means data=testlib.AE|;
run;
ods PDF close;
```

The SAS Output Delivery System (ODS) provides instructions to SAS for producing a variety of different formats of output, such as PDF, RTF, and HTML. In this example, all output produced by steps up to the ods PDF close; statement are sent to a PDF file (Figure 77).

**Note:** For more details, access the SAS® 9.3 Output Delivery System: User's Guide, Second Edition, from Support.SAS.com.

Figure 77: PDF Output

The MEANS Procedure								
Variable	Label	N	Mean	Std Dev	Minimum	Maximum		
AEENDT	End date	1739	18649.48	121.4552587	18444.00	19158.00		
AEENTM	End time	0						
AELLTCD	MedDRA lower level term code	2423	10029998.78	19062.98	10000081.00	10072131.00		
AESEO	Sequence number	2423	9541.33	2089.11	101.0000000	10029.00		
AESTDT	Start date	2423	18622.95	117.8843183	18444.00	18861.00		
AESTTM	Start time	0						
SUBJID	Subject ID	2423	2455.78	273.6774321	2000.00	2958.00		
TRTCD	Randomized treatment code	2409	4.0967206	1.9635871	1.0000000	7.0000000		
ATRTCD	Actual treatment code	2409	4.0967206	1.9635871	1.0000000	7.0000000		
AGE	Age in years	2267	74.2434936	7.8399027	52.0000000	88.0000000		
AEPTCD	MedDRA preferred term dictionary code		10028066.98	17903.94	10000059.00	10072713.00		
AESOCCD	MedDRA system organ class code	2423	10023055.36	8827.21	10005329.00	10047065.00		
AETRT1ST	Time from first dose to start of event	2350	174.4846809	115.4103548	1.0000000	403.0000000		
AETRTST	Time from last dose to start of event	2030	23.4152709	33.5489089	1.0000000	297.0000000		
AEDUR	Duration of event	1739	39.3421507	69.7156704	1.0000000	460.0000000		
ATTYPECD		2423	49.8926950	4.1230105	30.0000000	60.0000000		
AEACTSDY	y any arantara	2409	170.0298879	117.4068936	-14.0000000	403.0000000		
eyetpcd	Study eye code	761	1.3534823	0.4783652	1.0000000	2.0000000		

# 5 Using R

## 5.1 Overview

This section provides information on transferring (or downloading) files from the SAS Clinical Trial Data Transparency Repository to your working area on the Research Environment so you can use them in R. It also describes the R packages that are available and how additional R packages can be imported and used.

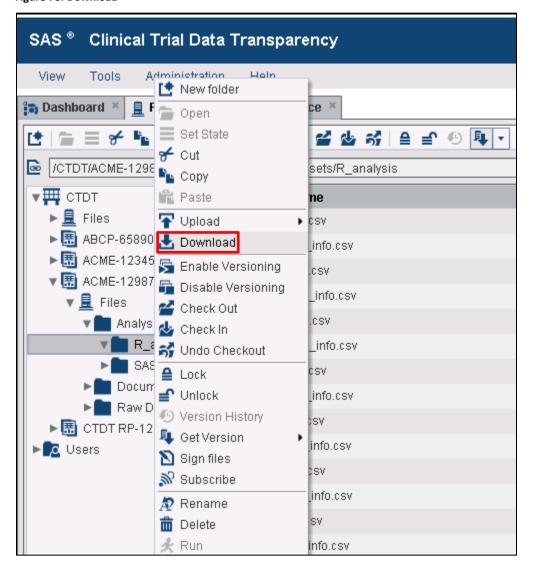
The general concept is:

- Retrieve files from the SAS Clinical Trial Data Transparency Repository and copy them to your My
   Documents folder.
- Run R programs on the relevant files. A number of R packages are provided. (See Figure 81).
- Import and use other R packages by saving them to a folder in your My Documents folder. (See Figure 81).
- Upload files and results back to your SAS Clinical Trial Data Transparency research area.
- Move files to the exports folder in your research area to export them from the Research Environment (see section 5.4 Transferring Results for Export).

## 5.2 Retrieving Files for Use

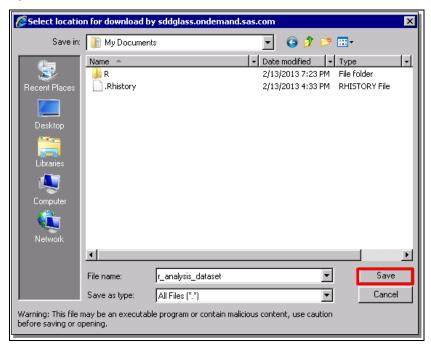
- 1. Once in the Research Environment, use your SAS Clinical Trial Data Transparency system account to access the data in the SAS Clinical Trial Data Transparency Repository (see section 4.1 Logging on).
- 2. Navigate to the R files you wish to use.
- 3. Right-click the folder(s) and select **Download** (Figure 78).

Figure 78: Download



4. Navigate to your **My Documents** folder (in the Research Environment) and select the desired folder within this area (Figure 79).

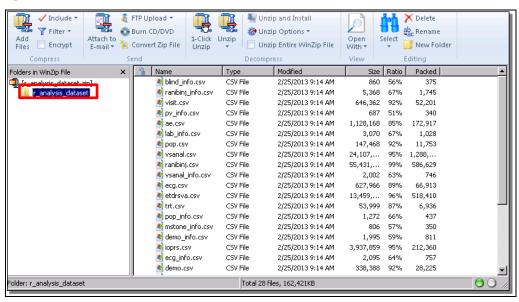
Figure 79: Select Location



5. Select **Save**. The files are now saved to the location specified.

**Note:** If folders (rather than files) are selected in SAS Clinical Trial Data Transparency for download (<u>Figure 80</u>), a ZIP file containing the files from the selected folders is downloaded. Expand the ZIP file to begin using them with R.

Figure 80: Save Location



6. Note the path to these files in order to use them in **R and RStudio**.

# 5.3 Using R and RStudio

#### 5.3.1 Overview

Using R and RStudio in the Research Environment is very similar to using R on your local PC. R (console) 32-bit and 64-bit versions (version 2.15.2) and RStudio 64-bit (version 2.15.2) are provided. Figure 81 shows an example of the package list from R Studio within SAS Clinical Trial Data Transparency.

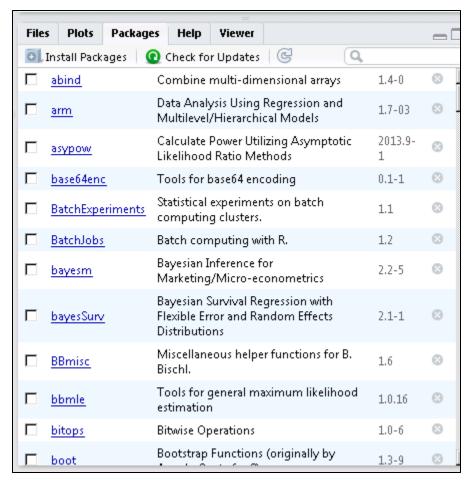
**Note:** Your installation may include later versions of packages and/or additional base packages. Additional R packages can be imported as described in section <u>5.3.2 Importing Additional R Packages</u>. Also, some packages do not run without additional software on the Research Environment server. Contact SAS Technical Support with any software issues as follows:

o Email: CTDTsupport@sas.com

URL: http://support.sas.com/ctx/supportform/index.jsp

o North America: Call 919-677-8008

Figure 81: R Studio List of R Packages



#### 5.3.2 Importing Additional R Packages

Follow the steps below to add R packages that are not provided to the Research Environment.

- 1. In the Research Environment, open **Windows Explorer** and confirm that the **Library** folder exists in your **My Documents** folder. If the folder does not exist, create the folder.
  - The library path can be confirmed using the .libPaths() command in the R console. The paths should include the user's local library directory and the shared system level library as in Figure 82.

#### Figure 82: R LIBPATHS

```
> .libPaths()
[1] "D:/Users/mseOtxr/Documents/library"
[2] "C:/Program Files/R/R-3.0.2/library"
> |
```

- 2. Import R packages to SAS Clinical Trial Data Transparency using the Import function (see <u>6.1</u> Imports).
- 3. Download the package from the SAS Clinical Trial Data Transparency **imports** folder using the following steps:
  - a. Navigate to the **imports** folder in the SAS Clinical Trial Data Transparency Repository and download the appropriate file(s) to a folder in your **My Documents** folder in the Research Environment. (For example, you could name this folder **newpackages**).
  - b. Open **R** from the Research Environment desktop and execute the following command:

```
install.packages("[local file reference]", repos=NULL,
lib=.libPaths()[1])
```

This command installs the package(s) in the referenced ZIP file in the local path.

The following example installs the survival package when the package has been placed in the My Documents/newpackages folder:

```
install.packages("d:/users/user ID/documents/newpackages/survival_2.37-
4.zip", repos=NULL, lib=.libPaths()[1])
```

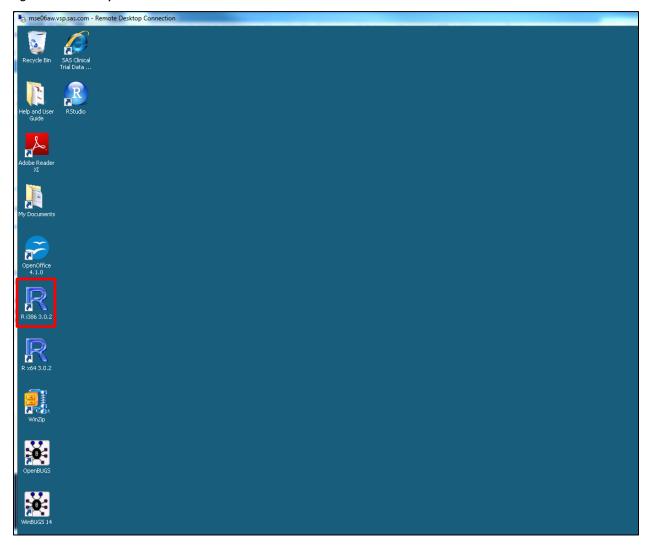
c. The installation of the module can be confirmed by using the commands:

```
installed.packages() and/or require (packagename).
```

## 5.3.3 Accessing R

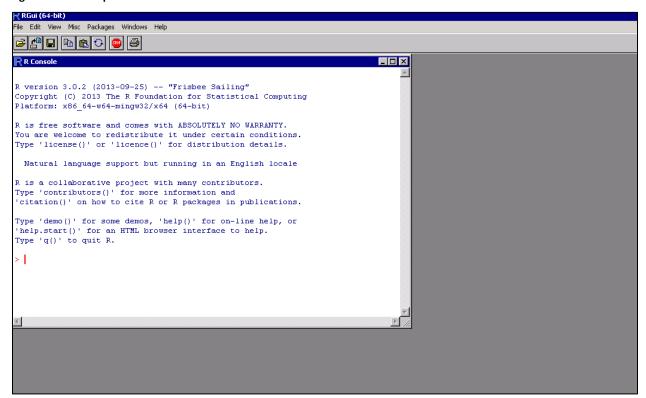
To access R, double-click the R icon on the desktop of the Research Environment (Figure 83).

Figure 83: R Desktop Icon



The R startup screen appears (Figure 84).

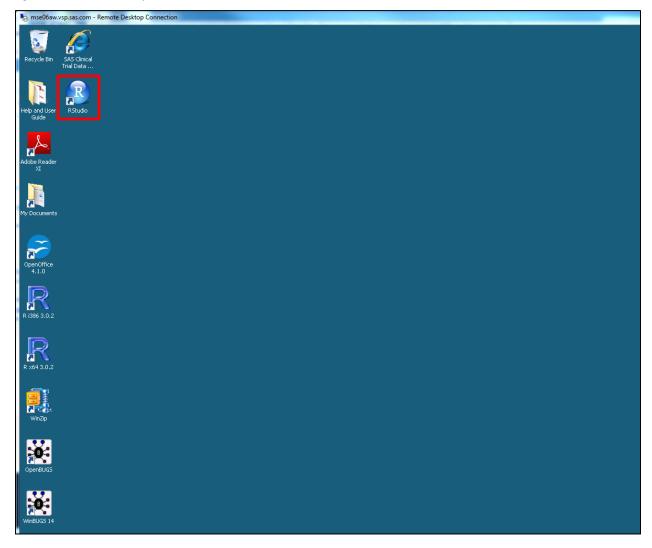
Figure 84: R Startup Screen



## 5.3.4 Accessing RStudio

To access RStudio, double-click the RStudio icon in the Research Environment (Figure 85).

Figure 85: RStudio Desktop Icon



The **RStudio** startup screen appears (Figure 86).

Figure 86: RStudio Startup Screen

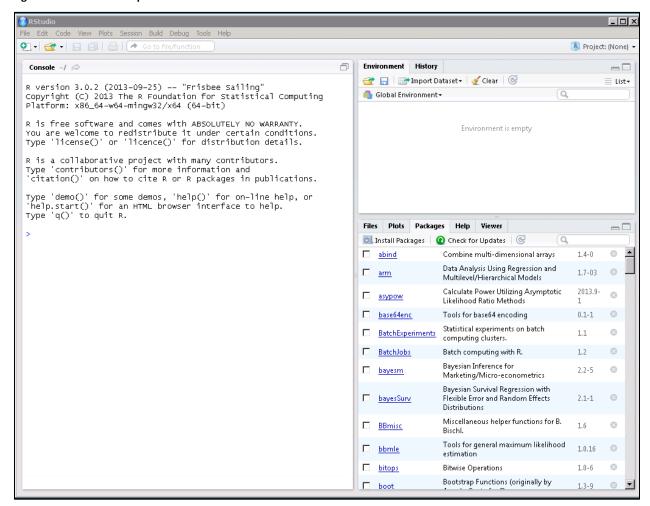


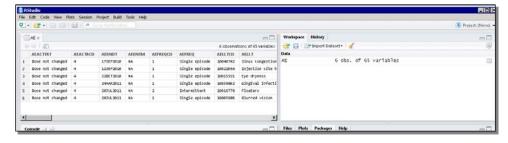
Figure 87 shows an example of reading in a CSV file saved locally:

Figure 87: Locally Saved CSV File

```
> AE <- read.table("C:/Users/____/Documents/r_analysis_dataset/ae_small.csv", sep=",", header=TRUE)
```

This opens the **RStudio** view with browsing ability (Figure 88).

Figure 88: RStudio View

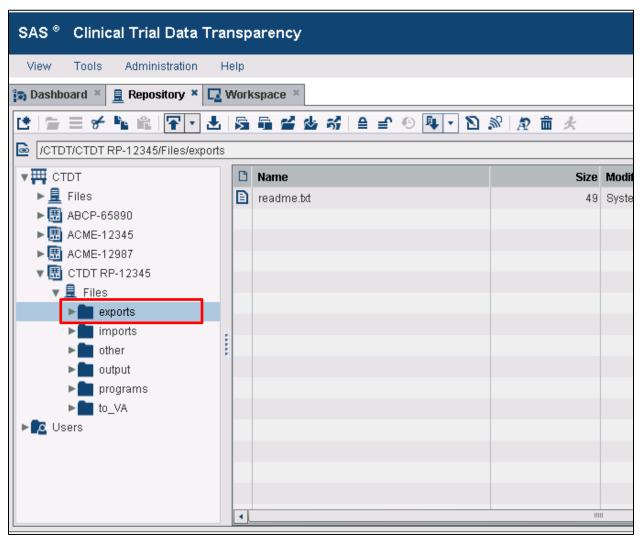


# 5.4 Transferring Results for Export

Results or files saved to your **My Documents** folder are not immediately available to export from the Research Environment. You must upload the files into the SAS Clinical Trial Data Transparency Repository and then queue them for export.

- 1. Consider zipping the files before transferring them to SAS Clinical Trial Data Transparency.
- Open the SAS Clinical Trial Data Transparency Repository and navigate to the desired exports folder. (See section 4.1 Logging on.) Figure 89 shows the exports folder of a research area named CTDT RP-12345.

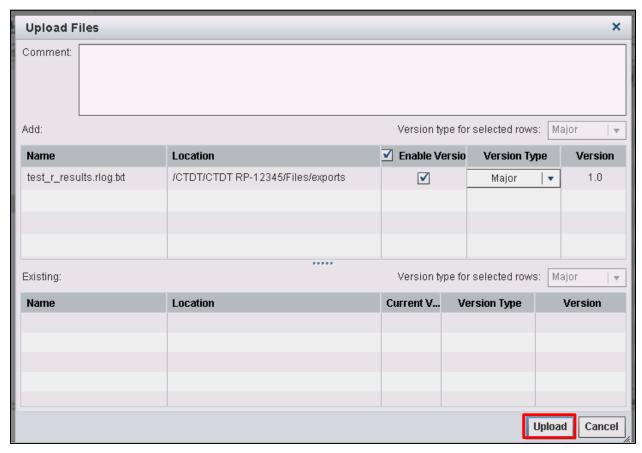
Figure 89: Exports Folder



- 3. Click the **Upload toolbar** icon and select **Upload Files**.
- 4. Select the file(s) from the location where they are saved.
- 5. A screen appears to transfer the files to the SAS Clinical Trial Data Transparency Repository (<u>Figure 90</u>). Select **Upload**.

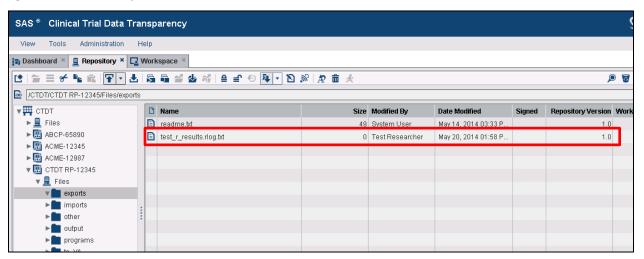
Note: You do not need to version the files.

Figure 90: Upload Files



6. The file or files are displayed in the **exports** folder (<u>Figure 91</u>). At this point, you are ready to queue an export from the Research Environment. For more details, see section <u>6 Importing and Exporting</u>.

Figure 91: Contents of Exports Folder



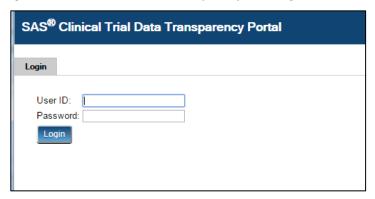
**Note:** There are several rules regulating what can and cannot be exported from the Research Environment. If any files for export do not meet these rules or criteria, your export request requires approval before downloading to your computer. For details, see section <u>6 Importing</u> and Exporting. Every sponsor company involved in your research is required to grant approval.

# 6 Importing and Exporting

To import or export files to or from your research project, you must use the SAS Clinical Trial Data Transparency system.

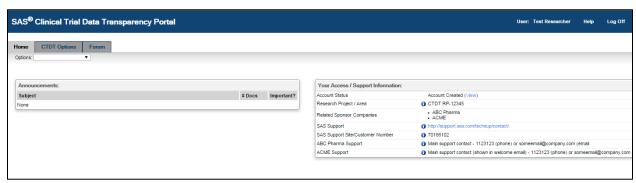
- 1. If not already connected, access the SAS Clinical Trial Data Transparency Portal at <a href="https://mseportal.ondemand.sas.com/ctdt/">https://mseportal.ondemand.sas.com/ctdt/</a>
- 2. On the logon screen, enter your SAS Clinical Trial Data Transparency system User ID (or user name) and Password (Figure 92).

Figure 92: SAS® Clinical Trial Data Transparency Portal Logon



3. The SAS Clinical Trial Data Transparency Portal opens (Figure 93).

Figure 93: SAS® Clinical Trial Data Transparency Portal after Logon



## 6.1 Imports

### 6.1.1 Adding / Starting a Request

1. After logging on to the SAS® Clinical Trial Data Transparency Portal, select the **CTDT Options** tab (Figure 94).

Figure 94: CTDT Options Tab



2. Select Imports: Show List.

**Note:** The **Home -> Options** dropdown also allows direct access to options.

- 3. To initiate an import, do one of the following:
  - Click the Add button on the far right-hand side of the screen.
     Or
  - From the Home tab > Options dropdown menu (Figure 95), select Imports: Add Request.

**Figure 95: Imports Section** 



4. Enter a description (required) of the import request. To import files you have previously imported, choose the **Overwrite / Version Existing** option to ensure the files replace existing ones in **the Research Environment** (specifically the relevant SAS Clinical Trial Data Transparency **imports** folder) (Figure 96).

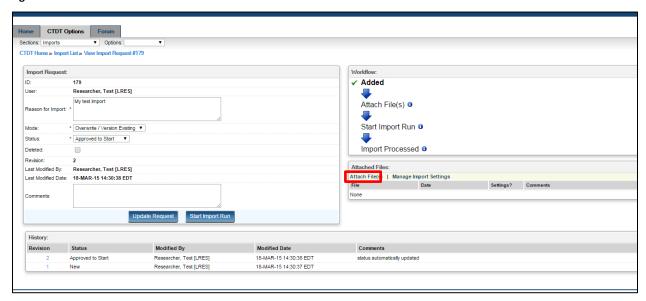
Figure 96: Add Import



- 5. Click Add (Figure 96).
- 6. The detail view appears (<u>Figure 97</u>) with the following options, allowing you to make required updates:
  - The Import Request pane on the left-hand side of the screen displays the following:
    - o The details entered on the previous screen including ID, User, and Summary / Details.
    - o The **Status** field shows your import request is automatically approved to start.
    - The **Deleted?** check box is blank. This field is used for mistakenly added requests. Check this box to delete the request. The request then appears with the strikethrough text in your SAS Clinical Trial Data Transparency imports list.
  - The **History** of the import appears at the bottom of the screen.
  - The **Attached Files** pane on the right-hand side of the screen displays a list of the files you intend to import with two links at the top:
    - o **Add Files**: allows you to add files to your Import Request.
    - Manage Import Settings: allow you to define specific settings related to the import of your files. (*Note*: As shown in <u>Figure 97</u>, settings can be copied and applied to multiple files.)

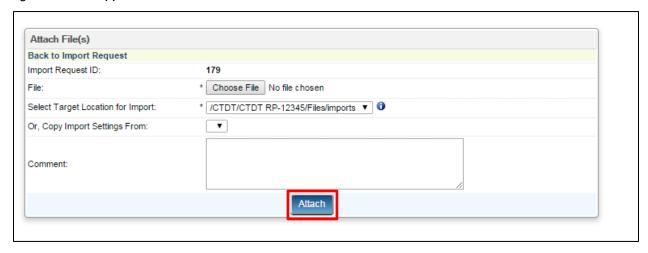
### 7. Select Attach File(s) (Figure 97).

Figure 97: Detail View



- 8. A dialog appears for browsing and selecting a file and the target location for the imported file in SAS Clinical Trial Data Transparency (Figure 98).
  - Select Browse and navigate to the desired file.
  - Select the file and click the **Open** button.
  - The file name appears in the **File**: text box. Select a target location from the drop-down list of research areas to which you have access.
  - If you have defined settings for another file in this Import Request (using the Manage Import Settings selection), you can select Copy Import Settings From: to apply the same settings to the current file.
  - Click **Attach** to add the selected file to the import request. The **File:** text box is cleared when the upload is complete.
  - Click Browse: again to add an additional file.

Figure 98: Add File(s)



9. Click **Back to Import Request.** The files you selected are listed (Figure 99).

Figure 99: Attached Files



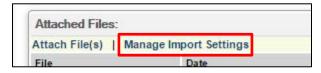
**Note:** Your files have **not** been imported to the relevant SAS Clinical Trial Data
Transparency **imports** folder at this point. They have only been attached to the **Import Request**. The next two sections cover the final steps in the import process.

#### 6.1.2 Managing Import Settings

The default settings for imported files are to enable versioning when the files are imported into SAS Clinical Trial Data Transparency, and if importing a ZIP file, not to unzip it. If these settings are acceptable, **skip** to section <u>6.1.3 Starting the Import</u> to start your import. Otherwise, to change these settings, or alter other previous settings, do the following:

1. Select the **Manage Import Settings** link (<u>Figure 100</u>).

Figure 100: Manage Import Settings Link



2. A list of files and their import settings are displayed (Figure 101). Select the **Modify** link.

Figure 101: Manage Import Settings Screen



3. The **Modify** screen appears (<u>Figure 102</u>). Select a research area from the drop-down menu and select **Continue.** 

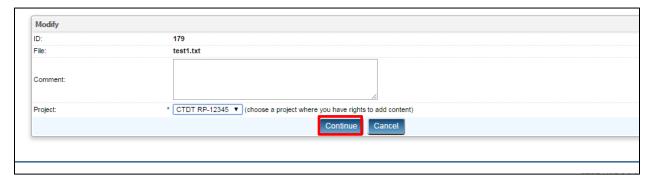
**Note:** Make sure you select a research area and not a study. Files can only be imported into the **imports** folder of a research area.

Figure 102: Modify



4. Select a folder from the dropdown menu and select **Continue** (Figure 103).

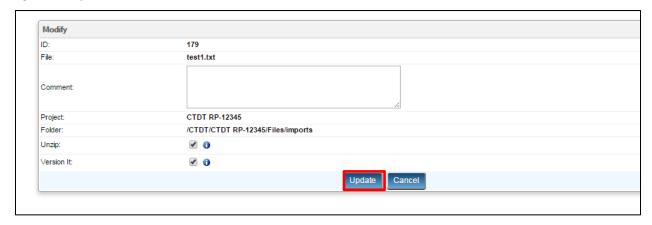
Figure 103: Select Folder



**Note:** Only the **imports** folder of the selected research area is available. You can move files to other locations in the research area after this import is complete.

- 5. Final confirmation appears for the settings (<u>Figure 104</u>). Select one, both, or neither of the following options:
  - **Unzip** If selected, the uploaded file is a ZIP file that expands (unzips) as part of the import process. The files are placed in the **imports** folder. If the ZIP file contains a folder structure, that structure is created under the **imports** folder.
  - **Version it** If selected, and the file uploaded already exists in the imports folder, a new version of the file is created. If the file does not exist in the **imports** folder, the file is indicated as a 1.0 version in SAS Clinical Trial Data Transparency.
- 6. Select Update (Figure 104).

Figure 104: Update



7. Your settings are displayed in the summary table. If you have multiple files and want the same settings to be used for all of them, use **Copy to All** to copy settings for all files (<u>Figure 105</u>).

Figure 105: Copy to All



8. Select the previous item in the breadcrumb trail at the upper right to return to the Import Request Screen.

### 6.1.3 Starting the Import

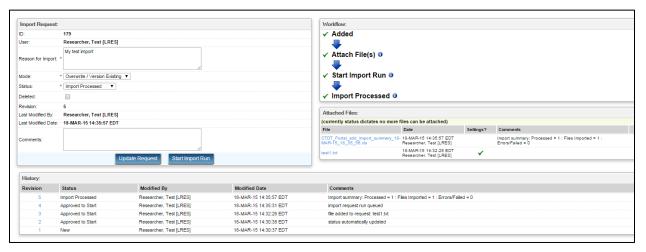
- 1. From the Import Request screen, go to the bottom of the Import Request box
- 2. Select the **Start Import Run** button (Figure 106).

Figure 106: Start Import Run



- 3. A confirmation appears. Select **Yes** to place your import in the queue to run.
- 4. Once the import completes (within a few minutes), a refresh of the screen (Figure 107) shows that:
  - The Import Request status has changed to Import Processed.
  - An import summary file is attached to the request.
  - An import summary appears in the History panel.

Figure 107: Import Summary



5. Your files are now available in the SAS Clinical Trial Data Transparency Repository (in the **imports** folder of the location specified). Log on to the Research Environment to work with them.

**Note:** Once an import request is run, no more files can be added to the request. A new request must be created to import more files.

### 6.2 Exports

#### 6.2.1 Adding a Request

1. After logging on to the SAS Clinical Trial Data Transparency Portal, select the **CTDT Options** tab (Figure 108).

Figure 108: Imports / Exports Tab



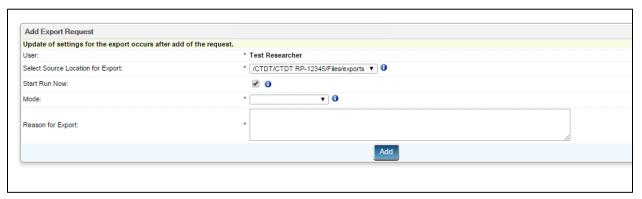
- 2. Select Exports.
- 3. To initiate an export request, do one of the following:
  - Select the Add button on the far right hand side of the screen.
    - -Or
  - From the Home tab > Options dropdown menu (Figure 109), select Exports: Add Request.

Figure 109: Exports Section



4. Enter the details for the Export Request (all fields are required) (Figure 110).

Figure 110: Add Export Request



Note: The Mode selection enables you to export only the most current version of a file or to export all versions. (See the SAS Clinical Trial Data Transparency Repository User Guide for more information on file versions.) Generally, selecting Full – All File Versions is appropriate.

If	Then
The <b>Start Run Now</b> option is available to run the export, and you do not need to modify the settings for the export.	Go to section <u>6.2.2 Starting the Export from the Add Export Request Screen</u> to start the export processing.

If	Then	
You need to review or modify the Export Detail Screen or the <b>Start Run Now</b> option is not available.	<ol> <li>Uncheck the Start Run Now box if it is available.</li> <li>Click Add.</li> <li>Go to section 6.2.3 Export Detail Screen to make the necessary modifications.</li> </ol>	

#### 6.2.2 Starting the Export from the Add Export Request Screen

- 1. Leave the **Start Run Now** check box selected and click the **Add** button (<u>Figure 110</u>). The Export List appears, showing the status of export request run as *in progress*.
- 2. If the export has a status of **Approved for View**, a download icon appears next to the export list when the export run finishes (Figure 111). Select the **download** icon.

Figure 111: Export List Screen with Download Icon

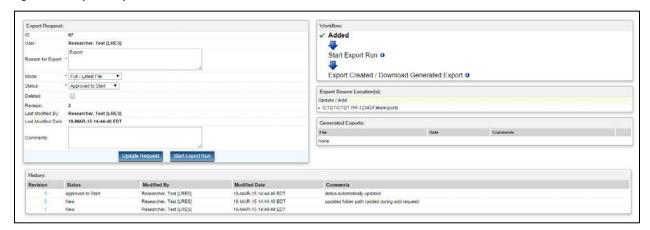


3. Enter your user ID (or username) and password to download the resulting export file.

### 6.2.3 Updating the Export Detail Screen

- 1. Access the Export Detail Screen using one of these two methods:
  - Click **Add** on a new request after deselecting the **Start Run Now** check box.
    - Or
  - Click the **Reason for Export** hyperlink from the Export List screen line for the desired export request.
- 2. The Export Request detail screen appears. Make any necessary updates to the following options before starting the export process (Figure 112):
  - The Export pane on the left-hand side of the screen displays the details entered on the Add Export Request screen.
    - The Status is automatically assigned as Approved to Start.
    - The **Deleted?** check box is blank. This field is used for mistakenly added requests. Check this box to delete the request. The request then appears with the strikethrough text in your SAS Clinical Trial Data Transparency exports list.
  - A **History** of the export appears at the bottom of the page.
  - The **Export Paths** panel enables you to update or add folders from which to export within the SAS Clinical Trial Data Transparency Repository.
  - Comments allows you to enter comments about the export request (for example, during approval steps by sponsor companies).
  - Generated Exports displays your exports.

Figure 112: Export Request Detail Screen



3.

If	Then
You want to modify one of fields in the <b>Export Request</b> panel.	Make the desired modifications, then click Update Request.
You are exporting files from only the location selected when creating the request.	Skip to section <u>6.2.5 Starting the Export</u> to start the export processing.
You want to modify your export path(s) or settings.	Go to section <u>6.2.4 Updating Export Path(s)</u> and Settings.

### 6.2.4 Updating Export Path(s) and Settings

1. In the Export Source Locations panel select Update / Add (Figure 113).

Figure 113: Export Paths Section



2. A list of folders and their export settings are displayed (Figure 114). To replace an existing folder from which files are to be exported, first delete the existing folder by selecting the **X**.

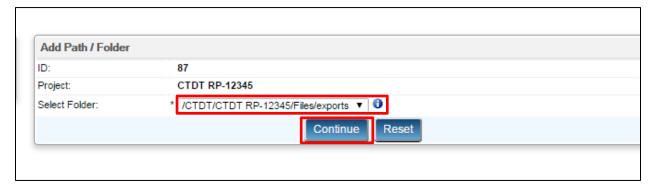
Figure 114: Add / Edit Export Paths



- 3. Add a new folder (Figure 115):
  - a. Select a research area from the **Project** dropdown menu and click **Continue**.
  - b. Select a folder and click Continue.

**Note:** In the Research Environment, exports can only include files from research area **exports** folders in the SAS Clinical Trial Data Transparency Repository. You must move all files desired for export to a research area **exports** folder before running the export request.

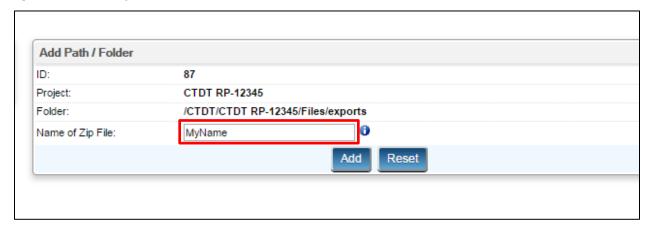
Figure 115: Select Folder



4. You can also enter a name for the resulting export file in the Name of Zip File field (Figure 116).

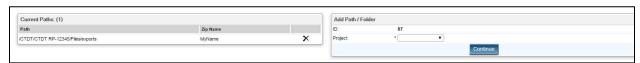
**Note:** The resulting export is a ZIP file. You can enter text for the file in the **Name of Zip File** field. This text appears at the start of the resulting ZIP file name. If you do not include text in this field, the name of the folder (**exports**) is used to name the file. The ZIP file name also includes the date and time of the export, regardless of whether you have entered text into the **Name of Zip File** field.

Figure 116: Name of Zip File



- 5. Select Add (Figure 117).
- 6. The added or modified location appears in **Current Paths** (Figure 117).

Figure 117: Current Paths



7. Click the previous link in the breadcrumbs trail in the upper-right corner to return to the Export Request Details screen.

### 6.2.5 Starting the Export from the Export Request Detail Screen

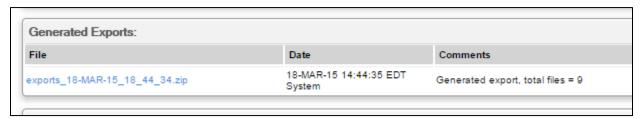
- 1. If you did not choose to start the export run from the **Add Export Request** screen, go to the bottom of the **Export Request** box located on the Export Request Detail screen.
- 2. Select the Start Export Run button (Figure 118).

Figure 118: Status



- 3. When the verification screen appears, select **Yes** to place your export request in the queue for processing.
  - When the export finishes, the resulting ZIP file appears when the screen is refreshed. (Figure 119).

Figure 119: Attached Files / Generated Exports



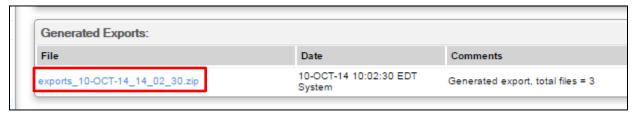
 If your export request meets preset rules for export, the Status appears as Export Created / Approved for View (Figure 120).

Figure 120: Export Created / Approved for View



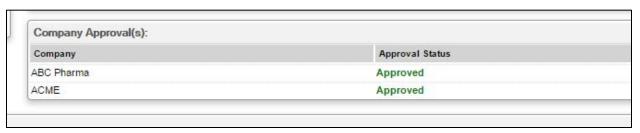
4. Download the file by clicking the file link in the Generated Exports section (<u>Figure 121</u>). You are required to re-enter your user ID and password to download the file.

Figure 121: Export Available to Download



Note: If you receive an error message about needing approval to download after clicking the file hyperlink, then your export request must go through an approval process. If your export request does not meet the preset rules for export, a system representative reviews your request and updates the Status based on the outcome. You are notified of Status changes through email. When the Status is modified to Export Created/Approved for View, you can download the export. If your request is in review, an additional section appears that tracks each company's approval or denial (Figure 122):

Figure 122: Company Approval(s)

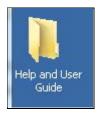


# 7 Online Help

Online help is available in the terminal server and in the SAS Clinical Trial Data Transparency Portal.

- 1. User Guide and other help is available at: <a href="http://support.sas.com">http://support.sas.com</a>.
- 2. From the Research Environment desktop, open the Help and User Guide folder (Figure 123).

Figure 123: Help and User Guide Desktop Icon



-Or

From the SAS Clinical Trial Data Transparency Portal, click Help at the top of the screen (Figure 124).

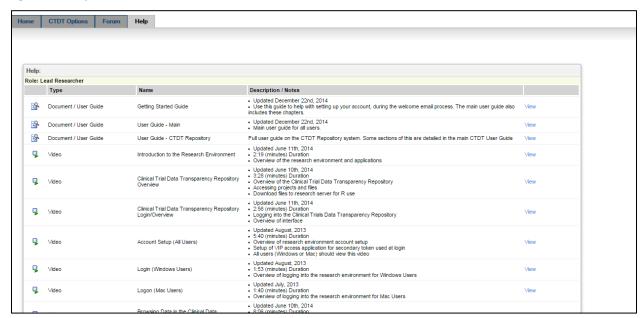
Figure 124: Help Link



3. The Help screen displays guides and how-to videos (Figure 125). To access them, click View.

**Note:** QuickTime is the recommended media player to use when viewing the SAS Clinical Trials Data Transparency how-to videos. Using the Windows Media Player to view the videos hosted on the Clinical Trials Data Transparency Portal can sometimes result in short (one second or less) distortions in the visual display during the playback of some of the videos.

Figure 125: Help Screen



**Note:** For help related to the SAS Clinical Trial Data Transparency system, you can also contact SAS Technical Support as follows:

o Email: <a href="mailto:CTDTsupport@sas.com">CTDTsupport@sas.com</a>

o URL: <a href="http://support.sas.com/ctx/supportform/index.jsp">http://support.sas.com/ctx/supportform/index.jsp</a>

o North America: Call 919-677-8008

# 8 Troubleshooting

<u>Table 2</u> provides a quick reference for troubleshooting the most common issues.

**Table 2: Common issues** 

Issue	Steps to Remedy
Trouble connecting to the Research Environment (Terminal Server Session)  Lost password or account information	<ul> <li>Verify that you have performed all steps of the one-time setup of your SAM Access Credential ID.</li> <li>Verify that your account is not locked out, by selecting My account is locked in the problem menu under the Account Help tab at: <a href="https://www.ondemand.sas.com/sam">https://www.ondemand.sas.com/sam</a>.</li> <li>Visit <a href="https://www.ondemand.sas.com/sam">https://www.ondemand.sas.com/sam</a>.</li> <li>Select Account Help.</li> <li>Select an appropriate problem in the menu under the Account Help tab</li> </ul>
Account is locked	Contact SAS Technical Support as follows:  • Email: <a href="mailto:ctpl:/ctplescom/ctx/supportform/index.jsp">Ctpl:/ctpl:/ctplescom/ctx/supportform/index.jsp</a> • URL: <a href="mailto:http://support.sas.com/ctx/supportform/index.jsp">http://support.sas.com/ctx/supportform/index.jsp</a> • North America: Call 919-677-8008
Trouble viewing how-to videos in the Windows Media Player	QuickTime is the recommended media player to use when viewing the SAS Clinical Trials Data Transparency how-to videos. Using the Windows Media Player to view the videos hosted on the Clinical Trials Data Transparency Portal can sometimes result in short (one second or less) distortions in the visual display during the playback of some of the videos. Distortions in the visual display do not occur when the videos are viewed with QuickTime. If Windows Media Player is the user's default media player, the user may download the video and play it locally on their computer using a different media player.  The videos might start and stop intermittently if the user is attempting to view them while using a slow internet connection. If the user experiences viewing problems to the point that the video is unwatchable, the user may download the video and play it locally on their computer.  To download the how-to video to their local computer, the user should right click on the "View" link and select "Save target as" The user will then be prompted for a location to save the video. After downloading the video, the user may use any media player they have installed on their local computer to view the video. QuickTime is available for download at: https://www.apple.com/quicktime/download/

# **Document Information**

### **Document Control**

Title	Multi-Sponsor Environment SAS SAS® Clinical Trial Data Transparency User Guide	
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### **Revision History**

JIRA Ticket	Date	Version	Name	Description
MSE-16	19JUN2014	1.0	Eric Emerton, Donna Dutton, and Robin MacBain	Prepare for delivery
MSE-16	15JUL2014	1.1	Eric Emerton, Donna Dutton, and Robin MacBain	Screenshots for SAS Clinical Trial Data Transparency Portal's 2.1.0 release
MSE-16	24NOV2014	1.2	Eric Emerton, Donna Dutton, and Robin MacBain	Edits for SAS Clinical Trial Data Transparency Portal's 2.1.0 release
MSE-16	19DEC2014	1.3	Donna Dutton, Melissa Martinez, Sharon Trevoy, Nancy Cole, Ben Bocchicchio, and Eric Emerton	Additional edits.
MSE-16	22DEC2014	2.0	Robin MacBain	Prepare for delivery.
MSE-249	16-MAR-2015	2.1	Eric Emerton	2.2.0 Portal changes
MSE-249	31-MAR-2015	2.2	Robin MacBain	Prepare for delivery.
MSE-249	29-APR-2015	3.0	Robin MacBain	Finalize for delivery

JIRA Ticket	Date	Version	Name	Description
MSE-249	24-NOV-2015	4.0	Eric Emerton and Robin MacBain	Add section 2.5 Accepting Terms in the Portal.
MSE-569	11-APR-2017	5.0	Adam LaManna and Zachary Moser-Katz	Finalize for delivery.
MSE-750	29-NOV-2017	5.1	Adam LaManna and Zachary Moser-Katz	Updated section 3.1.2.
MSE-750	01-DEC-2017	6.0	Adam LaManna and Zachary Moser-Katz	Finalize for delivery.

## **Typographical Conventions**

Blue Underline	Hypertext link. Control + Click to open hyperlink target.
Calibri	Standard type style used for most text.
UPPERCASE	Names of variables and data sets, programming statements, options, and other language elements when they appear in the text. Within specific operating environments, these elements may be case-sensitive.
UPPERCASE BOLD	Keywords such as the names of procedures, statements, and options.
bold	Window names, selectable items.
<italics></italics>	User-supplied values, shown within angle brackets in statements where substitution should occur.
Monospace	Examples of programming statements in text, SAS code, and values of variables.